OMNIBUS SOLICITATION OF THE NATIONAL INSTITUTES OF HEALTH, CENTERS FOR DISEASE CONTROL AND PREVENTION, FOOD AND DRUG ADMINISTRATION, AND ADMINISTRATION FOR CHILDREN AND FAMILIES FOR

SMALL BUSINESS INNOVATION RESEARCH (SBIR)

AND

SMALL BUSINESS TECHNOLOGY TRANSFER (STTR)

GRANT APPLICATIONS

NIH, CDC, FDA, and ACF Program Descriptions and Research Topics

SUBMISSION DATES

SEPTEMBER 5, 2015, AND JANUARY 5, APRIL 5, 2016

National Institutes of Health (SBIR and STTR)

Centers for Disease Control and Prevention (SBIR)

Food and Drug Administration (SBIR)

Administration for Children and Families (SBIR)

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Funding Opportunity Announcements, Application Instructions, and Appendices are contained in separate files. Follow the links below to view these documents.

FUNDING OPPORTUNITY ANNOUNCEMENTS

REMINDER: ALL APPLICATIONS MUST BE SUBMITTED IN RESPONSE TO A FUNDING OPPORTUNITY ANNOUNCEMENT THROUGH GRANTS.GOV

SMALL BUSINESS INNOVATION RESEARCH PROGRAM PARENT ANNOUNCEMENT (SBIR [R43/R44]) HTTP://GRANTS.NIH.GOV/GRANTS/GUIDE/PA-FILES/PA-15-269.HTML

SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAM PARENT ANNOUNCEMENT (STTR [R41/R42]) HTTP://GRANTS.NIH.GOV/GRANTS/GUIDE/PA-FILES/PA-15-270.HTML

ADDITIONAL SPECIAL ANNOUNCEMENTS FOR SMALL BUSINESS RESEARCH OPPORTUNITIES HTTPS://SBIR.NIH.GOV/FUNDING/INDIVIDUAL-ANNOUNCEMENTS

APPLICATION INSTRUCTIONS

SF424 (R&R) APPLICATION INSTRUCTIONS AND ELECTRONIC SUBMISSION INFORMATION (HTTP://GRANTS.NIH.GOV/GRANTS/FUNDING/424/INDEX.HTM)

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EXTRAMURAL INVENTION REPORTING COMPLIANCE RESPONSIBILTIES (HTTPS://S-EDISON.INFO.NIH.GOV/IEDISON/TIMELINE.JSP)

PROGRAM DESCRIPTIONS AND RESEARCH GRANT TOPICS

The research topics shown in this solicitation represent program areas that may be of interest to applicant small business concerns in the development of projects that have potential for commercialization. Small business concerns are encouraged to submit SBIR/STTR grant applications in these areas.

APPLICABLE TO NIH ONLY: SBIR and STTR grant applications will be accepted and considered in any area within the mission of the awarding components (i.e., Institutes and Centers (ICs)) identified in this solicitation.

Applicants are strongly encouraged to subscribe to the NIH Guide for Grants and Contracts LISTSERV (http://grants.nih.gov/grants/guide/listserv.htm) or query program administrators periodically via email to learn of new or emerging scientific interests of the NIH, CDC, FDA, and ACF awarding components.

You may also subscribe to the SBIR-STTR LISTSERV list to get timely information about the NIH SBIR/STTR Programs (https://sbir.nih.gov/engage/listserv).

Additional information on each of the awarding components (ICs) and their research interests is available electronically on the home pages shown throughout the “Research Topics” section of the solicitation.

The Fogarty International Center, which provides support only for conferences, postdoctoral fellowships for research in the United States and abroad, and senior scientist exchanges between the United States and other countries, does not participate in the SBIR/STTR program.

NATIONAL INSTITUTES OF HEALTH (NIH)

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

The goals of the agency are as follows:

1. to foster fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health;
2. to develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease;
3. to expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and
4. to exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research:

- in the causes, diagnosis, prevention, and cure of human diseases;
- in the processes of human growth and development;
- in the biological effects of environmental contaminants;
- in the understanding of mental, addictive and physical disorders; and
- in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

In addition, the NIH sponsors training of research personnel; career development of new and established scientists; construction and renovation of research facilities and provision of other research resources.

To carry out these responsibilities, the NIH is organized into awarding components (Institutes/Centers). Those components that have an extramural element, that is, those that provide funds for research and research training activities in organizations external to the NIH, are shown below. The NIH makes every effort to finance worthy applications, including the co-funding of such applications by one or more awarding components having relevance in the projects.

Funding levels for projects are determined through the combined interaction among peer review, grants management, program, budget, and other Institute and/or Centers (IC) staff. These levels are based on allowable costs that are consistent with the principles of sound cost management and in consideration of IC priorities, constraints on the growth of average grant costs, and the availability of funds.

Before considering and/or preparing an application to the SBIR & STTR programs, all applicants are **strongly encouraged** to review the agencies' and NIH Institutes' and Centers' websites and to contact the SBIR-STTR program coordinators listed in the Omnibus Solicitation.

TRANS-NIH RESEARCH PROGRAMS

Phase IIB Competing Renewal Awards

Some NIH Institutes/Centers (ICs) offer Phase II SBIR/STTR awardees the opportunity to apply for Phase IIB Competing Renewal awards. These are available for those projects that require extraordinary time and effort in the R&D phase and may or may not require FDA approval for the development of such projects, including drugs, devices, vaccines, therapeutics, and medical implants related to the mission of the IC. Some ICs have announced this opportunity through the NIH Guide for Grants and Contracts (see link below), and some are using this Omnibus SBIR/STTR Grant Solicitation. Only those small business concerns who have been awarded a Phase II are eligible to apply for a Phase IIB Competing Renewal award. Prospective applicants are strongly encouraged to contact NIH staff prior to submission. Additional requirements and instructions (e.g., submission of a letter of intent) are available in the specific IC research topics section and in the specific IC Program Funding Opportunity Announcements (http://grants.nih.gov/grants/funding/sbir_announcements.htm). The following NIH ICs will accept applications for Phase IIB Competing Renewal awards: **NIA, NIAAA, NIAID** (SBIR only)**, NICHD** (SBIR only and only Competing Renewals of NICHD-supported Phase II awards)**, NIDA, NIDCD, NIDDK** (only Competing Renewals of NIDDK-supported Phase II awards**), NEI, NIGMS** (SBIR only), **NIMH** (SBIR only), **NCATS** (SBIR only and only Competing Renewals of NCATS-supported Phase II awards), and **ORIP** (SBIR only). **NCI** offers Phase IIB opportunities that focus on the commercialization of SBIR-developed technologies. Contact the NCI SBIR Development Center at 301-594-7709, NCISBIR@mail.nih.gov for additional information. NHLBI offers Phase IIB Competing Renewals that focus on the commercialization of technologies requiring regulatory approval through the **NHLBI** Bridge Awards (RFA-HL-16-009) and the Phase IIB Small Market Awards (RFA-HL-14-012). Contact Jennifer C. Shieh, Ph.D., at 301-496-2149 or jennifer.shieh@nih.gov for additional information. **NINDS** accepts Phase IIB SBIR/STTR Competing Renewal applications through specific opportunities that focus on the commercialization of SBIR and STTR developed technologies. These opportunities can be found on the NINDS SBIR webpage: http://www.ninds.nih.gov/funding/small-business/small_business_funding_opportunities.htm. Contact Stephanie Fertig, M.B.A., at 301-496-1779 or fertigs@ninds.nih.gov for additional information.

Research Supplements to Promote Diversity in Health-Related Research

(See Funding Opportunity Announcement at http://grants.nih.gov/grants/guide/pa-files/PA-12-149.html.)

Every facet of the United States scientific research enterprise—from basic laboratory research to clinical and translational research to policy formation–requires superior intellect, creativity, and a wide range of skill sets and viewpoints. NIH's ability to help ensure that the nation remains a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further NIH's mission. Research shows that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogenous teams. Scientists and trainees from diverse backgrounds and life experiences bring different perspectives, creativity, and individual enterprise to address complex scientific problems. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the researchers, advancing the likelihood that underserved or health disparate populations participate in, and benefit from, health research, and enhancing public trust.

The NIH notifies Principal Investigators holding specific types of NIH research grants (including SBIR and STTR awards) that funds are available for administrative supplements to improve diversity by supporting and recruiting students, postdoctorates, and eligible investigators from groups that have been shown to be underrepresented in the biomedical, behavioral, clinical, and social sciences research workforce. Although the administrative supplements supported under this program provide funding for less than one percent of all individuals involved in NIH supported research, the NIH has found these awards to be an effective means of encouraging institutions to recruit from currently underrepresented groups. Further information on the NIH diversity policy and the groups that have been identified as underrepresented in biomedical research can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-053.html. Administrative supplements must support work within the scope of the original project.

All NIH awarding components and the National Institute for Occupational Safety and Health at the CDC participate in this program. Candidates eligible for support under this supplement program include individuals at various career levels who come from groups that have been shown to be underrepresented in science. Such candidates include individuals from underrepresented racial and ethnic groups, individuals with disabilities, and individuals from disadvantaged backgrounds. Detailed eligibility criteria are described in the full announcement.

An application for a supplement may be submitted at any time. Administrative supplements normally end with the competitive cycle of the parent grant.

TECHNICAL ASSISTANCE PROGRAMS (SUBJECT TO CHANGE)

Available to HHS SBIR/STTR Awardees

One of the goals of the SBIR and STTR programs is to "increase private sector commercialization of innovations developed through Federal Research and Development." To help HHS SBIR/STTR awardees move their products into the marketplace, NIH has developed assistance programs that provide technical and/or commercialization assistance specific to the individual needs of HHS SBIR/STTR awardees. In accordance with the SBIR/STTR Reauthorization Act of 2011, applicants can also identify and utilize their own technical assistance vendor, however they are required to include this as a consultant in the budget section with a detailed budget justification. See SF424 (R&R) SBIR/STTR Application Guide for instructions. Please note, if funds are requested to utilize your own technical assistance vendor and an award is made, the awardee cannot apply for the NIH-provided technical assistance program for the phase of their award.

Additional information about these programs is available at https://sbir.nih.gov/tap. Questions may be addressed to the NIH SBIR/STTR Office at sbir@od.nih.gov.

Niche Assessment Program

(FOR HHS SBIR/STTR PHASE I AWARDEES)

The Niche Assessment Program focuses on providing strategic information about the technology's market and customer opportunities. Often, a research scientist does not have the entrepreneurial skills to assess whether there are other applications or market niches for their SBIR/STTR-developed technology. As a result, they may underestimate its true market value. This program assesses the market opportunities, needs and concerns of end-users and helps to discover new markets for possible entry for the SBIR/STTR-developed technology. With the assistance of the participant, a contractor helps identify niches and potential partners. The contractor performs the due diligence and provides an in-depth report that assesses such items as the potential end-users needs, the competing technologies and products, the competitive advantage, the market size and share that the participant might expect, etc. Targets (end users) are contacted to ensure they are viable leads and their contact information is included in the report for possible follow-up. Participants may find this report helpful in preparing the requisite Commercialization Plan required for a Phase II application. For detailed information about the Niche Assessment Program, see https://sbir.nih.gov/nap.

Participation in this program is open to active HHS SBIR and STTR Phase I awardees (grants, cooperative agreements, and contracts) and participants need only commit a few hours to inform and make the contractor fully conversant on their technology and the niche they would like to have investigated. There is no cost to the HHS awardee to participate in this program.

Commercialization Assistance Program (CAP)

(FOR HHS SBIR/STTR PHASE II AWARDEES)

The Commercialization Assistance Program (CAP) assists small companies with getting their SBIR/STTR-developed technologies more rapidly into the marketplace. It provides assistance with developing and implementing an appropriate business strategy aimed at commercializing the products or services that have resulted from HHS-supported SBIR/STTR awards.

CAP can include distinctive tracks that offer customized assistance to meet the specific needs of both early stage and seasoned companies: 1) Emerging company track, 2) Advanced company track, and 3) Regulatory assistance track. The emerging track is aimed at assisting participants with evaluating their commercialization options based on their specific technologies and to develop a solid market-entry plan covering an 18-month period. It also assists in the development of market-appropriate tools to accomplish these objectives.

The advanced track assists those companies that may have successfully commercialized products and/or services, generated revenue, established partnerships, and/or otherwise achieved a level of market development that is sustainable over a definitive period. However, they may be lacking in a specific, applicable issue (such as a license-focused IP strategy or a term sheet for investors), whose resolution is key to their continued growth.

The regulatory track is focused on providing individualized assistance to those companies whose technologies must go through the Food and Drug Administration (FDA) approval process and, therefore, seek help in developing a sound regulatory plan and strategy to navigating the regulatory landscape.

Participation in CAP is open to HHS SBIR and STTR Phase II awardees (grants, cooperative agreements, and contracts) from the previous five years. Participation is free to the HHS SBIR/STTR awardee; however, participants are responsible for travel and lodging expenses associated with attending workshops and partnering events. Detailed information about the CAP is available at https://sbir.nih.gov/cap.

NIH, CDC, FDA, AND ACF AWARDING COMPONENT CONTACT INFORMATION

Questions of a general nature about the NIH SBIR/STTR program may be directed to:

NIH SBIR/STTR Program Office

Telephone: 301-435-2688

Fax: 301-480-0146

Email: sbir@od.nih.gov

For Agency, Institute and Center Scientific/Research (Program) and Financial/Grants Management contacts, please see here:

https://sbir.nih.gov/engage/ic-contacts

NATIONAL INSTITUTE ON AGING (NIA)

The NIA SBIR-STTR Programs support biomedical, behavioral, and social research on the aging as well as on the diseases and other special problems and needs of older people. NIA supports SBIR and STTR research under four divisions: Behavioral and Social Research, Aging Biology, Geriatrics and Clinical Gerontology, and Neuroscience.

For additional information about areas of interest to the NIA and on NIA's SBIR and STTR programs please visit: http://www.nia.nih.gov/research/dea/small-business-innovation-research-and-technology-transfer.

Research topics within the mission of the NIA and the scope of NIA's SBIR and STTR programs include but are not limited to the following:

Phase IIB Competing Renewal Awards

NIA accepts Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing aging- and health-focused products, including pharmaceutical compounds and medical devices. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to advance research to a stage where interest in and investment by third parties would be more likely.

Prospective Phase IIB Competing Renewal applicants are strongly encouraged to submit via email a letter of intent to NIA's SBIR-STTR program coordinator (see contact information below) that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Anticipated Budget
- Participating institutions
- Funding Opportunity Announcement Number (e.g., PA-12-XXX, if relevant)

Although a letter of intent is not binding and does not enter into the review of a subsequent application, it allows NIA staff to estimate the potential review workload, plan the review, and consider budget implications. It is anticipated that only a small number of NIA SBIR/STTR Phase II awards would be eligible for a Phase IIB Competing Renewal award.

For questions relating to NIA's Phase IIB SBIR-STTR Competing Renewal applications, please contact:

Michael-David ("M-D") A.R.R. Kerns, M.M., M.S., Ph.D.
Telephone: 301-402-7713
Email: kernsmd@mail.nih.gov

Division of Behavioral and Social Research (DBSR)

Basic and translational social and behavioral research on aging processes and the place of older people in society. The division focuses on how people change with age, on the interrelations between older people and social institutions (e.g., the family, health-care systems), and on the societal impact of the changing age-composition of the population. Special emphasis areas are (1) Health Disparities; (2) Aging Minds; (3) Increasing Health Expectancy; (4) Health, Work, and Retirement; (5) Interventions and Behavior Change; (6) Genetics, Behavior, and the Social Environment; and (7) the Burden of Illness and the Efficiency of Health Systems.

A. Development and translation of behavioral economics approaches (incentives or disincentives) to motivate sustainable behavior change to improve health and well-being.

1. Increasing levels of physical activity or promoting treatment adherence.
2. Addressing biases such as loss aversion, errors in affective forecasting, present bias, ambiguity effect, base-rate neglect, and susceptibility to framing effects in health and financial decision making.
3. Using information, or the mode of data presentation to systematically improve decision making (e.g., through “nudges”, policies, or practices that constrain choices).

B. Development of robotics applications to aid elderly.

1. Socially assistive robots allowing elderly to remain independent in their homes. Technology could support machine cognition, language understanding and production, human-robot interaction (cognition, perception, action control, linguistics, and developmental science), perception, and systems.
2. Use of robots to motivate elderly to exercise and improve social interaction.

C. Development of cognitive training applications/intervention to improve cognitive function in elderly.

1. Rapidly develop novel, engaging computer-based cognitive training programs that are based on efficacious approaches and which use cognitive training to target a specific neural system/functional domain.
2. Augment existing computerized cognitive interventions to be individually tailored, engaging, adaptive, sufficiently challenging, and optimized for sustaining functional abilities and maximizing real world improvements.
3. Interventions to remediate age-related cognitive decline, especially using technology platforms with wide acceptance among older adults.

D. Development of applications for smartphones to track exercise, sleep, time use, and health status to identify, track, and monitor psychological and physical health measures that are HIPPA-sensitive for healthcare practitioners as well as for data collection in clinical trials and surveys.

E. Social, behavioral, environmental and or/technical interventions on the individual, institutional, family, community or national level intended to maintain older adult independence or functioning, increase well-being and prevent disease and/or disability.

1. Interventions that can promote a safe home environment, including those which make use of technological innovations for improved monitoring, surveillance, and communication.
2. Interventions directed at self-management of chronic diseases among the elderly, including behavioral change and applications to enhance compliance.
3. Interventions designed for caregivers to promote self-awareness and attention to self-care health and well-being needs in managing stress, maintaining a healthy diet, creating and maintaining contact with a supportive social network, and attending to one’s own physical health.
4. Interventions that can promote productive and effective communication with health care providers, to increase understanding and communication of changes in symptomology , promote transparency of care needs, increase receipt of family-centered optimal care, and make informed health care decisions, and for informed advance care planning and directives.

F. Genetics and Genome Wide Association Approaches

1. Development of innovative methods and software to facilitate analysis of personal data linked to geocoded data, biological, cognitive or genetic measures, with improved protection for confidentiality.
2. Develop online genetic counseling for users to interface with professionals regarding issues that may have arisen after learning about genetic risk for disease.
3. Develop a more targeted understanding of who will engage in Direct-to-Consumer genetic testing and who will not, based on personality and other characteristics. This could be accomplished through comparisons with other large-scale surveys.

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G. The development of practical applications using innovative technologies (hand-held, internet, GPS, social networking and communications technologies) to support and improve quality of life, well-being, and the ability of older adults to live independently and safely at home.

H. New sampling and data collection methodologies for use in large population-based household surveys and behavioral interventions of relevance to aging. These include:

1. Experience sampling and new devices for real-time collection of data; particularly, for recording and analysis of social interactions
2. Improvements to blood spot technology for biological data collection (this includes the development of multiple and reliable assays for limited blood spot specimens).

I. Survey Development/Archiving/Database support

1. Development of new databases and database support infrastructure to satisfy data and research needs in aging as well as the development of innovative data archives to make current statistical and epidemiological data more accessible and policy relevant.
2. Development of data extraction web tools and archiving for public use databases.
3. Development of innovative methods and software to provide improved access to complex longitudinal studies or surveys that preserve confidentiality
4. Development of innovative methods and software to facilitate analysis of personal data linked to geocoded data, biological, cognitive or genetic measures, with improved protection for confidentiality of respondents.
5. Development of data infrastructure and tools for assessing the economic impact of federally-funded research.

J. Forecasting tools and Software for analyzing of healthcare claims

1. Development of models that will lead to improved forecasting of national, state and county level estimates of the demand for aging-related services; and improved prediction of the costs and effects of public health interventions, changes in health-care financing and insurance, social security, pension coverage or changes in the retirement age. Both domestic and international projections are of interest;
2. Development of software which will provide insight on key factors that contributes to growth of medical expenditures through analysis of claims data.

K. Develop risk reduction programs (also referred to as health promotion, health management, demand management, and disease prevention programs) among those aged 45-64 within the private sector or

health. The goal of these interventions is to improve the health of older workers, reduce avoidable health care utilization, and be cost-effective for employee insurance plans.

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Division of Aging Biology (DAB)

DAB sponsors research on the molecular, cellular, genetic, and physiological causes and consequences of aging processes. The ultimate goal is to develop interventions to reduce and/or delay age-related degenerative processes in humans. DAB also has responsibility for maintaining existing resources and developing new resources for aging research, such as populations of well-characterized animals and specific cell lines including, for example, human fetal lung fibroblasts.

DAB areas of research that may be of interest to small businesses include, but are not limited to:

A. Effects of metabolism on the aging process, e.g., how metabolic regulation influences longevity, and the development of anti-oxidants or other interventions to reduce oxidative or other stresses and aging-related diseases.

Max Guo, Ph.D.
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B. Development of minimally-perturbing techniques for collecting blood from mice, rats, and other animals several times a day in sufficient quantities for measurement of hormone levels and other circulating factors in young and old animals, or development of non-invasive research and test methods for use in animals.

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C. 1. Development of molecular probes such as antibodies, DNA sequences and expression vectors useful in studying aging, senescence, and longevity both *in vivo* and *in vitro*.

2. Validation and further development of candidate interventions which have been found to enhance longevity or slow aging, either in cultured cells, animal models, and humans, and which may affect other age-related conditions or diseases such as cancer and cardiovascular diseases.

3. Development of interventions that improve the immune response to foreign molecules or reduce the response to self or suppress age-induced inflammation.

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D. Development of novel strategies for treating age-related renal, pulmonary, urology, reproductive disorders, and age-related changes in hormone production and function. The topics could include devices, pharmacological targets and their validation, small molecules and other approaches to treat these disorders in the elderly. Early-stage pharmacological validation of novel targets and accompanying pre-therapeutic leads for these age-related diseases are encouraged.

Mahadev Murthy, Ph.D., M.B.A.
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E. 1. Development of treatments for wound healing in the aged. These would include devices, processes, and pharmacological agents with the potential to (1) promote wound healing in aged tissues, or (2) reduce scar formation without compromising effective healing. Wounds produced by accidental damage or resulting from surgery would be appropriate for consideration.

2. Development of novel methodology for treating osteoarthritis. These could include devices, processes and pharmacological agents with the potential to (1) Slow the rate of joint deterioration, (2) promote the remodeling of damaged joints, (3) reduce the likelihood of progression to osteoarthritis, and/or (4) improve outcomes for patients with active osteoarthritis.

3. Development of anabolic treatments to delay bone loss and or promote new bone deposition for the treatment of metabolic bone disorders.

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F. 1. Development of cell-based therapies or other treatments to repair myocardial or vascular tissues after ischemia. The work should include consideration of age-related effects on the therapy or treatment.

2. Early development to re-purpose FDA-approved drugs or interventions for common diseases (cancer, cardiovascular, etc.) on aging-related diseases or conditions using senescence cell culture or animal models.

3. Development of biologics or mimetics to slow the rate of aging.

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G. 1. Development of tools and technologies to characterize cellular heterogeneity in aging tissues at the single cell level.

2. Development of interventions to alter the senescence status of cells in tissues and organs of old animals.

3. Development of computational and bio statistical methods for systems biology approaches.

4. Development of new interventions using screens for senescence in cell culture or animal models.

5. Development of interventions that reduce the level of damage to nucleic acids, proteins and lipids and the macromolecular complexes formed from these molecules, and improve the damage surveillance and repair potential of cells.

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H. 1. Development of tools and resources in genetics and genomics to study molecular mechanisms of normal aging or aging-related diseases.

2. Development of biomarkers for prognosis, diagnosis, or treatment monitoring of aging or aging-related diseases. Analysis and integration of large data sets are encouraged for developing such biomarkers or biomarker signatures.

3. Development of computational, statistical, or bioinformatics tools and resources to manage, integrate, and mine large aging-related data sets; Development of databases, methods, or data analysis systems for aging research; Development of technologies, tools, methods, and resources useful for the study of aging and aging-related diseases at the systems biology level.

4. Development of probiotics or prebiotics which are beneficial for age-related diseases or conditions.

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Division of Neuroscience (DN)

DN supports research on age-related changes in the brain or nervous system in the context of other age-related physiological or homeostatic regulator changes (e.g., endocrine, dietary, sleep and circadian rhythms, immune, disease states); degenerative processes or pathological changes in the aging brain in the context of understanding normal age-related changes; and the sensory, motor, perceptual, cognitive and affective processes and changes that occur with aging as related to their underlying biological mechanisms.

An important component of DN is the support of studies on Mild Cognitive Impairment (MCI), Alzheimer's disease (AD), and other dementias of aging such as Frontotemporal Dementia, Lewy Body Dementia, and Vascular Dementia.

Areas that may be of interest to small businesses include, but are not limited to:

A. Development of sensitive, specific and standardized tests for diagnostic screening of MCI and dementia; for example, the development of novel neuropsychological, biochemical and neuroimaging methods for the early detection of cognitive impairment and MCI and the early diagnosis of AD, and development of new tests for detection of pre-clinical AD.

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or

Nina Silverberg, Ph.D. (neuropsychological detection methods in MCI, AD)
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B. Discovery, development, and/or evaluation of drugs, biological or natural products, including central-nervous-system delivery systems to remediate age-related cognitive decline, and to treat the cognitive impairment and/or behavioral symptoms associated with MCI, AD, and other dementias of aging as well as to slow and/or reverse the course of the disease or to prevent it entirely.

Larry Refolo, Ph.D. (Alzheimer's disease & other dementias of aging)
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or

Molly Wagster, Ph.D. (age-related cognitive decline)
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Email: wagsterm@mail.nih.gov

C. AD target discovery and validation through the application of systems biology and systems pharmacology approaches.

Suzana Petanceska, Ph.D.
Telephone: 301-496-9350

D. The development of practical applications using innovative technologies (e.g. hand-held, internet, telemedicine GPS, robotics, social networking and communications technologies) to support and improve quality of life, well-being, and the ability of people with MCI, AD or other dementias of aging to live independently and safely at home for an extended period of time. Examples include systems and devices to: evaluate, monitor and improve or adapt to changes in cognition; improve health service delivery; support independent living and the conduct of everyday tasks at home; provide information to health care providers and family members with which to evaluate the need for intervention; and promote communication and interaction between individuals living in the community or in institutional settings and their health care providers, friends and family members.

Nina Silverberg, Ph.D.
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E. Testing in clinical trials of drug, nutritional, behavioral, cognitive or other types of interventions to remediate age-related cognitive decline, and to treat cognitive impairment and/or behavioral symptoms associated with MCI, AD, and other dementias of aging as well as to slow and/or reverse the course of disease or to prevent the onset of disease.

Laurie Ryan, Ph.D. (MCI, AD, & other dementias of aging)
Telephone: 301-496-9350
Email: ryanl@mail.nih.gov

or

Molly Wagster, Ph.D. (age-related cognitive decline)
Telephone: 301-496-9350
Email: wagsterm@mail.nih.gov

F. Devices or intervention strategies that may prolong functional independence when there are dysfunctions of the central nervous system.

G. Behavioral, environmental, pharmacological, & nutritional interventions to prevent and/or remediate brain biochemical and/or neurophysiological changes caused by normal aging and neurodegenerative diseases, including age-related sensory dysfunction (e.g., pain, hearing loss, speech communication disorders, olfaction loss, & vision loss), motor dysfunction (including Parkinson's disease & other age-related psychomotor disorders) or age-related decrements in balance & postural control, gait performance, and mobility.

H. Biosensors and prosthetic devices, technologies, and related software development to aid in the assessment, diagnosis, and remediation of age-related cognitive decline or sensory dysfunction (including pain, age-related vision loss, and age-related hearing loss), motor dysfunction (including Parkinson's disease and other motor disorders of aging), or age-related changes in balance, postural control, and gait. Novel markers of normal age-dependent cognitive decline or sensory and/or motor system changes at the molecular cellular, circuitry, physiological or behavioral level in humans or relevant animal models.

Molly Wagster, Ph.D. (cognition)
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I. New technologies to screen for the presence of sleep disorders in older persons, to aid in the diagnosis of these disorders, and to enable their remediation.

J. Minimally invasive technologies to detect prion diseases early in the course of the disease process in older adults, as well as effective treatment strategies to slow, halt or prevent these diseases.

Miroslaw Mackiewicz, Ph.D.
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K. Improved instrumentation, imaging technology, related devices, and software packages for use in visualizing neural activity during cognitive or sensory behavior in older adults. Also of interest would be new technologies to combine neural imaging and behavioral assessment in awake animals.

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L. Development of technology and analysis tools to examine, in a systematic way, genetic, epigenetic, transcriptomic, metabolomic, and cell stress pathways in neurons and glia of the aging brain. Development of molecular imaging technology for the *in vitro* and *in vivo* analysis of gene, epigenome, proteostasis and metabolic function in the normal aging brain and in the diseased aging nervous system.

M. Improved technology for the analysis of structural and functional brain connectivity at the cell, neural circuitry and global network levels to define the normal trajectory of brain structure and function over the adult lifespan. Development of technology, including non-invasive methods and novel probes, to monitor and manipulate the plasticity of neural circuits in the adult and aged nervous system. Development of novel markers of neural stem cell function (proliferation, migration, and differentiation) as well as methods to assess the integration and function of stem cells in the nervous system.

Bradley Wise, Ph.D. (neurobiology of brain aging)
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or

Austin Yang, Ph.D. (aetiology of AD)
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N. Novel approaches for analysis of next-generation sequence data.

Marilyn M. Miller, Ph.D.
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Division of Geriatrics and Clinical Gerontology (DGCG)

DGCG supports clinical and translational research on health and disease in the aged and research on aging over the human life span and its relationships to health outcomes. Translational research is of interest for developing and testing the effectiveness of interventions known to be efficacious for everyday

clinical practice and health decision making. Research on Geriatrics focuses primarily on health issues regarding the aged, and deals with research on disease and disability in older persons, including both specific conditions and issues related to multiple morbidity. Clinical Gerontology Research focuses primarily on clinically related issues regarding aging, and deals with research on aging changes over the life span. A major focus is on the determinants of rates of progression of age-related changes that affect disease risk, particularly those affecting risk for multiple age-related conditions.

Areas of interest include but are not limited to:

A. Development of vaccines and other agents for preventing and treating infections in older persons, including development of new vaccines or preventive interventions, and new methods using currently available vaccines or preventive medications.

B. Development of clinical decision support tools that help physicians caring for patients with multiple chronic conditions to prioritize the interventions that are most beneficial and relevant within the context of these patients' lives; or tools for patient self-management of multiple chronic conditions.

C. Devices and/or techniques for preventing or treating urinary incontinence.

D. Development of improved post-surgical treatments/technologies promoting wound healing, prevention of chronic wounds, or reduced scar formation.

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E. Refinements in techniques for the measurement of age-related changes in hormone levels, status or pharmacokinetics (e.g., those of growth hormone, IGF-1 and its binding proteins; estrogen, progesterone, testosterone; other markers of ovarian, testicular, hypothalamic and pituitary function). The objective is to enhance sensitivity and achieve greater economy in the assay cost.

F. Effects of menopause on woman's aging and subsequent health. Effects of age-related changes in endocrine status in men on subsequent aging, morbidity and mortality.

1. Refinements in techniques for the measurement of age-related changes in hormone levels or pharmacokinetics (e.g., those of growth hormone, IGF-1 and its binding proteins; estrogen, progesterone, testosterone; other markers of ovarian, testicular, hypothalamic and pituitary function).

2 Development and testing of alternative strategies (to conventional estrogen/ progestin therapy) for the management of short-term menopausal symptoms and for the reduction in risks of cardiovascular disease, osteoporosis, and other menopause-related conditions, disorders and diseases. Development and testing of new tissue-specific modulators of estrogen/ androgen receptor activity in men and in women for the prevention or treatment of age-related diseases.

3. Development, testing and validation of new surrogate measures of clinically relevant outcomes and endpoints (e.g., fractures) for (1) more immediate and accurate assessment of the risk or progression of age-related diseases (e.g., osteoporosis) or (2) to predict or monitor efficacy of treatment or enhanced risk or progression of adverse effects/events.

4. Determine drug interactions, i.e., potential alterations in pharmacokinetics and pharmacodynamic properties of drugs taken concomitantly with postmenopausal hormones.

Chhanda Dutta, Ph.D.
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G. Improved instrumentation and imaging techniques for measuring body composition and properties such as muscle function in older persons.

H. Development of techniques/devices (e.g., non-invasive, portable) for improved monitoring of caloric intake and/or energy expenditure in epidemiological studies.

Chhanda Dutta, Ph.D.
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I. Measuring ambulation and assessing factors contributing to problems in and/or related to ambulation and mobility in general

1. Development of improved instrumentation for biomechanical assessment of ambulation and falls.
2. Development of improved instrumentation to assess balance, sway, gait, and postural control to identify stable and unstable patterns of movement during activities of daily living
3. Development of improved quantitative methods of assessing postural perturbations relevant to activities of daily living.

J. Development of improved, lightweight, and absorbent materials or other interventions to prevent, protect against and minimize injuries suffered from falls.

K. Development of assistive technologies to enable and support older persons to live independently and safely at home

1. Development of devices/assistive technologies addressing complications of limited mobility among older persons.

L. Development of technologies to assist in the improvement of physical function and mobility in older persons prior to (prehabilitation) or following (rehabilitation) elective/planned surgery.

M. Research on better ways to prevent injuries and deaths associated with the use of currently-available bed rails in populations of older patients. Such research would include work on their identification and testing of improved designs of bed systems for use in homes, skilled nursing facilities, and hospitals.

Lyndon Joseph, Ph.D.
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N. Development of devices and techniques for screening substantial numbers of individuals for particular alleles at loci of relevance to human genetic studies of aging.

O. Development and validation of imaging and sensor technologies to improve measures of physiologic changes with age.

P. Osteoporosis. Development, testing, and validation of new surrogate measures of clinically relevant outcomes and endpoints (e.g., fractures) for (1) more immediate and accurate assessment of the risk or progression of age-related diseases (e.g., osteoporosis) or (2) to predict or monitor efficacy, response to treatment or enhanced risk or progression of adverse effects/events.

1. Development and validation of non-invasive methods of examining bone quality (density, architecture, and strength of bone).

Winifred Rossi, M.A.
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Email: wr33a@nih.gov

Q. Development and validation of improved approaches for evaluation, monitoring or treatment of diastolic dysfunction in older adults.

R. Development and validation of improved techniques for hemodynamic monitoring of older adults in emergency and/or critical care settings.

S. Development and validation of instruments or methods to evaluate fatiguability—the level of fatigue related to the intensity, duration, and/or frequency of activity (in contrast to measures of fatigue), particularly in adults with or at-risk of developing age-related conditions or diseases leading to physical disability.

T. Development and validation of innovative approaches to pain control that consider age-related physiologic changes such as gastrointestinal absorption, cutaneous integrity, and musculoskeletal structure and function.

U. Development and evaluation of treatment approaches to age-related diseases or conditions based on modulation of the thyroid hormone axis.

V. Interventions and methods for screening, diagnosis, and treatment of cancer in older persons.

W. Development of methods to accurately determine the renal glomerular filtration rate (GFR) in older persons and patients with chronic kidney disease. The new methods should justify the effects of age-related changes in muscle mass, levels of serum creatinine, renal blood flow and renal concentrating ability.

X. Identification of novel biomarkers of acute kidney injury and chronic kidney disease in older persons. Such research would include identification of biomarkers and evaluation of their clinical utility for early diagnosis, prediction of the course of progression of diseases and/or monitoring the effects of treatment.

Y. Development and validation of new technology such as non-invasive methods to examine blood-flow velocity in arteries, individual coronary arteries, renal arteries, and cerebral arteries.

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For additional information on research topics and administrative questions, contact:

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For budget management questions, contact:

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NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

NIAAA supports research on the causes, prevention, control, and treatment of the major health problems associated with alcohol use. Through its extramural research programs, NIAAA funds a wide range of basic and applied research to develop new and/or improved technologies and approaches for increasing the effectiveness of diagnosis, treatment, and prevention. NIAAA also is concerned with strengthening research dissemination, scientific communications, public education, and data collection activities in the areas of its research programs.

In addition to Phase I studies in the pursuit of the above aims, NIAAA will also accept Phase II and Phase IIB applications. For additional information about areas of interest to the NIAAA, you are invited to visit our home page at http://www.niaaa.nih.gov.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NIAAA may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. NIAAA will make awards compliant with all statutory guidelines as outlined above. Total funding support (direct costs, indirect costs, fees) normally may not exceed $150,000 for 6 months for Phase I awards and $1,000,000 for up to two years for Phase II awards. With appropriate justification from the applicant, NIAAA may consider awards that exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II, a hard cap). Applicants considering a requested budget greater than the standard limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards

NIAAA will accept SBIR/STTR Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue the process of developing products that require approval of a Federal regulatory agency (e.g., FDA, FCC). Such products include, but are not limited to, medical implants, drugs, vaccines, and new treatment or diagnostic tools that require FDA approval. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely.

Prospective applicants are strongly encouraged to contact NIH staff prior to submission of a Phase IIB Competing Renewal application. Please contact Dr. Kathy Jung (contact information provided below) before beginning the process of putting an application together. Prospective applicants are strongly encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NIAAA SBIR/STTR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

The following examples would make appropriate topics for proposed SBIR or STTR Phase IIB Competing Renewal projects.

These examples are meant for illustrative purposes and are not exclusive of other appropriate activities:

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the Phase I (R43) and initial Phase II (R44) grants. Some *in vivo* or *in vitro* studies would be expected to have been carried out in Phase I or the initial Phase II grant.
- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application
- Development and clinical evaluation of new alcohol-sensitive biomarkers
- Assessment of devices with regard to performance standards related to the FDA approval process
- Safety and effectiveness studies of novel medical devices
- Biocompatibility studies of surface materials of putative medical implants
- Evaluation of novel imaging approaches for diagnostic purposes
- Clinical studies in support of New Drug Application approval by the FDA
- Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA

Direct your questions about scientific/research issues to:

Kathy Jung, Ph.D.
Phone: 301-443-8744
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Medications Development

Alcohol use disorder (AUD) is a global health problem, affecting over 76 million adults world-wide, including over 17 million Americans, resulting in a myriad of medical, psychological, social, economic, and personal problems. NIAAA is committed to the preclinical and clinical development of new pharmacological agents to treat AUD.

Pharmacotherapy offers a promising means for treating AUD. During the past two decades, progress has been made in developing medications to treat alcohol problems. Currently, there are four Food and Drug Administration (FDA)-approved pharmacotherapies for the treatment of alcohol dependence: disulfiram (Antabuse®), oral naltrexone (Revia®), acamprosate (Campral®), and the injectable suspension formulation of naltrexone (Vivitrol®). In addition, nalmefene (Selincro®) has recently been approved by the European Medicines Agency (EMA). However, given the heterogeneous nature of AUD, many patients have limited or no response to the aforementioned medications. Because of this, developing and evaluating new, more efficacious medications remains a high priority.

During the past three decades, alcohol research has enriched our understanding of biological mechanisms underlying alcohol dependence. Various neurotransmitter systems, neuromodulators, and intracellular signaling pathways have a role in alcohol dependence. Currently, over 35 promising targets have been shown to alter alcohol drinking behavior. Some of the new promising targets include, but are not limited to, corticotrophin-releasing factor1 (CRF-1), adrenergic α1 and α2, vasopressin 1B, orexin 1 and 2, opioid receptor-like (NOP), opioid kappa, 5-HT2, GABA-A and GABA-B, metabotropic glutamate (mGluR), glutamate transporter (GLT), nicotinic acetylcholine (nAChR), phospodiesterase (PDE), glial derived neurotrophic factor (GDNF), and neuroimmune and epigenetic modulators. New medications that bind to these and additional targets are needed.

Candidate medications may include novel and re-purposed compounds. However, grant applications that propose to study compounds already extensively investigated or currently being studied in alcohol dependent patients will not be accepted. Thus, applications proposing the use of naltrexone, acamprosate, disulfiram, topiramate, ondansetron, varenicline, gabapentin, and baclofen are not responsive to this topic.

Specific areas of interest include medications that target one or more domains of alcohol addiction, including reward, stress and negative affect, incentive salience, executive function, habituation, and impulsivity/compulsivity.

For questions, contact:
Raye Z. Litten, Ph.D.
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Additional targets for pharmaceutical development include, but are not limited to:

- Development of agents to attenuate excessive alcohol drinking and other symptoms of alcohol dependence, e.g., craving, sleep problems, negative affect. Drugs for the treatment of alcoholic hepatitis, liver fibrosis, cirrhosis, pancreatitis, cardiomyopathy, or other alcohol-induced tissue damage

For pre-clinical questions, contact:
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Svetlana Radaeva, Ph.D. (Organ damage)
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Technological Methods for the Treatment of Hazardous Drinking and Alcohol Use Disorders

- Develop, improve, and validate ecological momentary assessment (EMA) methods for capturing real-time data for use in clinical trials and treatment paradigms.
- Use technology (e.g. EMA, brain imaging) and innovative statistical methods (e.g., machine learning, systems science dynamic models) appropriate for analysis of “big data” (i.e., time intensive, multisource data) to inform our understanding of mechanisms underlying the initiation, maintenance, and recovery from problematic drinking in both treatment and naturalistic settings.
- Leverage unique features of mobile technologies to provide personalized monitoring and just-in-time interventions
- Optimize existing technologies to increase their utilization and effectiveness in specific treatment contexts (e.g., primary care) and improve patient-provider communication to decrease harmful drinking
- Develop and test computerized versions of empirically-supported treatments
- Develop and test novel computerized interventions which capitalize on hypothesized brain-based or behavioral mechanisms underlying drinking
- Develop software to train potential treatment professionals how to provide evidence-based treatments
- Devise novel methods (e.g., Web-mining software of social networking sites) that capture social network information among groups at risk for alcohol use disorder and high-risk drinking.

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Prevention

This area of interest focuses on the development and evaluation of innovative prevention and intervention programs, or specific materials for integration into existing programs, which utilize state-of-the-art technology and are based on currently accepted clinical and behavioral strategies. Applicants are strongly encouraged to consult with research methodologists and statisticians to ensure that state-of-the-art approaches to design, analysis, and interpretation of studies under this topic are used. Areas that may be of interest to small businesses include, but are not limited to:

A. Development and evaluation of innovative prevention/intervention programs, or specific materials for integration into existing programs, which utilize state-of-the-art technology and are based on currently accepted clinical and behavioral strategies. Special emphasis should be placed on the needs of high-risk groups, ethnic and minority populations, youth, children of alcoholics, women, the handicapped, and the elderly. Examples of such materials include school-based curricula, interactive videos, computer-based multimedia programs, training manuals for teachers or parents, and community-based programs.

B. Development and evaluation of educational materials designed to intervene with the elderly around specific age-related risks for alcohol problems. Particular attention should be given to age-related reductions in alcohol tolerance, interactions between alcohol and prescription and over-the-counter medications, possible exacerbation of some medical conditions common among the elderly, potential biomedical and behavioral consequences of excessive alcohol use, and the role of alcohol in falls, fires, burns, pedestrian and traffic injuries, and other unintentional injuries.

C. Development and evaluation of statistical analysis programs tailored to the design and analysis of alcohol prevention-relevant research. Programs could focus on a variety of areas including: imputation of missing data under varying design assumptions; simulation of distributions of outcomes based on varying mixtures of sample populations; application of chronic or infectious disease models to targeted communities; and models of the potential effect of various policy-based interventions, such as increased taxation or reduction of outlet density by license revocation and control.

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Improving the Delivery of Alcohol Treatment Services

Applications are sought that will expand knowledge and improve delivery of alcohol treatment and prevention services. Research objectives include, but are not limited to, the effects of organizational structures and financing mechanisms on the availability, accessibility, utilization, delivery, content, quality, outcomes, and costs of alcohol treatment services. Objectives also include studying the effectiveness and cost-effectiveness of alcohol prevention services in reducing the demand for health care services and improving the methodological tools useful for conducting health services research. Areas that may be of interest to small businesses include, but are not limited to:

Development and assessment of protocols

- to facilitate the selection, implementation, adoption, and maintenance of evidence-based services consistent with target population need, staffing and program resources, and expected outcomes. These protocols should be flexible enough to work across a variety of settings and modalities.

- to assist in the identification, recruitment, and selection of treatment personnel to enhance the matching of staff to program needs

Development and assessment of software

- to assist clinicians in scoring and assessment of score norms for commonly used assessment instruments. These packages should include protocols for guiding client feedback in a clinic or office-based setting.
- to assist patients, their families, or care providers in identifying available high-quality treatment services that best meet their treatment needs. Such projects should move beyond simple electronic directories of services to incorporate indicators of service quality, cost, duration, and other factors that can support shared decision making and effective referral to treatment.
- to support recovery by facilitating patients' continued engagement in recovery support services as an adjunct to or after treatment. Such projects might also include software that assists patients in self-management and self-monitoring of drinking behaviors, cues, or triggers.

Development and assessment of software or other protocols

- to assist in the management of treatment delivery. Software should be useful for assessment, diagnosis, patient placement criteria, monitoring of services received, tracking patient progress, and billing.
- to assist treatment programs and service agencies in measuring, assessing, or otherwise documenting clinically relevant performance indicators or improvements in quality of service provision.
- to promote engagement and mitigate burnout among counselors and others engaged in direct treatment service delivery. Tools are needed to reinforce training on therapeutic techniques (to enhance fidelity of service delivery), engage counselors in mindfulness or other strategies to manage job stress and reduce burnout, and provide front-line counselors with supports essential to maintaining productive therapeutic relationships with patients.
- to facilitate the incorporation of screening and identification tools into routine usage in primary care, emergency, obstetric, mental health, and/or other health care settings. Research projects should facilitate the provisions of brief interventions, medical management, effective referral to specialized alcohol treatment, and follow-up.
- for monitoring service costs of alcohol treatment services including core, ancillary, out-sourced services. These tools should provide a user-friendly system of monitoring costs that could be implemented without additional accounting expertise by the staff at a typical treatment setting. At the same time, such tools should be defensible as measures of the true opportunity costs of providing alcohol treatment services. Such software might be bundled with billing software.

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Fetal Alcohol Spectrum Disorder (FASD) and Alcohol-Related Birth Defects

FASD is the collective term for the broad array of adverse effects resulting from in utero alcohol exposure. The most severe of these is fetal alcohol syndrome (FAS), a developmental disorder characterized by

craniofacial abnormalities, growth retardation, and nervous system impairments that often include mental retardation. Other diagnostic categories include partial FAS, alcohol-related neurodevelopmental disorder (ARND), and alcohol-related birth defects (ARBD). Children and adults with FASD may exhibit multiple cognitive, behavioral, and emotional deficits that impair daily functioning in many domains. The NIAAA supports research leading to improved diagnosis and assessment of prenatal exposure, impairment and disability, as well as the development of therapeutic interventions, including tools to enhance academic and daily living skills. Areas that may be of interest to small businesses include, but are not limited to:

A. Development and assessment of diagnostic and/or screening methods, tools or technology that can be used prenatally to identify fetuses affected by ethanol.

B. Development and validation of biomarkers that can be used to verify prenatal alcohol exposure in neonates.

C. Development and validation of assessment methods to provide more accurate clinical diagnosis of FASD at all life stages.

D. Development and testing of skill-building, therapeutic, and education program products that enhance the social, cognitive, adaptive and motor abilities of individuals with FASD.

E. Development of neurobehavioral tools or instruments to assess responsiveness of individuals with FASD to medications and/or cognitive/behavioral therapies.

F. Development of accurate measures of the responsiveness of children affected by prenatal exposure to alcohol to stress and predictors of vulnerability to alcohol-drinking or other psychopathology during adolescence and adulthood.

G. Development and evaluation of educational and training programs designed to enhance the skills of non-professional caregivers in dealing with the problems associated with FAS.

H. Development and validation of innovative methods, tools or technology to prevent harmful drinking during pregnancy.

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Development of Clinical Biomarkers of Alcohol Exposure and Alcohol-Induced Organ Damage

There is a well-recognized need for prognostic and diagnostic biomarkers of alcohol exposure, for biomarkers of the response to clinical treatment, and for biomarkers to monitor abstinence in high-risk individuals. Quantitative and qualitative markers of high-risk drinking behavior and alcohol-induced tissue damage would greatly improve medical efforts to recognize and treat alcohol-related disorders. Currently, no clinically available laboratory test can reliably diagnose duration of alcohol use or predict the progression of alcohol-induced organ damage. Traditional alcohol biomarkers fail to provide long-term information. More recently developed alcohol biomarkers (ethanol metabolites phosphatidylethanol (PEth), ethyl glucuronide (EtG) and ethyl sulfate (EtS)) display improved sensitivity, specificity, and

accuracy over classical biomarkers. Their useful range of a few days (EtG) to 2-4 weeks (PEth) addresses many, but not all, clinical needs.

Effective biomarkers are essential to early detection of alcohol use disorder or early stages of organ damage. Early detection will make it possible for patients to consider intervention to prevent long-term medical, psychological, and social consequences of alcohol use.

Several separate, distinct diagnostic settings and circumstances are in need of reliable specific biomarkers. Alcohol biomarkers that address the following are needed:

- Biomarkers that detect cumulative intake of alcohol over a period of months or more; thus a biomarker that is stable over months, reflecting duration and amount of alcohol exposure.
- Biomarkers that detect failure of compliance after withdrawal; thus a biomarker with a short half-life.
- Biomarker signatures of alcohol-induced organ damage, which are likely to be organ-specific.
- Biomarker signatures of familial risk factors for alcoholism. Early identification of subjects predisposed to alcoholism will allow for early intervention, possible prevention, and allow the subjects to make informed personal decisions.

Characteristics of useful biomarkers are:

- Sensitivity, specificity, accuracy, and reliability
- Ease of use and acceptability to patient and provider
- Found in easily obtained specimens, such as serum or plasma, urine, saliva, or hair.
- Validity, reproducibility, affordability, and transportability to a variety of settings, including alcoholism treatment centers, hospitals, primary care offices, or the workplace.

Pattern-based molecular signatures —as opposed to single component biomarkers --may be predicted to provide greater sensitivity, specificity, accuracy, and reliability than single component biomarkers. Thus, high throughput discovery approaches using genomics, epigenomics, transcriptomics, proteomics, metabolomics, lipomics, or glycomics are encouraged.

Also of interest:

- Improvement of turn-around time and cost efficiency of current assays for PEth, EtS, EtG and other alcohol biomarkers.
- Design and development of point of care devices, for use in rural or remote primary care and hospital settings.

Small business efforts for improvements at any stage in the biomarker pipeline are of interest, including discovery, validation, development, and implementation to real world settings.

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For pre-clinical questions, contact:
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Alcohol Biosensors

Small business applications proposing to design and produce a wearable device to monitor blood alcohol levels in real time are sought. The device should be able to quantitate blood alcohol level, and interpret and store the data or transmit it to a smartphone or other device by wireless transmission. The device should have the ability to verify standardization at regular intervals and to indicate loss of functionality. The power source should be dependable and rechargeable. Data storage and transmission must be completely secure in order to protect the privacy of the individual. A form of subject identification would be an added benefit. The device can be removable.

The alcohol biosensor device should be unobtrusive, appealing to the wearer, and can take the form of clothing, bracelet, jewelry, or any other format located in contact with the human body. A non-invasive technology is preferred.

Alcohol detection technology for personal alcohol monitoring will serve useful purposes in research, clinical and treatment settings, will play a role in public safety, and will be of interest to individuals interested in keeping track of personal health parameters.

This topic also includes the opportunity to develop appropriate data analysis systems for individual level evaluation as well as for assessment of trends in research populations.

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Alcohol Use and HBV or HIV Infection or Co-infection

Alcohol use, including hazardous drinking, by persons infected with HIV and HBV is quite common in the United States. Alcohol consumption is widely acknowledged as a co-factor in the sexual transmission, susceptibility to infection, and progression of the infectious diseases. However, detailed relationships between alcohol use and viral infections, diseases progression, antiretroviral therapy and adverse outcomes, notably in liver disease progression, are less recognized or understood. Recent research indicates that inflammatory pathways predominate in alcoholic hepatitis whereas adaptive immunity plays a primary role in viral hepatitis, offering multiple targets for novel preventive and therapeutic interventions. Comprehensive studies to improve understanding of the factors underlying alcohol and viral etiologies in liver disease and the impact of antiretroviral drugs on liver disease progression are needed. A better understanding of alcohol's effects on liver disease in patients with HIV and HBV infection or co-infection may improve diagnosis and treatment outcomes. NIAAA supports research leading to improved diagnosis and treatment of alcohol-induced disorders in people infected with HIV and HBV, or both.

Areas that may be of interest to small businesses include, but are not limited to:

A. New preventive and therapeutic approaches designed to protect the liver from alcohol and antiretroviral drug-induced liver injury in patients infected with HIV and HBV mono- or co-infection.

B. Development of therapies aimed at molecular targets that play a role in the development of alcoholic and viral liver diseases.

C. Development and evaluation of drugs that mitigate the effects of oxidative stress on mitochondrial function thereby preventing liver disease progression.

D. Development of biomarkers for individuals who are most prone to alcohol-induced damage in those patients infected with HIV and HBV mono- or co-infection.

For HBV and basic research questions on HIV, contact:

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For clinical or epidemiological questions on HIV, contact:
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Electronic Diagnostic Clinical Assessment of Frailty among HIV+ Individuals with Past and/or Current Alcohol Use Disorders: Severity and Patterns

Innovative self-report, biological, and/or common clinical measures for the identification and diagnosis of frailty related to alcohol use among alcohol-using HIV patients and those with related comorbidities are sought. Measurement of frailty should be calibrated for severity of alcohol use and be both clinically useful and predictive of morbidity and mortality. Applications proposing the development of a frailty index and an internet site are sought. The primary goal of this site will be to provide normative and educational information related to frailty index(es) related to morbidity and mortality as a useful tool for clinicians who encounter HIV patients who continue to drink and may or may not be compliant with antiretroviral treatment for suppression of viral replication and restoration of immune function.

- Development of this index should be tested in the widest range of individuals at various trajectories of progression of HIV disease and alcohol use. In particular, information from measures should be able to accurately identify individuals who are “sick quitters” and/or have high degree of frailty due to either past and/ or current alcohol use.
- This index should be of greatest value to diagnostic assessment and interventions within clinical settings and may include the development of audio, visual, and/or training modules to support the use of this diagnostic index.
- Support an electronic internet site for scoring and collection of information on frailty and patterns of alcohol use in clinical populations, and to provide information on a range of options for assessment of alcohol use severity in HIV+ populations (e.g. brief assessment instruments, calendar methods, biological markers, etc.)

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Monitoring Alcohol Use among HIV+ Patients

Of particular importance is the measurement of patterns of alcohol use among HIV+ individuals. Wearable alcohol biosensors (see related topic) should be developed to maximize acceptability and minimize stigmatization among the widest range of users. It is expected that the most effective devices will be unobtrusive devices (perhaps wrist-worn) that assess a variety of physiological measures in addition to alcohol use and that interact with smart phone technologies for additional assessment or data management features (e.g. momentary ecological assessment) related to medication adherence for HIV and related comorbidities.

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Stem Cell Research for Alcohol-induced Disorders

Stem cells are master cells in the body and they have the remarkable potential to develop into many different cell types. Stem cells may become a renewable source of replacement cells to treat alcohol related diseases. They can also be used to study disease processes, and to develop new and more effective drugs.

Recent research progress on stem cells has offered great opportunities to study conditions and diseases related to alcohol abuse and alcoholism. Stem cells can come from embryos or adult tissues. They are generally categorized into 1) Embryonic stem cells; 2) induced pluripotent stem cells (iPS cells); and 3) adult stem cells. The NIAAA supports SBIR/STTR research using any of these 3 types of stem cell, which can lead to improved understanding of alcohol related diseases and conditions, and better treatment.

Areas that may be of interest to small businesses include, but are not limited to:

A. Generate and disseminate induced pluripotent stem cells (iPS) from mature human cells to resemble diverse individual variations regarding alcohol metabolism. Use these genetic variant models to study alcohol dependence and pharmacotherapy development. Examples of these genetic variations include Alcohol Dehydrogenase (ADH), Aldehyde Dehydrogenase (ALDH), cytochrome P450 isozyme CYP2E1, and Glutathione S transferase (GST).

B. Generate and disseminate disease-specific iPS cell lines for studies on the biology and signaling pathways that contribute to the alcohol-related disease pathology.

C. Models derived from human iPS cells to study biological and pathological effects of alcohol and its metabolites.

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Role of Non-coding RNAs in the Neuroadaptation to Alcoholism

Gene expression changes after alcohol exposure are well documented. In particular, a vast network of expression changes is found in the brain (and other tissues) following both acute and chronic alcohol exposure. These neuroadaptations are thought to underlie tolerance and dependence on alcohol as well as mediating the toxic effects of alcohol on neurodevelopment. The discovery of gene expression regulation mediated by RNA molecules that are transcribed from DNA, but do not code for protein, has set into motion a revolution in molecular biology. These novel RNAs are classified broadly as non-coding RNAs (ncRNAs) and include both small (microRNAs or miRNAs) and large classes (long non-coding RNAs or lncRNAs) that function to alter the expression of genes to which they bind and modify chromatin states. Because it is estimated that the majority of the genome consists of non-protein coding regions, of which ncRNAs make up a substantial portion, understanding how alcohol alters the expression of ncRNAs and their targets has significant potential for understanding the mechanisms of alcohol neuroadaptation. However, because of their diverse role in cellular functions and combinatorial mechanisms of action, many challenges still exist in gaining a full appreciation of the role of ncRNAs in alcohol neuroadaptation.

NIAAA seeks the development of novel technologies to both measure and interpret ncRNA gene expression signatures in the brain and/or primary neuronal cultures following alcohol exposure. These technologies could include, but are not limited to: novel methods to tag and measure ncRNAs, new imagining techniques to monitor changes in ncRNAs, and novel bioinformatic algorithms to interpret alcohol-induced alterations in ncRNAs and predict and validate target genes.

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In vivo Detection of Neuromodulators in Behaving Animals

Neuromodulators, such as neuroimmune factors, modulate a wide range of brain functions and play an important role in neurodevelopment and synaptic function. To understand how activities of neuromodulators contribute to alcohol use disorders and how changes at the molecular level link to behavior, effective tools are needed to detect changes of neuromodulators in real time in the brain of behaving animals. Currently available methods that measure neuromodulator levels in the CSF fluid would not allow the analysis of dynamic changes of neuromodulators with spatial and temporal precision. To facilitate the understanding of how neuromodulators shape neuronal activity and contribute to alcohol use disorders, more accurate methods of detection are needed.

Recent advances in a variety of *in vivo* neurotechniques provide a great opportunity to achieve this goal. For example, cell-based fluorescent reporters, which detect the activity of G protein-coupled receptors through a fluorescent Ca2+ sensor, can be developed to detect neuromodulators that activate G protein-coupled receptors, such as chemokines. In addition, *in vivo* fluorescence imaging using target-activated small-molecule fluorochromes coupled with nanotechnology may also provide a powerful tool to visualize neuromodulator changes in the intact brain.

With this SBIR/STTR solicitation, NIAAA seeks the development and application of techniques that can detect neuromodulator changes in real time with spatial and temporal precision in behaving animals. Techniques that allow the *in vivo* detection of neuromodulators over an extended time period, such as implantable cell- or probe-based biosensors, will be particularly encouraged.

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Ex vivo Efficacy Screens to Identify Pharmacotherapies for Alcohol Dependence

High throughput screening efforts have identified many small molecules acting at biological targets thought to be important modulators of excessive alcohol drinking and other alcohol dependence phenotypes. Concurrently, *in vivo* animal models of alcohol drinking and related behavioral measures are currently used to assess potential therapeutic efficacy of medications under development. *Ex vivo* efficacy screens are an important link between these two activities. In contrast to many behavioral models, *ex vivo* tissue-based assays are desirable for their simplicity, speed, and capacity to test small drug quantities. To date, little attention has been devoted toward developing and validating neuronal tissue and cell based screening platforms that can be used to inform go/no go decisions for subsequent *in vivo* preclinical efficacy testing.

With this SBIR/STTR grant solicitation, NIAAA seeks the development and validation of *ex vivo* screens capable of predicting efficacy test results in preclinical behavioral models of alcohol dependence. Such assays may include arrays of parameters capable of differentiating the alcohol dependent from the non-dependent state. They should also discriminate positive and negative control drugs found in the alcohol dependence pharmacotherapy literature and be sensitive to drugs with diverse mechanisms of action. In addition, the assays developed under this solicitation should be relatively rapid, simple and produce consistent and reliable results in multiple laboratories.

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Develop Network Pharmacology Strategy for Preclinical Medication Development

The frequent failure of using highly selective drugs for disease treatment has challenged the concept of "one gene, one drug and one disease" and led to the emergence of a new paradigm, network pharmacology, as a drug development and treatment strategy. This strategy combines the knowledge of biological networks with multiple drug targets to simultaneously regulate multiple pathways perturbed by disease conditions. Given the multi-target nature of alcohol action, alcoholism arises from brain network perturbation. The network pharmacology/combined pharmacological approach, either using drug combinations or multi-target drugs, may serve as an effective strategy for the treatment of alcohol-induced brain dysfunction and behavior disorders.

NIAAA seeks preclinical development of combined pharmacological approaches to synergistically regulate multiple drug targets for alcoholism. Areas that may be of interest to small businesses include, but are not limited to:

Objective 1: Develop and validate new target combinations using cellular and animal models.

Objective 2: Prioritize multi-drug targets and identify the effective drug combinations or multi-target drugs for the medication development.

Objective 3: Use high-throughput screening of compound libraries to identify multi-target drugs.

Objective 4: Encourage adaption of low throughput assays to high throughput screening, development of lead compounds, and identification of drug candidate(s) with proper pharmaceutical properties for medication development.

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Novel Tools and Technologies to Detect the Effects of Alcohol on the CNS Structure and Activities

Alcohol affects virtually all of the major neurotransmission systems in the brain by interacting with membrane ion channels, neurotransmitter release machineries and receptors, signal transduction pathways, genes and epigenetic factors. In order to better understand the acute and chronic effects of alcohol and mechanisms of alcohol intoxication and dependence, it is important to be able to simultaneously detect the structure and activities of large numbers of neurons with intact connections to facilitate the analysis of neurocircuits. Equally important, structure and activities in different subcellular domains (soma, dendrites, spines, axon, etc.) of CNS neurons need to be monitored with high temporal resolution. Additionally, recent developments indicate that glial cells play more important roles in the normal function of the brain and may be important alcohol targets. There is a need to monitor glia-neuron interactions.

There have been great advances in recent years in chemical and optogenetic methodologies, enabling improved ability to monitor CNS structure and activities in larger numbers and at much higher spatial and temporal resolution. Building upon these advances, NIAAA seeks SBIR/STTR research to develop the novel tools and technologies to detect the effects of alcohol on activities of specific cell types, neuron-glia interactions, and the structure and activities of large numbers of neurons in alcohol-drinking/exposure settings, preferentially with intact neural network. These include, but are not limited to, the following:

- Improving chemical or genetic sensors to detect dynamic changes in calcium, voltage, cAMP etc.
- Developing tools and sensors to monitor structure and activities of neurons and glial cells, and their interactions

- Developing tools and sensors to monitor synaptic activities
- Defining cell types in the neurocircuits
- Developing miniature and nanoscale apparatus and sensors, or miniaturizing and optimizing detection apparatus for the study of alcohol effects
- Developing computational methods for the acquisition and analysis of large scale data

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Research Tools

The NIAAA supports the development of new or improved tools to enhance the ability to conduct alcohol-related laboratory studies on humans and animals and to more effectively analyze data from large databases. Areas that may be of interest to small businesses include, but are not limited to:

A. Development of novel animal models, including transgenic animals, possessing specific traits of significance for the study of alcoholism, or for the study of specific pathologic disease states which arise from excessive alcohol consumption.

B. Development of a hepatocyte cell line capable of maintaining viability and metabolic functions in culture systems for an indefinite period.

C. Development of specialized cell culture chambers to provide controlled administration of ethanol to *in vitro* cell systems.

D. Development of experimental systems that mimic organ function, including, but not limited to, co-culture and novel approaches to three dimensional culture.

E. Development of new methods of ethanol administration to animals that produce precise dose control or that closely mimic types of alcohol exposure occurring in humans, including, but not limited to, binge drinking, acute consumption, moderate consumption and chronic consumption.

F. Development of ligands which will enhance the potential usefulness of PET and SPECT neuroimaging technologies for the study of the etiology of alcoholism and related brain pathology.

G. Development of computational, statistical or bioinformatics tools to organize and manage high throughput data obtained by genomic, functional genomic or other ‘omic strategies.

H. Development of databases, methods for integration of databases, or data analysis systems for alcohol research.

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Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

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NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

The NIAID's Division of AIDS, Division of Allergy, Immunology, and Transplantation, and Division of Microbiology and Infectious Diseases fund SBIR/STTR grants on topics related to their mission and activities as described below. Questions on specific research areas may be addressed to the NIAID Program Officials listed below. General questions on the NIAID SBIR and STTR programs and on administrative and business management may be addressed to contacts listed for the NIAID section. When possible, *applicants are encouraged to use email* for communication.

For information about NIAID's Small Business Programs, please visit http://www.niaid.nih.gov/researchfunding/sb/pages/default.aspx.

Limited Total Amounts for Phase I and Phase II Awards

According to statutory guidelines, total funding support (direct costs, indirect costs, fees) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% (hard caps of $225,000 for Phase I and $1,500,000 for Phase II).

NIAID received a budgetary guideline waiver from the Small Business Administration for applications relating to the limited list of scientific topics (Appendix A). For these scientific topics, NIAID will allow Phase I applications with budgets of up to $300,000 total costs per year for up to 2 years; and Phase II or Phase IIB applications with budgets of up to $1,000,000 total costs per year for up to 3 years. Requests for these budget levels must be very well-justified.

NIAID will generally not fund applications at budget levels exceeding these budget guidelines. Applicants are strongly encouraged to contact NIAID program officials prior to submitting any application in excess of the budget levels stated above. For budgetary, administrative, or programmatic reasons, NIAID may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee.

Note that NIAID does not support clinical trials through the SBIR or STTR programs, with the exception of our NIAID SBIR Phase II Clinical Trial Implementation Cooperative Agreement (U44). For details, read "Can my small business obtain funding for a clinical trial?".

Division of AIDS

The Division of AIDS supports research infrastructure and scientific expertise needed to enable innovative approaches aimed at halting the spread of HIV through effective and acceptable prevention strategies and a preventive vaccine, treating and curing HIV infection, and establishing treatment and prevention strategies for the HIV co-infections and co-morbidities of greatest significance.

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BASIC SCIENCES PROGRAM

Supports basic and applied research on the causes, diagnosis, treatment and prevention of HIV and AIDS.

Director: Dr. Diana Finzi
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Email: Dfinzi@niaid.nih.gov

A. ***Epidemiology Branch.*** Population-based research, modeling, and comparative effectiveness studies (not including clinical trials) that assess the natural history, biologic, and clinical course of HIV/AIDS, and related outcomes, and could advance treatment and prevention of HIV. Specific interests include factors related to HIV transmission and associated biological and behavioral factors, basic research on immunology, virology, and antiretroviral therapy, issues surrounding care for HIV and other co-morbidities, interactions and impact on clinical outcomes. Development of novel electronic tools, including devices and computer programs to enhance behaviors such as treatment adherence or uptake of treatment guidelines, is also of interest.

Contact: Joana Roe
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JRoe@niaid.nih.gov
Email: jr108r@nih.gov

B. ***Basic Research Branch.*** Identification and characterization of potential targets for discovery or design of novel strategies to impact HIV transmission, virus-host interactions, host restriction factors, chronic immune activation, and HIV latency/persistence. Innovative approaches for monitoring or studying HIV infection, immunopathogenesis, and viral reservoirs that persist despite antiretroviral therapy. Development of assays and technologies involving nanotechnology and single-cell analysis is of particular interest.

Contact: Dr. Karl Salzwedel
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Email: salzwedelkd@niaid.nih.gov

C. ***Targeted Interventions Branch.*** Identification of small molecule inhibitors, using standard and high-throughput technologies, with novel or underexplored mechanisms of action; gene therapies; RNA-based therapeutics; novel targeting and delivery vehicles for agents active against HIV; therapeutic vaccines, monoclonal antibodies, and cell-based therapies; assays to quantitate latent virus; animal models to facilitate evaluation of agents to treat or cure HIV infection

Contact: Brigitte Sanders
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VACCINE RESEARCH PROGRAM

Supports the discovery, development and clinical evaluation of an HIV/AIDS vaccine.

Director: Dr. Mary Marovich
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Email: mary.marovich@nih.gov

A. ***Vaccine Clinical Research and Development Branch.*** Research areas: (1) phase I, II, and III domestic and international clinical trials of candidate AIDS vaccines; (2) evaluation and characterization of immune responses in HIV-infected and uninfected immunized volunteers, using micro and macro assays; and (3) studies to identify, validate, and standardize immunologic and virologic markers for monitoring response of participants in vaccine clinical trials.

Contact: Jim Lane
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Email: laneji@mail.nih.gov

B. ***Preclinical Research and Development Branch.*** Preclinical research and development of candidate AIDS vaccines, delivery methods, novel vaccine vectors, and adjuvants for the prevention of AIDS; promotion and evaluation of safety and efficacy of the prevention modalities, especially novel vaccine concepts identified in preclinical models including studies using non-human primates,

humanized mouse, and other animal models; genetic and immunologic variation studies in relation to AIDS vaccine development; and mucosal and innate immunity in SIV, HIV, and SHIV models.

Contact: Dr. Yen Li
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Email: yli@niaid.nih.gov

C. ***Vaccine Translational Research Branch (VTRB).*** Translational research to facilitate advancing novel promising basic SIV/HIV vaccine research concepts into HIV vaccine products that can be evaluated in human clinical trials. Research areas encompassed in translational research involve: (1) vector optimization for expression, safety, and manufacturability; (2) upstream and downstream development activities; (3) analytics development to support in process testing and release; (4) formulation development; (5) novel adjuvant approaches; (6) GMP manufacturing; and (7) preclinical safety and toxicology modeling.

Contact: Jeff Pullen, Ph.D.
Telephone: 240-292-6112
pullenj@niaid.nih.gov

THERAPEUTICS RESEARCH PROGRAM

Develops and oversees research and development of therapies for HIV disease, including complications, co-infections and co-morbidities, in adults.

Director: Dr. Sarah Read
Telephone: 301-451-2757
Email: readsa@niaid.nih.gov

A. ***Drug Development and Clinical Sciences Branch.*** Discovery and preclinical development of experimental therapies for HIV, TB and other infectious diseases; maintenance of a database of potential anti-HIV and anti-opportunistic infection compounds; immunologic, virologic, and pharmacologic research related to the design and conduct of clinical trials.

Contact: Dr. Joe Fitzgibbon
Telephone: 240-627-3088
Email: jfitzgibbon@niaid.nih.gov

B. ***HIV Research Branch.*** Clinical research of strategies to treat adult HIV infection and complications; strategies to augment HIV immune responses and general host immunity.

Contact: Tia Morton
Telephone: 240-627-3073
Email: frazierti@niaid.nih.gov

C. ***Complications & Co-Infections Research Branch.*** Preclinical and clinical research to develop new or improved therapies for the treatment and prophylaxis of Pneumocystis Pneumonia, Mycobacterium avium Complex, and cryptococcal disease.

Contact: Dr. Chris Lambros
Telephone: 240-627-3093
Email: clambros@niaid.nih.gov

D. ***For evaluation of therapeutic agents or diagnostics for hepatitis B or hepatitis C secondary to HIV infection in adults.***

Contact: Dr. Susan Brobst
Telephone: 240-627-3094
Email: sbrobst@niaid.nih.gov

E. ***Tuberculosis Clinical Research Branch.*** Translational and clinical research for tuberculosis, with and without HIV co-infection, to facilitate the development of biomarkers/diagnostics, therapies, and prevention/vaccines.

Contact: Daniel Johnson
Telephone: 240-627-3066
Email: daniel.johnson@nih.gov

PREVENTION SCIENCE PROGRAM

Supports basic research on mechanisms of HIV transmission supportive of new biomedical strategies for interrupting transmission. Domestic and international phase I, II, and III clinical trials to evaluate HIV/AIDS prevention strategies, including microbicides, chemoprophylactic agents, and other biomedical and behavioral risk reduction interventions.

Acting Director: Sheryl Zwerski, MSN, CRNP
Telephone: 301-402-4032
Email: szwerski@niaid.nih.gov

A. ***Preclinical Microbicides and Prevention Research Branch.*** Preclinical pipeline for non-vaccine biomedical prevention products including topical microbicides, pre-exposure prophylaxis (PrEP) and multipurpose prevention technologies (MPT). Iterative approaches of existing and emerging technologies into a translational pipeline to select and advance the most promising candidates to clinical evaluation.

Chief: Dr. Jim Turpin
Telephone: 301-451-2732
Email: jturpin@niaid.nih.gov

B. ***Clinical Microbicide Research Branch.*** Clinical development of promising microbicides to prevent HIV infection with the ultimate goal to advance safe, effective and acceptable microbicide products toward licensure.

Chief: Dr. Roberta Black
Telephone: 301-496-8199
Email: rblack@niaid.nih.gov

C. ***Clinical Prevention Research Branch.*** Development of safe and effective non-vaccine biomedical and integrated HIV prevention interventions to reduce the number of new HIV infections in adults and adolescents. Support the development of HIV incidence assays, biomarkers of adherence, and mathematical modeling.

Chief: Dr. David Burns
Telephone: 301-435-8896
Email: burnsda@niaid.nih.gov

D. ***Maternal, Adolescent and Pediatric Medicine Branch.*** Therapies for cure, management, treatment and prevention of HIV and HIV associated complications in pregnant women, infants, children and adolescents. Strategies to reduce transmission of HIV and HIV co-infections from mother to child.

Contact: Judi Miller, R.N.
Telephone: 240-292-4801
Email: jmillera@niaid.nih.gov

Division of Allergy, Immunology, and Transplantation

The Division of Allergy, Immunology, and Transplantation (DAIT) supports studies of the immune system in health and the cause, pathogenesis, diagnosis, prevention, and treatment of disease caused by immune dysfunction.

Director: Daniel Rotrosen, M.D.
Telephone: 301-496-1886
Email: drotrosen@niaid.nih.gov

A. ***Allergy, Asthma and Airway Biology Branch.*** Conditions of interest: asthma, food allergy, eosinophilic esophagitis and gastroenteritis in relation to food allergy, atopic dermatitis, urticaria, rhinitis, rhinosinusitis, drug allergy, sepsis. The Branch supports basic and clinical studies investigating mechanisms of disease and new approaches to diagnose, treat or prevent these conditions. Special interest for SBIR/STTR includes the development of methodologies to manage, and analyze clinical and epidemiologic research in the above conditions and the development of biomarkers as diagnostic markers, markers of disease severity, predictive markers for treatment effectiveness, particularly of immunologic interventions such as allergen immunotherapy for food and respiratory allergy.

Chief: Alkis Togias, M.D.
Telephone: 301-496-8973
Email: togiasa@niaid.nih.gov

B. ***Basic Immunology Branch.*** Origin, maturation, and interactions of immune cells, immune cell receptors, ligands, cytokine biology, molecular basis of activation, antigen recognition, immune tolerance, immune response regulation, hematopoiesis and stem cell biology, enhancement of vaccine effectiveness in neonates and adults, and basic immunology of vaccines and immunotherapeutics as medical countermeasures for biodefense.

Chief: Dr. Alison Deckhut-Augustine
Telephone: 301-496-7551, Fax: 301-480-2381
Email: augustine@niaid.nih.gov

C. **Autoimmunity and Mucosal Immunology Branch.** Preclinical and clinical research to develop and improve therapies for the treatment of autoimmune diseases, primary immune deficiencies (not HIV), basic research of disease mechanisms, and biomarkers, immunotherapy of disease processes, disorders mediated by lymphocyte products, and mucosal immunity.

Chief: Dr. James McNamara
Telephone: 301-451-3121, Fax: 301-480-1450
Email: jmcnamara@niaid.nih.gov

D. ***Transplantation Branch.*** Preclinical and clinical research in organ, vascularized composite tissue and cellular transplantation: acute and chronic graft rejection, allogeneic and xenogeneic transplantation, development of immunomodulatory agents to prevent and treat graft rejection and to promote acute and long term graft acceptance and immunologic tolerance, genomics of the alloimmune response, graft versus host disease and engraftment for hematopoietic stem cell transplantation, minor histocompatibility antigens, complications of immunosuppression in transplantation, and major histocompatibility complex (MHC) region genomics and technologies for MHC typing.

Chief: Nancy D. Bridges
Telephone: 301-496-5598
Email: nbridges@niaid.nih.gov

E. ***Radiation Countermeasures Program.*** Identification and evaluation of medical countermeasures (MCMs) for public health radiation emergencies through the development of mitigators and therapeutics for acute radiation syndrome or the delayed effects of acute radiation exposure; radionuclide-specific therapies, including chelating agents, blocking agents, and other novel decorporation agents; improved methods of accurate and high-throughput radiation biodosimetry and bioassays for radionuclide contamination; biomarkers of organ-specific radiation injury; therapeutics for radiation combined injury; therapeutics for radiation-induced immunosenescence; and formulations for pediatric administration.

Chief: Dr. Bert Maidment
Telephone: 301-594-0641
Email: maidmentb@niaid.nih.gov

Division of Microbiology and Infectious Diseases

The Division of Microbiology and Infectious Diseases (DMID) supports research to better understand, treat, and ultimately prevent infectious diseases caused by virtually all infectious agents, except HIV. DMID supports a broad spectrum of research from basic molecular structure, microbial physiology and pathogenesis, to the development of new and improved vaccines and therapeutics. DMID also supports medical diagnostics research, which is defined as research to improve the quality of patient assessment and care that would result in the implementation of appropriate therapeutic or preventive measures. DMID does not support research directed at decontamination or the development of environmentally oriented detectors, whose primary purpose is the identification of specific agents in the environment. Note that some of the organisms and toxins listed below are considered NIAID priority pathogens or toxins for biodefense and emerging infectious disease research.

Division Small Business Representative: Dr. Barbara Mulach
Telephone: 240-627-3322
Email: bmulach@niaid.nih.gov

A. ***Bacteriology and Mycology Branch.***

The branch oversees research on medical mycology, hospital infections (including Acinetobacter, Klebsiella, Serratia, Legionella, Pseudomonas, Aeromonas, Enterobacter, Proteus, non-enteric E. coli, actinomycetes and others), staphylococci, enterococci, bacterial zoonoses (plague, anthrax, tularemia, glanders, melioidosis, Lyme disease, rickettsial diseases, anaplasmosis, ehrlichiosis and Q fever), and leptospirosis. Research is encouraged in the following general areas: (1) vaccines, adjuvants, therapeutics and diagnostics (including target identification and characterization, device or apparatus development, novel delivery, and preclinical evaluation); (2) products to combat antibacterial and antifungal drug resistance; (3) applied proteomics and genomics; (4) host-pathogen interactions, including pathogenesis and host response; (5) genetics, molecular, and cell biology; and (6) microbial structure and function.

Research in the following areas is of particular interest to the branch, but research on all of the above is welcome:

- Vaccines, therapeutics, and medical diagnostics for hospital infections
- Adjunctive therapies and non-traditional approaches to combat antimicrobial resistance
- Diagnostics for invasive fungal disease
- Novel approaches for the diagnosis of Lyme disease
- Vaccines against Coccidioidomycosis

Contact: Dr. Alec Ritchie
Telephone: 240-627-3356
Email: aritchie@niaid.nih.gov

B. ***Enteric and Hepatic Diseases Branch.***

Special emphasis areas include vaccines against hepatitis C virus; antimicrobials and antivirals that focus on novel targets such as host-pathogen interactions to combat the development of resistance; vaccines and therapies for botulinum neurotoxins, especially therapies that that target toxins once they enter cells; therapies and diagnostics for *Clostridium difficile* that include recurrent disease issues; development of a simple, rapid point-of-care diagnostic tools for the simultaneous identification of multiple diarrheal pathogens that includes their antibiotic resistance profiles; diagnostics for use in low-resource settings, pediatric vaccines to prevent the major worldwide causes of diarrhea; more fieldable vaccines and improved formulation methods; and novel therapeutics and point-of-care diagnostics for chronic hepatitis B and C.

Research areas of the Branch include the following organisms and diseases: astrovirus, *Bacteroides spp.*, *Campylobacter spp.*, enteric *Clostridia spp.* including botulinum neurotoxins, commensals and normal flora, pathogenic *Escherichia coli*, gastroduodenal disease, gastroenteritis, *Helicobacter spp.*, *Listeria spp.*, Noroviruses including Norwalk, ricin toxin, rotaviruses, *Salmonella* serovars, *Shigella spp.*, Staphylococcus enterotoxin B, *Vibrio spp.* enteric *Yersinia spp.*, hepatitis viruses A, B, C, D, and E, as well as cholera, diarrhea, enterotoxins, gastroenteritis, gastroduodenal disease and ulcers, and Guillain-Barre syndrome.

Contact: Dr. Rodolfo Alarcon
Telephone: 240-292-0871
Email: alarconrm@niaid.nih.gov

C. ***Parasitology and International Programs Branch.***

Research areas: (1) protozoan infections, including amebiasis, cryptosporidiosis, cyclosporiasis, giardiasis, leishmaniasis, malaria, trypanosomiasis, toxoplasmosis; helminth infections, including cysticercosis, echinococcosis, lymphatic filariasis, schistosomiasis, onchocerciasis, others (e.g., roundworms, tapeworms, and flukes); invertebrate vectors/ectoparasites, black flies, sandflies, tsetse flies, mosquitoes, ticks, snails, mites; (2) parasite biology (genetics, genomics, physiology, molecular biology, and biochemistry); (3) protective immunity, immunopathogenesis, evasion of host responses; (4) clinical, epidemiologic, and natural history studies of parasitic diseases; (5) research and development of vaccines, drugs, immunotherapeutics, and medical diagnostics, and (6) vector biology and management; mechanisms of pathogen transmission.

Research in the following areas is of particular interest to the branch, but research on all of the above is welcome:

- New drug discovery or re-purpose of existing drugs for new indications for treatment of protozoan related diseases
- Highly sensitive diagnostics tools for parasitic diseases
- Vaccines applicable to disease prevention or elimination

Contact: Dr. Annie Mo
Telephone: 301-496-2544
Email: moa@niaid.nih.gov

D. ***Respiratory Diseases Branch.***

Research areas: (1) **viral respiratory diseases** caused by influenza viruses, human coronaviruses including SARS, MERS, and novel emerging coronaviruses, rhinoviruses,respiratory syncytial virus and other related paramyxoviruses; (2) **mycobacterial diseases**, including tuberculosis, leprosy, Buruli ulcer and non-tuberculous mycobacterial diseases; (3) **other bacterial respiratory diseases** including acute otitis media, community acquired pneumonia, acute exacerbations of chronic obstructive pulmonary disease, diphtheria, pertussis, acute rhinosinusitis, streptococcal disease; and (4) **mixed viral/bacterial respiratory infections**.

Special emphasis areas: development of new or improved antimicrobials and antivirals, including immunotherapeutics, new or improved vaccines (with and without adjuvants), improved delivery systems and formulations for drugs/vaccines, biomarkers, rapid multiplex diagnostic tests, including low cost point-of-care, or other tools to detect infection prior to active disease and identify drug resistance. There is particular need for preventive and treatment countermeasures for influenza, including universal vaccine platforms and broad-spectrum antivirals, for tuberculosis (TB) diagnostics, including drug susceptibility tests and novel anti-TB vaccines and antimicrobials, and for new vaccines and improved diagnostic and treatment options for *Bordetella pertussis* and *Streptococcus pneumoniae*.

Contact: Dr. Xin-Xing Gu
Telephone: 240-627-3265
Email: guxx@niaid.nih.gov

E. ***Sexually Transmitted Infections Branch.***

Areas of emphasis include the development of medical diagnostics including better and more rapid multiplex point of care tests, ability to rapidly determine antibiotic sensitivity, and novel technologies enabling testing in low resource settings while maintaining high sensitivity/specificity; development of new classes of antimicrobials and non-antimicrobial treatment approaches, particularly those focused on reducing the development of antibiotic resistance; novel delivery systems for microbicides, vaccines and therapeutics for Sexually Transmitted Infections (STIs) and other reproductive tract syndromes such as bacterial vaginosis and pelvic inflammatory disease; understanding vaginal ecology and immunology and approaches to developing synthetic microbiota for use as biotherapeutics or as adjunct therapy to antibiotic treatment; development of epidemiologic and behavioral strategies to reduce transmission of STIs; developing and evaluating interventions and products to better serve adolescents, medically underserved populations, and minority groups who are disproportionately affected by STIs; development of multipurpose prevention technologies to prevent STIs, HIV, and unintended pregnancies; better understanding of the role of STIs in infertility, premature birth, and adverse outcomes of pregnancy and how to improve outcomes; and better understanding of the role of STIs in HIV transmission and the role of HIV in altering the natural history of STIs.

Contact: Dr. Carolyn Deal
Telephone: 301-402-0443
Email: cdeal@niaid.nih.gov

F. ***Virology Branch.***

Areas of emphasis for SBIR/STTR applications include: 1) vaccine development; 2) development of therapeutic interventions or diagnostics; 3) development and validation of assays for disease diagnosis and to measure response to therapy; 4) approaches to identify antiviral targets and agents; 5) chemical design and synthesis of novel antiviral agents; 6) development of new preclinical model systems that predict clinical efficacy of vaccines, therapeutics and diagnostics. The Virology Branch does not support applications covering environmental detection and decontamination.

The Virology Branch focuses on the following: acute viral infections (including Nipah and Hendra viruses), arthropod-borne and rodent-borne viral diseases (including Dengue, West Nile, Japanese encephalitis, Chikungunya, yellow fever, hantavirus, etc.), viral hemorrhagic fevers (Ebola, Lassa fever, etc.), measles, polio, coxsackie virus, enteroviruses, poxviruses, rabies, rubella, and persistent viral diseases (including adenoviruses, BK virus, bornaviruses, coronaviruses, herpesviruses, human T-lymphotrophic virus, JC virus, human papillomaviruses, parvoviruses, emerging human polyomaviruses, and prion diseases).

Contact: Dr. Ramya Natarajan
Telephone: 240-627-3325
Email: natarajanr@niaid.nih.gov

Other Research Topic(s) Within the Mission of the Institute

Please visit our Small Business High-Priority Areas of Interest:
http://www.niaid.nih.gov/researchfunding/sb/Pages/default.aspx

For additional information about the NIAID SBIR/STTR program contact:

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NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

The mission of the National Institute of Arthritis and Musculoskeletal and Skin Diseases is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases, the training of basic and clinical scientists to carry out this research, and the dissemination of information on research progress in these diseases.

For additional information about areas of interest to the NIAMS, please visit NIAMS Long Range Plan at http://www.niams.nih.gov/About_Us/Mission_and_Purpose/long_range.asp.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NIAMS may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Generally, NIAMS does not fund Phase I applications with a total cost greater than $225,000 or a project period greater than 2 years and Phase II applications with a total cost greater than $1,500,000 or a project period greater than 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application. It is not the intent of NIAMS to support clinical trials through the SBIR/STTR mechanism. Applicants who wish to submit clinical trials applications to the NIAMS are encouraged to utilize one of the NIAMS FOAs listed HERE.

Arthritis and Musculoskeletal and Skin Diseases

A. ***Division of Skin and Rheumatic Diseases.*** This division promotes and supports: basic and clinical studies of the skin in normal and disease states; and research leading to prevention, diagnosis and cure of rheumatic and related diseases. In the area of Skin Diseases, the division has a wide range of skin diseases under study with NIAMS support, to include keratinizing disorders such as psoriasis and ichthyosis, atopic dermatitis and other chronic inflammatory skin disorders, the vesiculobullous diseases such as epidermolysis bullosa and pemphigus, acne, and vitiligo. In the area of Rheumatic Diseases, the division supports basic, epidemiologic, and clinical research on etiology, pathogenesis, course, interventions, and outcomes in rheumatic and related diseases.

   This is not an inclusive list of all research topics covered by the Division of Skin and Rheumatic Diseases. To learn more, please visit the Division page at http://www.niams.nih.gov/Funding/Funding_Opportunities/Supported_Scientific_Areas/Skin_Rheumatic_Diseases/default.asp

B. ***Division of Musculoskeletal Diseases.*** The musculoskeletal system is composed of the skeleton, which provides mechanical support and determines shape; the muscles, which power movement; and connective tissues such as tendon and ligament, which hold the other components together. The cartilage surfaces of joints and the intervertebral discs of the spine allow for movement and flexibility.

   The Division of Musculoskeletal Diseases of the NIAMS supports research aimed at improving the diagnosis, treatment, and prevention of diseases and injuries of the musculoskeletal system and its component tissues. Key public health problems addressed by this research include osteoporosis, osteoarthritis, and muscular dystrophy. Research is conducted at every level, from fundamental biology to clinical intervention.

   This is not an inclusive list of all research topics covered by the Division of Musculoskeletal Diseases. To learn more, please visit the Division page at http://www.niams.nih.gov/Funding/Funding_Opportunities/Supported_Scientific_Areas/Musculoskeletal_Diseases/default.asp.

Special Emphasis Areas of Interest to Small Businesses:

NIAMS supports all Research and Development activities within its mission, Particular areas of programmatic interest relative to small business initiatives include, but are not limited to:

A. Innovation research on rare musculoskeletal, rheumatic and skin diseases

B. Multiplex assay development for arthritis and musculoskeletal and skin diseases

C. Lab to marketplace: translation of scientific discoveries in NIAMS mission areas from labs into products on the market

D. Test and/or validation of novel, state-of-the-art candidate biomarker platforms for predicting the onset and progression of inflammatory diseases of interest to the NIAMS and for determining the pharmacodynamics, safety and/or efficacy of therapeutic agents targeting those diseases.

For general SBIR/STTR program information, contact:

Dr. Xibin Wang, NIAMS SBIR/STTR Coordinator
Telephone: 301-451-3884, Fax: 301-480-1284
Email: wangx1@mail.nih.gov

For administrative and business management questions, contact:

Mr. Erik (Timothy) Edgerton
Telephone: 301-594-3968, Fax: 301-480-5450
Email: edgertont@mail.nih.gov

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to improve health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and medical care. This is achieved through: research and development of new biomedical imaging and bioengineering techniques and devices to fundamentally improve the detection, treatment, and prevention of disease; enhancing existing imaging and bioengineering modalities; supporting related research in the physical and mathematical sciences; encouraging research and development in multidisciplinary areas; supporting studies to assess the effectiveness and outcomes of new biologics, materials, processes, devices, and procedures; developing technologies for early disease detection and assessment of health status; and developing advanced imaging and engineering techniques for conducting biomedical research at multiple scales. More specifically, the mission of the NIBIB includes the following research areas:

A. ***Biomaterials.*** Development of new or novel biomaterials that can be used for a broad spectrum of biomedical applications such as implantable devices; drug and gene delivery; tissue engineering; imaging agents; and biosensors and actuators. Research that is supported includes the design, synthesis, characterization, processing and manufacturing of these materials as well as the design and development of devices constructed of these materials and their clinical performance.

B. ***Biomechanics and Rehabilitation Engineering.*** Research on biomechanics which can be applied to a broad range of applications including implants, prosthetics, clinical gait and posture biomechanics, traumatic injury, repair processes, rehabilitation, sports and exercise, as well as technology development in other NIBIB interest areas applied towards biomechanics. Rehabilitation engineering research that is supported includes theoretical models and algorithms for understanding neural, motor, and robotic control strategies; quantitative analysis algorithms for predicting therapeutic outcomes; and early stage development of neuroprosthesis technology, virtual rehabilitation, and robotics rehabilitation.

C. ***Biomedical Informatics.*** Development of new technologies to collect, store, retrieve, and integrate quantitative data; large-scale data-driven knowledge base and database methods that support data mining, statistical analysis, systems biology and modeling efforts; and improvement of computer science methods to protect confidentiality of patient data.

D. ***Drug and Gene Delivery Systems and Devices.*** Development of new and improved technologies for the controlled and targeted release of therapeutic agents. Areas of emphasis include: the development of new delivery vehicles such as nanoparticles and micellar systems; energy-assisted delivery using ultrasound, electroporation, etc.; and the integration of biosensing with controlled dosage delivery using BioMEMS and other emerging technologies.

E. ***Image-Guided Interventions.*** Research on use of images for guidance, navigation and orientation in minimally invasive procedures to reach specified targets. Examples include image-guided interventions for minimally invasive therapies such as surgery and radiation treatment, for biopsies, and for the delivery of drugs, genes and therapeutic devices.

F. ***Image Processing, Visual Perception, and Display.*** Study, invention, and implementation of structures and algorithms to improve communication, understanding, and management of information related to biomedical images. Research that is supported includes software and hardware for image reconstruction, analysis, display and perception, visualization, and computer-aided interpretation.

G. ***Imaging Agents and Molecular Probes.*** Development and application of novel imaging agents and probes for clinical or pre-clinical applications. Examples of supported research include the development and application of quantum dots, nanoparticles, nanoshells, microbubbles, and radio-labelled contrast materials, and smart imaging agents that are bio-activatible or activated by other chemical, physical, or biological means.

H. ***Magnetic, Biomagnetic and Bioelectric Devices.*** Development of magnetic, biomagnetic and bioelectric devices, e.g., EEG, MEG, etc. Examples include (but are not restricted to) novel detectors, increased sensitivity and spatial resolution, improved reconstruction algorithms, multiplexing with other imaging techniques, etc.

I. ***Magnetic Resonance Imaging and Spectroscopy.*** Development of MR imaging and MR spectroscopic imaging, for both animal and human research, and potential clinical applications. Examples include (but are not restricted to) fast imaging, high field imaging, design of novel RF and gradient coils, novel pulse sequences, design of novel contrast mechanisms, imaging informatics, *in vivo* EPR imaging, molecular imaging, etc. The emphasis should be on technological development rather than detailed applications to specific diseases or organs.

J. ***Mathematical Modeling, Simulation and Analysis.*** Development of mathematical models and computational algorithms with potential clinical or biomedical applications, including multi-scale modeling, modeling at or above the cellular level, and modeling at subcellular level, including those developed to support technology development in other program areas related to the NIBIB mission. Research that is funded includes studies that focus on the development of algorithms, mathematical models, simulations and analysis of complex biological, physiological, and biomechanical systems and use genomics and proteomics.

K. ***Medical Devices and Implant Science.*** Design, development, evaluation and validation of medical devices and implants. This includes exploratory research on next generation concepts for diagnostic and therapeutic devices; development of tools for assessing host-implant interactions; studies to prevent adverse events; development of predictive models and methods to assess the useful life of devices; explant analysis; improved *in vitro* and animal models for device testing and validation.

L. ***Micro- and Nano-Systems, Platform Technologies.*** Development of BioMEMS, microfluidics and nanoscale technologies, including micro-total analysis systems, arrays, and biochips, for detection and quantitation of clinically relevant analytes in complex matrices. Application areas include biomedical research, clinical laboratory diagnostics, biodefense, high-throughput screening, drug delivery, tissue engineering, and implantable devices, among others.

M. ***Nanotechnology.*** Research and development of new enabling technologies for the fabrication and use of nanoscale components and systems in diagnostic and therapeutic applications. Examples include: development of new nanoscale patterning and manipulation systems; new approaches to the sensing and quantification of biologically important molecules using nanoscale specific properties; studies relating to the safety and commercialization of nanotechnology-enabled biomedical products.

N. ***Nuclear Medicine.*** Research and development of technologies that create images out of the gamma-ray or positron (and resulting photon) emissions from radioactive agents that are injected, inhaled, or ingested into the body and then concentrate in specific biological compartments. Two particularly active areas are the wedding of positron emission tomography (PET) and single photon emission computed tomography (SPECT) to CT and/or to MRI, and the design of higher resolution, lower cost PET and SPECT devices for the study of molecular probes in small animals. Other topics of interest include the development of better radiopharmaceuticals, crystal scintillators, and collimators, and novel approaches to dual-isotope imaging and to dosimetry.

O. ***Optical Imaging and Spectroscopy.*** Development and application of optical imaging, microscopy, and spectroscopy techniques; and development and application of optical imaging contrasts. Examples of research areas include fluorescence imaging, bioluminescence imaging, OCT, SHG, IR imaging, diffuse optical tomography, optical microscopy and spectroscopy, confocal microscopy, multiphoton microscopy, flow cytometry, development of innovative light sources and fiber optic imaging devices.

P. ***Sensors.*** Development of sensor technologies for the detection and quantitation of clinically relevant analytes in complex matrices. Application areas include (among others) biomedical research, clinical laboratory diagnostics, and biodefense, covering *in vitro* diagnostics, noninvasive monitoring, and

implantable devices. Technologies encompassed include novel signal transduction approaches, materials for molecular recognition, biocompatibility, signal processing, fabrication technologies, actuators, and power sources.

Q. ***Structural Biology.*** Development of structural biology techniques, including (but not restricted to) solid state NMR, EPR, synchrotron radiation, etc. The emphasis is on technological development, rather than applications to specific structural biology problems.

R. ***Surgical Tools and Techniques.*** Research and development of new medical technologies to improve the outcomes of surgical interventions. Examples of relevant technologies include: minimally invasive surgeries, energy-based interventions such as RF ablation, robotically assisted surgical systems, integration of imaging and interventional modalities, image guided interventions and telehealth.

S. ***Telehealth.*** Development of software and hardware for telehealth studies that have broad applications as well as early stage development of telehealth technologies that may have specific focus areas. Research that is supported includes methods to address usability and implementation issues in remote settings, and methods to develop technology for standardizing and incorporating state of the art security protocols for verifying user identities and preserving patient confidentiality across remote access.

T. ***Tissue Engineering and Regenerative Medicine.*** Development of enabling technologies including real-time, non-invasive tools for assessing the function of engineered tissues; real-time assays that monitor the interaction of cells and their environment at the molecular and organelle level; predictive computational models for engineering function 3D tissues; high-throughput assays and instruments to reduce the cost, time, and complexity of tissue engineering; novel bioreactor techniques for expanding stem cells and growing tissues and organs on a large scale; and strategies for preserving, sterilizing, packaging, and transporting living-tissue products. The program also supports applications of rational engineering design principles to functional engineered tissues; the development of novel biomaterials for use as tissue scaffolds that mimic the extracellular matrix and support multiple cell types in defined spatial orientation; and engineering approaches to study how biomaterials interact with cells and guide cell growth, differentiation, and migration.

U. ***Ultrasound.*** Improvement of technologies for diagnostic, interventional and therapeutic uses of ultrasound. The diagnostic ultrasound program includes, but is not limited to the design, development and construction of transducers, transducer arrays, and transducer materials, innovative image acquisition and display methods, innovative signal processing methods and devices, and optoacoustic and thermoacoustic technology. It also includes the development of image-enhancement devices and methods, such as contrast agents, image and data presentation and mapping methods, such as functional imaging and image fusion. The interventional ultrasound program includes the use of ultrasound for therapeutic use, or as an adjunct for enhancement of non-ultrasound therapy applications. Examples include, but are not limited to, high-intensity focused ultrasound (HIFU) as a non-invasive or minimally invasive interventional surgical or therapy tool, and as an adjunct interventional tool. It also includes the use of ultrasound contrast agents for therapy and for targeted drug delivery, and the use of ultrasound for image-guided surgery, biopsy, and other interventions.

V. ***X-ray, Electron, and Ion Beam.*** Enhancement of computed tomography (CT), computed radiography (CR), digital radiography (DR), digital fluoroscopy (DF), and related modalities. Research areas of support include the development of: flat panel detector arrays and other detector systems; flat-panel CT; CT reconstruction algorithms for the cone-beam geometry of multi-slice CT; approaches to radiation dose reduction, especially with CT; and novel x-ray applications, such as those utilizing scattered radiation, tissue-induced x-ray phase shifts, etc.

For additional information on research topics, contact:

Mr. Todd Merchak

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For administrative and business management questions, contact:

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NATIONAL CANCER INSTITUTE (NCI)

The National Cancer Institute (NCI) is committed to dramatically lessening the impact of cancer. The Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs are NCI's engines of innovation for developing and commercializing novel technologies to better prevent, diagnose, and treat cancer while enhancing cancer research and control. NCI's SBIR and STTR Programs offer funding for therapeutic agents and devices; *in vitro* and *in vivo* diagnostics, including companion diagnostics and imaging agents; agents and technologies for cancer prevention; tools for research in cancer biology, cancer control, and epidemiology; digital health, including health information technology and bioinformatics; and many more areas of interest to the NCI.

NCI's SBIR and STTR programs focus on research, development, and delivery of cancer technologies by funding small business concerns to conduct innovative research and development. The NCI SBIR Development Center is committed to helping small business concerns advance promising technologies towards the marketplace through funding as well as initiatives designed to facilitate external investments and commercialization. NCI is interested in following the progress of its funded small business concerns and the products they develop. Funding priority will be given to those small business concerns that show not only the ability to develop products but also growth towards independence from the SBIR/STTR programs.

The major NCI SBIR/STTR portfolio areas are listed below as a guide to general technology areas funded through the program. Applications proposing innovative cancer-related technologies, with strong commercial potential, that fall outside these topic areas are also encouraged through this Omnibus solicitation.

Major NCI SBIR/STTR Portfolio Areas:

- Therapeutics (e.g., Small Molecules, Biologics, Radiomodulators, and Cell-based Therapies)
- *In Vitro* and *In Vivo* Diagnostics (e.g., Companion Diagnostics and Prognostic Technologies)
- Imaging Technologies (e.g., Agents, Devices, and Image-Guided Interventions)
- Devices for Cancer Therapy (e.g., Interventional Devices, Surgical, and Radiation and Ablative Therapies)
- Tools for Cancer Biology Research
- Technologies and Agents for Cancer Prevention
- Technologies for Cancer Control (e.g., Behavioral Health Interventions, Tools for Genetic, Epidemiologic, Behavioral, Social, and/or Surveillance Cancer Research)
- Digital Health (e.g., Mobile Health, Health Information Technology, and Bioinformatics)

NCI particularly encourages applications in the following current research topics of interest:

- Development of Low Cost Technologies for Global Health
- Development of Companion Diagnostics
- Vaccine Development for Cancer Prevention
- Novel Technologies to Address "Undruggable" Drug Targets
- New Technologies to Assess Tissue-Based Markers of Tumor Death and Mitochondrial Stress in Response to Therapy
- Advances in Chimeric Antigen Receptor (CAR) Vector Engineering to Improve CARs Functionality and Safety
- Natural Language Processing (NLP) Applications to Electronic Health Records (EHR) to advance cancer prevention and control
- Automated Methods for Extraction and Consolidation of Cancer Registry Data
- Development of Novel Cancer Therapeutics Targeting Epigenetic Alterations
- Image-Guided Biopsy Platforms for Assessing Tumor Tissue Teterogeneity

- Cloud Computing Based Sharing, Integration and Analysis of Imaging Data for Cancer Diagnosis, Prognosis and Monitoring
- New Technologies for Ultrasensitive Molecular Histopathology

NCI accepts and encourages SBIR/STTR applications to support clinical trials.

For up-to-date information on high priority technology areas, and to learn about programmatic initiatives and upcoming events, visit the NCI SBIR Development Center homepage: http://sbir.cancer.gov/.

In addition, please see the contact list at the end of the NCI section to identify the Program Director within the NCI SBIR Development Center who specializes in your technology area.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NCI may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Generally, NCI will not fund Phase I applications greater than $225,000 total costs or project periods greater than 2 years; nor Phase II applications greater than $1,500,000 total costs or project periods greater than 3 years. For certain topical areas (http://bit.ly/NCIwaiver), the Small Business Administration has approved an NIH SBIR/STTR Topic Waiver list for which the NCI generally will not fund Phase I applications greater than $300,000 total costs or project periods greater than 2 years; nor Phase II applications greater than $2,000,000 total costs or project periods greater than 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB SBIR Competing Renewal Awards

The NCI does not accept applications for Phase IIB SBIR competing renewal award through this Omnibus solicitation. However, the NCI offers Phase IIB opportunities in the form of the NCI SBIR Bridge Award, which is announced via a separate funding solicitation. The SBIR Bridge Award is designed to support the next stage of development for previously funded NIH-wide SBIR Phase II projects in the areas of cancer therapeutics, imaging technologies, interventional devices, diagnostics and prognostics. The purpose of this award is to address the funding gap known as the "Valley of Death" between the end of the SBIR Phase II award and the subsequent round of financing needed to advance a product or service toward commercialization. To achieve this goal, the Bridge Award funding opportunity is specifically designed to incentivize partnerships between NIH's SBIR Phase II awardees and third-party investors and/or strategic partners. Competitive preference and funding priority will be given to applicants that demonstrate the ability to secure substantial independent third-party investor funds (i.e., third-party funds that equal or exceed the requested NCI funds).

Budgets up to $1 million in total costs per year and project periods up to three years (a total of $3 million over three years) may be requested from the NCI. Development efforts may include preclinical R&D needed for regulatory filings (e.g., IND or IDE) and/or clinical trials. NCI intends to commit up to $10M for up to 10 new awards in FY2015.

To ensure that you will be notified upon the release of the NCI SBIR Phase IIB Bridge Award solicitation, please sign up for the NCI SBIR mailing list. If you have any questions regarding the Bridge Award, please contact your Phase II program director.

For additional information about the NCI SBIR/STTR programs, please contact the NCI SBIR Development Center:

Small Business Innovation Research (SBIR) Development Center
National Cancer Institute

9609 Medical Center Drive
Rockville, MD 20850
Website: http://sbir.cancer.gov
Email: NCIsbir@mail.nih.gov
Phone: 240-276-5300

For additional information on research topics, please contact a Program Officer with the relevant area of expertise:

Michael Weingarten, MA
Director, NCI SBIR Development Center
Email: weingartenm@mail.nih.gov

Gregory Evans, PhD
Program Director and Team Leader
Email: evansgl@mail.nih.gov

Areas of expertise: Therapeutics (Immunotherapy, Gene Therapy), Cancer Imaging, Cancer Control, Tools for Cancer Biology Research, and Digital Health

Andrew Kurtz, PhD
Program Director and Team Leader
Email: kurtza@mail.nih.gov

Areas of expertise: Therapeutics (Small Molecules, Biologics, Nanotherapeutics), and Molecular Diagnostics

Patricia Weber, DrPH
Program Director
Email: weberpa@mail.nih.gov

Areas of expertise: Digital Health and Therapeutics (Small Molecules, Biologics, Immunotherapy)

Xing-Jian Lou, PhD
Program Director
Email: loux@mail.nih.gov

Areas of expertise: *In Vitro* Diagnostics and Therapeutics (Gene Therapy)

Deepa Narayanan, MS, CCDM
Program Director
Email: narayanand@mail.nih.gov

Areas of expertise: Radiation Therapy, Cancer Imaging, Medical Devices, and Clinical Trials

Amir Rahbar, PhD, MBA
Program Director
Email: amir.rahbar@nih.gov

Areas of expertise: *In Vitro* Diagnostics, Proteomics, and Therapeutics (Biologics)

Todd Haim, PhD
Program Director
Email: haimte@mail.nih.gov

Areas of expertise: Therapeutics (Small Molecules, Biologics, Immunotherapy) and Cancer Prevention

Ming Zhao, PhD
Program Director
Email: zhaoming3@mail.nih.gov

Areas of expertise: *In Vitro* Diagnostics, Cancer Stem Cells, Molecular Imaging, Bioinformatics, Therapeutics (Small Molecules, Biologics, Immunotherapy), and Cancer Control (Community-Based Participatory Research)

Jonathan Franca-Koh PhD, MBA
Program Director
Email: jonathan.franca-koh@nih.gov

Areas of expertise: Cancer Biology, Biologics, Small Molecules, Cell Based Therapies

For administrative and grants management questions, please contact:

Jacquelyn Boudjeda
Grants Management Specialist
Office of Grants Administration
National Cancer Institute
9609 Medical Center Drive
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For NCI-related SBIR Information, visit: http://sbir.cancer.gov.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

The mission of the NICHD is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation.

For additional information about research areas of scientific interest to the NICHD, please visit our home page at http://www.nichd.nih.gov.

Budget Guidelines

For NICHD award topic areas included in PHS 2015-2 Omnibus Solicitation, the NICHD will accept SBIR/STTR applications up to $225K total costs for Phase I and $1.5M for Phase II. Requests for costs above the SBIR/STTR budgetary guidelines of $150K for Phase I and $1M for Phase II must be very well justified.

The NICHD received a budgetary guideline waiver from the Small Business Administration for applications relating to the limited list of scientific topics (Appendix A). For these the NICHD will accept applications up to $300K total costs for Phase I and $2M for Phase II. Requests for costs above the guidelines of $150K for Phase I and $1M for Phase II must be very well justified.

Applicants are strongly encouraged to contact the listed NICHD Branch Contact Program Officer for scientific-related questions about a project's eligibility for a budgetary waiver. For general budgetary questions applicants are encouraged to contact the Institute's SBIR/STTR Grants Management Coordinator.

Phase IIB Competing Renewal Awards

NICHD will accept Phase IIB SBIR Competing Renewal grant applications to continue the process of developing products that require approval of a Federal regulatory agency (e.g., FDA, FCC). Such products include, but are not limited to: medical implants, pediatric devices, drugs, vaccines, and new treatment or diagnostic tools that require FDA approval. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. Applicants who received NICHD SBIR Phase I or Phase II support and who are currently Phase II awardees are eligible (NICHD SBIR only and only competing renewals of NICHD supported Phase II awards). Budgets for Phase IIB renewals should not exceed 3 million dollars total costs for three years. Depending on the research proposed the amounts may vary each year for the time requested.

You are strongly encouraged to contact Dr. Louis Quatrano or the Program Contact listed at the end of each topic area before beginning the process of putting a Phase IIB Competing Renewal application together. Prospective applicants are strongly encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NICHD SBIR/STTR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

Examples of research that would be considered responsive to this announcement are listed below for illustrative purposes and are not exclusive of other appropriate activities.

NICHD Topic Areas

CHILD DEVELOPMENT AND BEHAVIOR BRANCH

The CDBB encourages innovative developmentally-sensitive theoretically-grounded evidence-based small business initiatives that develop technology and products addressing the psychological, social and emotional, psychobiological, language, numerical, literacy, cognitive and intellectual development and health of persons from infancy to maturity recognizing the important role others have in contributing to the healthy development of an individual. Products that target at-risk populations and/or exploit new technologies that can expand the effective reach or inclusion of underserved populations in order to encourage healthy development and/or our understanding of the influences of context and/or behavior on development are especially encouraged.

Foci of specific interest include, but are not limited to (please also see the CDBB description):

- Social-emotional health and skill development in children, prevention of child abuse and neglect in at-risk populations, parenting skills, assessment of emotion, the impact of human-animal interactions on development
- Functional assessment of brain processes in young children, quantification of behavior in animal models, memory, learning, facilitation in children and adolescents
- Behavioral and developmental aspects of health risk behaviors and health promotion from infancy to young adulthood
- Tools to address reading, writing, and related learning disabilities, for use within or outside of the classroom
- Biliteracy learning and English Language Learners (ELLs), including struggling primary and/or second language learners (of any age from birth through young adulthood)
- Assessment of and promotion of early learning and development of school readiness skills and abilities, including those designed for at-risk children and their families
- Measures of home, child care and preschool environments and practices that are related to child learning and development
- Study and promotion of behavioral and developmental aspects of mathematical and/or scientific thinking, problem solving, reasoning, learning, and discovery
- Assistive or instructional technologies for use by at-risk or struggling learners of any age cohort from birth through young adulthood in any context (e.g., home, school, work) where improved learning, understanding and/or reasoning is needed.

Dr. Kathy Mann Koepke
301-435-6855, Fax: 301-451-5650
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CONTRACEPTIVE DISCOVERY AND DEVELOPMENT BRANCH

Emphasis is on developing new and improved methods of fertility regulation as well as research on the benefits and risks of contraceptive drugs, devices and surgical procedures. Areas of interest include, but are not limited to:

- Development of new and improved methods of fertility regulation, for men and women, that are safe, effective, inexpensive, reversible and acceptable.
- Validation and characterization of targets whose modulation may be contraceptive.
- Synthesis and testing of novel chemical compounds that are potential contraceptives.

- Initiate an interdisciplinary bioinformatics approach to perform data mining through the NCBI, MGI and genome wide associated database to facilitate target discovery and maximize the success rate for contraceptive development.
- Studies to clarify the mechanism of interaction between contraception and other disease processes or conditions.
- Small molecule lead discovery through screening targeted and natural product compound libraries on validated male and female contraceptive targets.
- Screening non-traditional sources of natural products on validated male and female contraceptive targets.
- Medicinal chemistry component in support of drug design and synthesis on validated male and female contraceptive targets.
- Integrated computational/modeling, fragment library screening, structure biology, medicinal chemistry and biological screening infrastructures for structure based drug discovery (SBDD).
- Discovery and validation of male and female specific targets involved in control of fertility through research on the processes of spermatogenesis, follicular development, ovulation or fertilization.
- Multipurpose technologies designed to prevent sexually transmitted infections, such as HIV, as well as pregnancy.

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DEVELOPMENTAL BIOLOGY AND STRUCTURAL VARIATION BRANCH

Biomedical research on the cellular, molecular, and genetic aspects of normal and aberrant embryonic and fetal development including early embryogenesis, organogenesis, development of the nervous system, and causative factors in teratogenesis, as well as related topics on regeneration [e.g. limb, CNS, etc.] and regenerative medicine. Areas of interest include but are not limited to:

- Development and application of new animal model systems to understand developmental mechanisms and causes of structural birth defects
- Innovative technologies for in vivo imaging of developmental processes (cell and tissue dynamics) and gene expression
- Development of antibodies for use in *Xenopus* research through production of new antibodies that cross-react with *Xenopus* antigens or testing of existing antibodies to establish their utility in recognizing *Xenopus* antigens.
- Technologies for quantitative measurement of physical properties of cells/tissues in vivo
- Innovative and high throughput genomic and proteomic techniques
- Technologies to facilitate and advance systems biology approaches to the study of embryonic development and structural birth defects
- Innovative technologies to facilitate and advance high throughput plating of zebrafish embryos, larva, and adults to facilitate chemical screening (including small molecules) for advancing structural birth defects research
- Software development to facilitate the collection and analyses of data generated through the use of high throughput screening platforms using zebrafish embryos, larva, and adults
- Technologies/methodologies to generate and software to mine data related to wound healing and regenerative responses across animal species
- Technologies for iPS cell-based regenerative medicine
- High throughput screening of small molecules in human ES cells or iPS cells and disease specific iPS cells for targeted modification of signaling pathways pertaining to regenerative medicine
- Development of novel ligands, promoters and other probes that can facilitate regenerative mechanisms

Dr. Mahua Mukhopadhyay

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FERTILITY AND INFERTILITY BRANCH

Research on the reproductive processes of men and women and of animals with similar reproductive systems related to developing safer and more effective means of regulating, preserving or achieving fertility. Particular areas of programmatic interest relative to small business initiatives include, but are not limited to:

- Development of reagents to facilitate study of reproductive and developmental processes.
- Development of improved methods of growing and differentiating stem cell lines *in vitro*, including feeder cell-free approaches.
- Development of novel assays, kits, and devices to monitor fertility and treat infertility and gynecological disorders.
- Use of genomics and proteomics to develop novel diagnostics and treatments for reproductive diseases and disorders.
- Development of high resolution technologies to provide invasive or noninvasive assessments of reproductive and developmental competence.
- Development of experimental animal models that would be useful for studying the physiology and pathophysiology of reproductive processes.
- Development of techniques and identification of novel biomarkers to produce, identify, and use healthy gametes.
- Development of improved and novel technologies for the preservation of human gametes.
- Development of improved technologies for preimplantation genetic diagnosis.
- Development of improved technologies for the reprogramming of cells, including embryonic stem cells or adult cells, into eggs and sperm.

Dr. Ravi Ravindranath
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GYNECOLOGIC HEALTH AND DISEASE BRANCH

Emphasis is on biomedical research related to gynecologic health throughout the reproductive lifespan, beginning at puberty and extending through early menopause. Areas of interest include, but are not limited to:

- Development of new and diagnostic approaches and treatments for female pelvic floor disorders, including drugs, and devices used for treatment of pelvic organ prolapse, urinary incontinence, fecal incontinence and other female pelvic floor disorders.
- Development of new diagnostic methods and novel surgical and non-surgical treatments for uterine fibroids, endometriosis, adenomyosis, and benign ovarian cysts.
- Generation of new approaches to the treatment of abnormal menstrual cyclicity and other symptoms associated with the perimenopause/menopausal transition.
- Research on mechanisms, diagnosis and treatment of gynecologic pain disorders including chronic pelvic pain, vulvodynia and dysmenorrhea.

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INTELLECTUAL AND DEVELOPMENTAL DISABILITIES BRANCH

The IDD Branch sponsors research aimed at preventing, diagnosing, and ameliorating intellectual and developmental disabilities (IDD). Emphasis is on studies related IDD, including common and rare neuromuscular and neurodevelopmental disorders, such as Down, Fragile X, and Rett syndromes, mitochondrial conditions, inborn errors of metabolism, autism spectrum disorders, and others. Areas of interest include, but are not limited to:

- Studies designed to understand the etiology and pathophysiology of abnormal nervous system development
- Studies designed to delineate genetic, genomic, and epigenetic bases of IDD
- Studies designed to examine the screening, diagnosis, treatment, and management of IDD and other conditions identified by newborn screening or other screening methods
- Studies that promote multidisciplinary and translational research in IDD through programs that integrate basic and applied research, training, and service activities
- Studies that advance efforts toward the prevention and diagnosis of IDD as well as early intervention and treatment for these conditions.

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MATERNAL AND PEDIATRIC INFECTIOUS DISEASE BRANCH

The MPIDB supports domestic and international research on human immunodeficiency virus (HIV)/acquired immune deficiency syndrome (AIDS) and related infections (such as tuberculosis, hepatitis and malaria) in women of child bearing age, pregnant women, mothers, fetuses, infants, children and adolescents. Specific areas of interest include but are not limited to epidemiology, clinical manifestations, pathogenesis, transmission, treatment and prevention (including vaccines and other biomedical modalities) of HIV infection and other infectious diseases in children, adolescents and pregnant women, including prevention of mother to child transmission of HIV and other congenital infections, and HIV-related and other infectious-disease related complications in these populations. Additional areas of interest include:

- New technologies relevant to resource-limited countries for:
    - diagnosis of infectious diseases in pregnant women, infants and children, including but not limited to HIV (e.g. congenital CMV);
    - point of care assays to monitor disease activity and response to therapy for relevant infections in infants and children (e.g. malaria, tuberculosis)
    - diagnosis and treatment of HIV-related co-morbidities (e.g., diagnosis of tuberculosis in children);
    - simple and less technologically demanding point of care assays to monitor CD4 cell percentage/count, HIV viral load, or other surrogate markers of HIV disease progression in children;
    - interventions designed to promote or optimize medication adherence.
- Child-friendly formulations (preferably not liquid preparations) of drugs used to treat or prevent HIV infection, complications of HIV infection, and/or other high-priority infections such as tuberculosis, hepatitis, and malaria relevant to children, particularly in resource-limited countries and including fixed-dose drug formulations and innovative methodologies for development of solid heat stable formulations capable of being administered to young children (e.g., sustained release beads, etc).
- Innovative long-lasting drug formulations for antiretroviral and other anti-infective drugs that would allow less frequent drug administration (e.g., once daily, weekly or monthly).

- Simple, standardized, validated tools to evaluate neurodevelopmental outcomes in children in resource-limited settings.
- Biomedical modalities, including vaccines, to prevent acquisition of HIV and other infectious diseases in children, adolescents and women.
- Topical microbicide agents to prevent sexual acquisition of HIV and other sexually transmitted infections in adolescents, adult women and pregnant or postpartum women.
- New, non-invasive technologies to evaluate complications of antiretroviral drugs (e.g., mitochondrial toxicity, bone toxicity) in HIV-infected infants, children, adolescents and pregnant women, their fetuses and children.

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OBSTETRIC AND PEDIATRIC PHARMACOLOGY AND THERAPEUTICS BRANCH

The OPP Branch promotes research to improve the safety and efficacy of pharmaceuticals and to ensure centralization and coordination of research, clinical trials, and drug development activities for obstetric and pediatric populations. This includes developing and supporting a comprehensive national effort to increase the knowledge base for understanding how to appropriately treat disease during pregnancy, infancy, and childhood using pharmaceuticals that are appropriately tested within their target populations.

Applications to advance the study of obstetric and pediatric pharmacology include:

- Research and tools to better characterize the impact of physiological and developmental changes on pharmacokinetics and pharmacodynamics, drug disposition and response;
- Advancements in pharmacokinetic/pharmacodynamics modeling which improve therapy during pregnancy, among premature infants, children and adolescents;
- Research on devices to monitor the state of various organ systems during therapy in pregnancy or infancy;
- Development of non-invasive devices for evaluating adherence to chronic therapy in life-threatening conditions (e.g. HIV, diabetes, asthma, liver and kidney transplantation);
- Development of novel approaches for oral mucosal, transdermal, nasal, ocular and pulmonary drug delivery systems and device technologies.
- Use of a materials science approach to overcome solubility limitations of pediatric drugs, increase bioavailability, decrease excipient exposure, and provide effective taste masking.
- Development of nanosized formulations to optimize efficacy and minimize toxicity of pediatric drugs
- Identification of targets for pregnancy associated/induced diseases that can lead to the development of new targeted therapeutics for diseases like pre-eclampsia, gestational diabetes, preterm labor.

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PEDIATRIC GROWTH AND NUTRITION BRANCH

The PGN branch supports research designed to lay the groundwork for future health so that children can achieve their full potential for growth and development. The burden of metabolic syndrome, obesity, cardiovascular disease, diabetes, and osteoporosis continue to increase in this country and abroad. These chronic conditions have their roots in infancy or childhood and are difficult or impossible to reverse in adulthood. The PGN encourages research that focuses on detecting the earliest aberrations in

molecular and biochemical pathways that lead to disease later in life. Areas of interest include, but are not limited to:

- Physical growth, body composition, bone health, nutrition, and obesity.
- Determinants of normal bone mineral accretion and peak bone mass. Interactions of muscle and bone during infancy and childhood.
- Neuroendocrinology of puberty, linear growth, obesity, and malnutrition.
- Prevention of chronic diseases such as diabetes, osteoporosis and metabolic syndrome.
- Genetic and molecular mechanisms of obesity, psychosocial risks of obesity, and therapeutic interventions for obesity.
- Mechanisms of hormone action during linear growth, pubertal maturation, and other aspects of development.
- Novel approaches to Type-1 Diabetes management and treatment, especially related to the development of the artificial pancreas.
- Technological innovations/inventions to diagnose and monitor diabetes.
- Nutritional requirements during pregnancy
- Aspects of nutrients related to growth and disease prevention during infancy and childhood.
- Training of the next generation of pediatrician scientists.
- Develop new class of antimicrobial agents based on human milk oligosaccharides.
- Develop platforms for implementation of biomarkers of nutritional status and biological function.

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PEDIATRIC TRAUMA AND CRITICAL ILLNESS BRANCH

The PTCIB supports research and research training in pediatric trauma, injury, and critical illness across the continuum of care. These efforts include:

- Research on the prevention, treatment, management, and outcomes of physical and psychological trauma and the surgical, medical, psychosocial, and systems interventions needed to improve outcomes for critically ill and injured children and youth.
- Studies of the continuum of psychosocial, behavioral, biological, and physiological influences that affect child health outcomes in trauma, injury, and acute care.
- Basic, clinical, and translational studies that explore short- and long-term consequences of such traumatic experiences as natural and man-made disasters, acute forms of child maltreatment, violence, and exposure to violence .
- Research linking the science of pediatric emergency and critical care medicine to the epidemiology, prevention, and treatment of trauma and injury in infants, children and adolescents.

SBIR/STTR Applications of interest include, but are not limited to:

- Research and development on pediatric-specific technologies and equipment used by emergency and trauma care personnel.
- Research and development of novel strategies approaches in caring for injured children prior to and during transport to treatment settings.
- Development of tools and technologies for efficient screening and determination of the nature of injury, bruising related to forms of child maltreatment.
- Research and development of devices and innovative therapeutic technologies for management of physical disabilities and related problems stemming from and acute injuries.
- Development of preventive intervention tools, materials, and technologies designed to improve clinical practice, parenting and social system support for injured children and children exposed to violence.

- Development of tools and technologies that support the diagnoses and treatment of critical illness in children, including nosocomial infections and iatrogenic injury.

Dr. Valerie Maholmes
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POPULATION DYNAMICS BRANCH

The PD Branch supports research and research training in demography, reproductive health, and population health. In **demography**, the Branch supports research on the scientific study of human populations, including fertility, mortality and morbidity, migration, population distribution, nuptiality, family demography, population growth and decline, and the causes and consequences of demographic change. In **reproductive health**, the Branch supports behavioral and social science research on sexually transmitted diseases, HIV/AIDS, family planning, and infertility. In **population health**, the Branch supports data collection and research on human health, productivity, behavior, and development at the population level, using such methods as inferential statistics, natural experiments, policy experiments, statistical modeling, and gene/environment interaction studies.

Applications are encouraged, but are not limited to these areas:

- Technological innovations or inventions to improve collection of biomarker data in large population-representative surveys.
- Hardware or software to improve collection of accurate cause of death information or health diagnosis in large population-representative surveys or in administrative data sets.
- Methods for integrating geographical information systems (GIS), spatial network analysis, and/or simulation methods for demographic research.
- Methods for improving collection, documentation, archiving, and dissemination of population representative data sets, including especially data sets that are complex, multilevel or multimodal.
- Methods for protecting and assuring confidentiality for human subjects when collecting, archiving, or disseminating population-representative data sets, especially data sets that are longitudinal or that include both spatial and individual-level data.
- Methods for reducing cost of collecting and disseminating large-population-representative data sets.
- Development of effective tools for prevention research and intervention programs related to STD/HIV, pregnancy, contraceptive use, divorce, child health, at risk youth, and other health-related topics, and to the dissemination of such tools.
- Innovative approaches to teaching population studies and other behavioral and social sciences at the undergraduate and graduate level.
- Innovative approaches for research design, data collection techniques, measurement, and data analysis techniques in the social and behavioral sciences, with particular attention to methodology and measurement issues in studying diverse populations, sensitive behaviors, confidential behaviors; in issues related to the protection of research subjects; and in issues related to the archiving and disseminating complex datasets.

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PREGNANCY AND PERINATOLOGY BRANCH

The PP branch supports research in the following areas: the physiology of pregnancy and labor; high-risk pregnancies, including those with hypertensive disorders, diabetes or seizure disorders; fetal pathophysiology; premature labor and birth; diagnostic, monitoring, and therapeutic devices and

instruments for newborn infants in the nursery and in Neonatal ICU setting; improving the existing products or developing new products that would improve the routine and extended care of the newborn infants; products and agents related to breastfeeding; hospital supplies specifically related to use in the care of newborn infants; nanotechnology and its application for the care of newborn infants; instruments and devices assessing and monitoring the nursery environment (noise, lighting, and odor); disorders of the newborn; sudden infant death syndrome; and biological and behavioral antecedents of low birth weight. The following topic areas are of high priority:

Neonatal:

- Non-invasive methods for assessing cardiovascular and pulmonary functions, including cardiac output, systemic blood pressure, airway resistance, pulmonary compliance, vital capacity and various lung volumes.
- Metabolic profile assessment using non-invasive or minimally invasive approaches. Particular area of expertise include measurement of glucose and lactate/pyruvate; assessing ketone body measurements; free indirect bilirubin (unconjugated, free indirect); major chemicals (Na^+ Ca^+ Cl^+ K^+ etc.) in the blood.
- Improved point of care methods to measure plasma glucose concentrations, electrolytes, and blood gas measurements quickly and accurately.
- Devices, instruments, and tools to minimize bacterial colonization, reduce proclivity for thrombus formation; reduce health-care associated infection risks.
- Rapid methods for diagnosis of bacterial infections and inflammation.
- Non-invasive measures to assess brain energy utilization, especially glucose, oxygen, lactate, ketones, and other energy substrates.
- Brain monitoring and assessment
- Innovative ideas to reduce stress for the staff, parents and infants in the NICU.
- Lab-on-Chip technologies for measuring and monitoring neonatal/perinatal disorders; for assessing routinely monitored biochemical analytes, and for measuring concentrations of drugs and medications using small biological samples.
- Improved devices and instruments for assisted ventilators for use in neonatal ICU
- Improved syringes, needles and injection set ups to help administer small doses of medications in over prolonged periods (example: insulin for treating hyperglycemia)
- Improved methods for naso-gastric feedings for preterm and other at risk (e.g., infants with cleft lip and/or cleft palate; micrognathia)

Perinatal :

- Non-invasive (or minimally invasive) methods to assess fetal well-being
- Non-invasive (or minimally invasive) methods to assess placental anatomy, physiology and function.
- Methods to predict spontaneous preterm birth.
- Methods to predict preeclampsia.
- Non-invasive methods for assessing placental structure and functions
- Refined methods for monitoring uterine contractions, fetal heart rate, and diagnosing predicting fetal conditions

Dr. Tonse Raju
Telephone: 301-496-5575, Fax: 301-496-3790
Email: rajut@mail.nih.gov

NATIONAL CENTER FOR MEDICAL REHABILITATION RESEARCH

This Center supports innovative research on the restoration, replacement, enhancement or adaptation of function for people with chronic physical disabilities. This includes rehabilitative approaches across

etiologies and the lifespan, as well as the environmental and policy factors that promote full participation. We encourage studies that integrate biomedical, engineering and/or psychosocial approaches to develop practical and creative solutions to the daily functioning of people with disabilities and their families. The mission of the NCMRR is to increase the effectiveness of medical rehabilitation practices through research. Information about specific program areas within NCMRR can be found at: https://www.nichd.nih.gov/about/org/ncmrr/Pages/overview.aspx. Examples may include but are not limited to:

- Neuroplasticity - Develop non-invasive and surrogate measures of neuroplasticity that would be appropriate for use in a clinical setting to monitor rehabilitation treatment effectiveness (e.g., biomarkers, imaging).
- Novel Technology – Using nanomaterials, biomarkers, imaging, and robotics to improve rehabilitation treatment for restoration of function. Develop techniques to improve/maximize parameters for non-invasive brain and/or peripheral nerve and muscle stimulation. Advancement of manufacturing of devices or tissues utilizing 3-D printing to increase function.
- Rehabilitation Interventions - Develop Virtual Reality, simulations, e-health and other approaches to promote participation, understand and support healthy behaviors, reduce health disparities and enhance clinical compliance especially in children with physical disabilities. Development and use of robotics, games, virtual reality and other strategies to promote rehabilitation therapies (interventions), enhance compliance, and/or measure outcomes.
- Systems Science - Develop methodologies/models for data analysis of existing data sources to address the health trajectories from pathophysiology to participation in the rehabilitation process, especially the development of algorithms from existing data to assist in prediction of utility, efficacy, or effectiveness of different rehabilitation interventions. Utilize methodology to understand whole body system responses to physical impairments and functional changes.
- Rehabilitation in the Community - Strategies to build or modify community and/or environmental resources that provide effective rehabilitation and health promotion services within the individual's own community.

Investigators proposing budgets exceeding the guidelines are encouraged to contact program staff six weeks prior to submitting the application.

For additional information on research topics, contact:

Dr. Louis A. Quatrano
Telephone: 301-402-4221, Fax: 301-402-0832
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Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

Dr. Louis A. Quatrano
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Email: Quatranol@mail.nih.gov

For administrative and business management questions, contact:

Mr. Ted Williams
Grants Management Specialist
Eunice Kennedy Shriver National Institute of Child Health and Human Development
Telephone: 301-435-6996, Fax: 301-451-5510
Email: williate@mail.nih.gov

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

The mission of the NIDA is to lead the nation in bringing the power of science to bear on drug abuse and addiction, through support and conduct of research across a broad range of disciplines and by ensuring rapid and effective dissemination and use of research results to improve prevention, treatment, and policy. For additional information about areas of interest to the NIDA, please visit our home page at https://sbir.nih.gov/nida/divisions2.

SBIR and STTR programs at NIH are primarily intended to encourage private-sector commercialization of technology and to increase small business participation in federally funded R&D.

Both the SBIR and STTR programs consist of the three phases. During Phase I, NIDA supports the projects which establish the technical merit and feasibility of proposed research / R&D efforts and determines the quality of performance of the applicant (small business concern or SBC) before providing further Federal support in Phase II. Provided that the feasibility is established, during Phase II, NIDA supports research or R&D efforts initiated in Phase I. During Phase III, SBC is to pursue commercialization with non-SBIR/STTR funds (either Federal or non-Federal). Applicants are encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR/STTR grant. Phase III funding may be from any of a number of different sources including, but not limited to: private, venture capital firms, investment companies, joint ventures, R&D limited partnerships, strategic alliances, research contracts, sales of prototypes (built as part of this and/or other project), public offering, state finance programs, non SBIR-funded R&D or production commitments from a Federal agency for use by the United States government or other industrial firms. NIDA monitors SBC efforts to pursue, with non-SBIR/STTR funds, the commercialization of the results of the research or R&D funded in Phases I and II of the SBIR/STTR Program.

NIDA funding decisions will be based on combination of factors:

- programmatic priorities (for current priorities, see NOT-DA-15-041)
- potential for commercialization and public health benefit
- whether the similar projects have already been funded (for reference, search http://projectreporter.nih.gov/reporter.cfm)
- the results of Phase I and the commercial potential and scientific/technical merit of the Phase II application (for Phase II applications);
- the quality of performance of the applicant, with emphasis on prior applicant success in Phase III;
- the peer review scores and critique;
- availability of funds.

Special Features of NIDA SBIR Program

Amount of Award

According to the statutory guidelines, total funding support levels (including direct costs, indirect costs, and fee) are $150,000 for Phase I awards and $1,000,000 for Phase II awards. In certain cases, the US Congress allows awards to exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II- hard cap). NIDA will only consider 50% allowable increase for applications in the areas of programmatic priority (NOT-DA-15-041), and with appropriate and strong justification from the applicant.

Budgets that exceed the hard caps (more than $225,000 for Phase I and more than $1,500,000 for Phase II) must receive a waiver of approval from US SBA. NIH - not the applicant - must apply for this waiver. The list of NIDA waivers can be found here: Program Descriptions and Research Topics and APPENDIX A). If adequate justification is provided and research focus is within NIDA's SBA approved waiver,

applicants may request up to $350,000 in total costs with the project period up to 2 years; or up to $2,500,000 in total costs with the project period up to 3 years for Phase II.

Applications outside of the areas of current strategic interest can be funded at the levels of statutory guidelines only ($150,000 for Phase I and $1,000,000 for Phase II, total costs).

Applicants are strongly encouraged to contact NIDA Division SBIR and STTR Representatives prior to submitting any application in excess of the guidelines. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project. For programmatic, budgetary or administrative reasons, NIDA may decrease the length of an award and/or the budget, or not fund an application.

FAST-TRACK APPLICATIONS

Important consideration for NIDA Fast-Track Mechanism:

- Convincing preliminary data
- Clear, measurable, achievable milestones
- Well-conceived Commercialization Plan
- Letters of Phase III support/interest encouraged
- Track record/previous success in commercializing product or services
- Discussion with NIH Program Staff strongly encouraged

The NIH Fast-Track mechanism expedites the decision and award of SBIR and STTR Phase II funding by incorporating a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together. The Fast-Track application will receive a single rating for the entire proposed project (i.e., it will receive a numerical score or it will receive an “unscored” designation). To be eligible for the Fast-Track option, the Phase I Research Plan must include well-defined, quantifiable milestones that should be achieved prior to initiating Phase II work. In addition, as is required for all Phase II applications, the Phase II portion of a Fast-Track application must present a well-defined Commercialization Plan. NIDA encourages Fast-Track mechanism for scientifically meritorious applications that have expressly high potential for commercialization. Applicants considering a Fast-Track application are strongly encouraged to contact program staff BEFORE submitting an application. NIDA staff will assist the applicant in determining whether the proposed project addresses NIDA’s programmatic priorities, and whether the proposed project satisfies NIDA’s criteria for Fast Track mechanism. Potential Fast-Track applicants are encouraged and expected to discuss with the NIDA program staff the following:

- **Value of the SBIR/STTR Project** - the public/market need addressed, specifying weaknesses in the current approaches to meet this need; the commercial applications of the research and the innovation inherent in this application.
- **Expected Outcomes and Impact** - the proposed project and its key technology objectives; the product, process, or service to be developed in Phase III; the potential societal, educational, and scientific benefits of this work; the non-commercial impacts to the overall significance of the project.
- **Market, Customer, and Competition** - the market and/or market segments targeted, a brief profile of the potential customer, significant advantages SBC’s innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability; the hurdles to overcome in order to gain market/customer acceptance of the proposed innovation; any strategic alliances, partnerships, or licensing agreements already in place to market and sell the product, FDA approval (if required), marketing and sales strategy, overview of the current competitive landscape and any potential competitors over the next several years, etc.

PHASE IIB COMPETING RENEWAL AWARDS

NIDA will accept SBIR/STTR Phase IIB Competing Renewal grant applications from Phase II SBIR/STTR awardees to continue advancing a developing medication for the treatment of Substance Use Disorders (SUDs) to the marketplace. Such products might include (but are not limited to) small molecule drugs and biological agents such as antibodies and vaccines. The financial and time constraints of Phase I and Phase II SBIRs present significant obstacles in the advanced stage development of medications. While Phase I and Phase II SBIR support maybe sufficient for initial discovery and development efforts (e.g., compound synthesis and some *in vitro* and *in vivo* preclinical pharmacological testing), it may not be sufficient to conduct clinical trials or even fully support generation of the preclinical data package needed for an Investigational New Drug (IND) application. The purpose of Phase II Competing Renewal Award is therefore, to provide a Phase II project the possibility of another three years of support. Only a fraction of NIDA SBIR/STTR Phase II awards will likely be eligible for a Phase IIB Competing Renewal award, and applications are considered in a similar pool as new Phase II applications. One key criterion for eligibility for a Phase IIB Competing Renewal award is that the project is sufficiently close to a marketable position that a Phase 2B award could significantly advance the product to the marketplace. A second and equally important criterion is that the Phase2 award results and current market conditions are such that the project continues to be deemed to be of high impact i.e., a high significance project with a similarly high likelihood of a successful outcome. Therefore, the outcome of studies conducted under the previous grant phases should be included in the justification and should provide a sound and convincing rationale for continued development of the medication. Prospective Phase IIB Competing Renewal applicants are strongly encouraged to consult with NIDA staff prior to submission in order to gauge programmatic interest in continued development. The consultation should include provision of a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions

Phase IIB Competing Renewal applications may focus on development efforts for medications targeted towards attainment of abstinence and/or relapse prevention for SUD patients with stimulant (e.g., cocaine and methamphetamine), opiate, cannabis, or nicotine dependence. Medications for emergency room management / stabilization of patients with acute toxic reactions to drugs, would also be appropriate for Phase 2b Competing Renewal applications. Agents currently recognized as presenting such concerns include stimulants such as cocaine, amphetamines and cathinones (Bathsalts), as well as synthetic drugs such as phenethylamines and the thermogenic empathogens (e.g., “Ecstacy”/ “Molly”).

The following examples would make appropriate topics for proposed SBIR or STTR Phase IIB Competing Renewal projects. These are meant for illustrative purposes only and are not exclusive of other appropriate activities:

- Pharmacological and toxicological studies, designed to provide data for preclinical studies section of an IND application.
- Chemistry Manufacturing & Control (CMC) studies to provide data for an IND application
- Human laboratory clinical trials (First in Man) / Escalating Dose studies to determine a medication's safety profile, metabolism, cardiovascular effects, interaction with drugs of abuse, etc.
- Clinical studies to assess the efficacy of the medication under development.

For more information, contact:

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Program Officer, Medications Research Grants Branch (MRGB)
Div. of Pharmacotherapies and Medical Consequences of Drug Abuse

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Research Topics of Interest to NIDA

NIDA emphasizes its need to discover, develop and clinically evaluate medications to treat substance use disorders (SUDs). Specifically, in this Omnibus, NIDA underscores the high programmatic priority given to research that seeks to achieve this goal in the following ways:

1. Drug discovery and development-enabling activities.

Development of innovative technologies, methods or tools, including but not limited to:

- Innovative in vitro, in situ, or in vivo tools for the analysis of the central nervous system, normal and/or diseased.
- Technologies, including molecular imaging, gene expression profiling, and genotyping and sequencing approaches designed to better inform the diagnosis and treatment of substance use disorders (SUD).
- Tools to simplify drug design and preclinical development for SUD.

2. Drug discovery and development activities.

Application of emerging and existing technologies and platforms to SUD drug development. Medical products with potential to minimize drug seeking, compulsive behavior, and/or addictive processes are strongly encouraged. Examples might include, but are not limited to:

- Chemistry / pharmaceutical drug development
- Preclinical and/or clinical drug development
- Technologies or Formulations to improve medication delivery
- New systems for patient adherence monitoring at the point of care in clinical trials
- Development of biomarkers related to treatment outcomes

Research Topics which are not aimed at development of medications for substance-use disorders or at modernizing the drug discovery and development toolkit, are accepted and very strong applications outside of the areas of current strategic interest could be funded at the levels of statutory guidelines (not to exceed $150,000 for Phase I and $1,000,000 for Phase II, in total costs, including direct costs, indirect costs and fee).

EXAMPLES OF TOPICS OF NIDA INTEREST ARE PRESENTED BELOW:

Tools & Technologies

- Development of epigenetic tools and/or technologies to identify, monitor, and/or manipulate:
  - RNA modifications or edited RNAs;
  - Epigenetic- or RNA-modifying enzymes;
  - Circular or long non-coding RNAs;
  - CNS chromatin structure;
  - Chromatin immunoprecipitation (ChIP) grade affinity reagents for epigenomic marks or other neuroscience relevant post-translational modifications;
- Development of epigenetic research probes;

- Development of computational methods or software packages to integrate epigenomics data with genome-wide association datasets
- Development of animal-imaging tools and technologies to facilitate basic addiction research
- Technologies for point-of-care (POC) evaluation for marijuana and/or other substances
- Renewable sources of antibodies for neuroscience research;

Screening assays / Animal Models

- Development of medium-to-high throughput functional assays for molecular phenotyping of neuronal and/or glial cells;
- Development of assays enabling 3D exploration of genomic structure within CNS tissues;
- Development of iPSC cortical organoid / 3D culture screening assays;
- Development of pulmonary self-administration (SA) chambers to assess marijuana abuse and treatment;

Novel Therapies / Formulation Development to Treat Substance Use Disorders (SUD)

- Development of novel, non-invasive brain stimulation-based therapeutics
- Development of novel compounds targeting: ORL1 receptor agonists, muscarinic (M5) antagonists, dopamine (D4) antagonists, kappa opioid receptor antagonists, mGluR5 antagonists; NMDA antagonists; CB2 receptor agonists, or other justified anti-SUD targets;
- Development of targeted ultrasound- or IR-activated release of drugs of abuse for drug self-administration studies;
- Development of targeted, nanotechnology delivery systems for new or existing pharmacotherapies (e.g., nanotechnology).

Contact: Kristopher Bough, PhD; 301-443-9800; Email: boughk@mail.nih.gov

Clinical Drug Development. NIDA seeks to support the clinical development of novel pharmacotherapeutic compounds or immunological treatments that have successfully completed (or are nearing completion of) preclinical evaluation as treatments for SUDs. Projects of interest can evaluate products in any clinical development phase, with the aim of helping subjects become drug free, reduce drug use, prolong abstinence, reduce craving or facilitate survival from drug overdose.

Therapies of interest include, but are not limited to the following:

- Novel compounds or drug formulations that could be used to treat SUDs. Any well rationalized target with a lead compound (at least) ready for “First in Man” studies would be considered.
- Repurposing of compounds previously developed for other indications, as novel treatments of SUDs.
- New or improved technologies (devices, markers, systems, services or software) to assess / remediate medication regimen adherence during clinical trials.
- New pharmacological strategies to reduce dependence on opioid medications to treat pain in outpatient subjects (opioid sparing strategies). These could be agents that can improve opioid-analgesia and therefore reduce the opioid dose required for pain management or analgesic medications can substitute for opioids in clinical indications where opioids are regularly employed
- Medications to treat benzodiazepine overdose. CDC Mortality numbers show deaths caused by alprazolam or diazepam rival those seen with oxycodone or morphine. A rescue medication that can reverse overdose symptoms in benzodiazepine abusers, without the potential for producing seizures in dependent individuals would be a significant public health value.
- Improved assays / devices that can quantitatively detect recent consumption of a substance of abuse and accurately assess a narrow time since ingestion. The system should be superior to urinalysis, which is the current gold-standard. The analytical

test/device should be non-invasive, portable and easy-to-use by a person with limited training in its use, such as a trial subject or a nurse at the point of care.
- Vaccines for substances of abuse (e.g., cocaine, nicotine)
- Discovery / development of biomarkers related to SUDs treatment outcomes. SUDs can change the structure and function of the brain, and in doing so present an opportunity to develop biomarkers that can objectively and reliably predict, diagnose or assess SUD treatment outcomes.

Late Stage drug discovery and development activities: Application of emerging and existing technologies and platforms to SUD drug development. This includes the identification, evaluation, development, approvability, and efficacy testing of new and improved pharmacotherapeutic agents, as well as the testing of marketed medications, and of behavioral treatments used alone or integrated with medications. Medical products with potential to minimize drug seeking, compulsive behavior, and/or addictive processes are strongly encouraged.

- Chemistry / pharmaceutical drug development
- Formulation and/or enhanced delivery of drugs
- Preclinical and/or clinical drug development
- Development of biomarkers related to treatment outcomes

Bioassays for drugs of abuse based on pharmacologic activity, not chemical structure. New "designer" drugs of abuse such as cathinone stimulants sold as “bath salts” and synthetic cannabinoids found in “herbal incense”, are a diverse range of structures identified from the medicinal chemistry literature with structures that have been modified to be novel but retain pharmacological activity. Frequently even the pharmacophore (structural skeleton) bear little resemblance to the canonical drug of abuse e.g., alkylindoles with cannabinoid activity. These untested drugs can be dangerous to users and those with whom they come in contact. Their attraction is their invisibility to drug testing laboratories, but they are similarly invisible to emergency room toxicology screens whose assays typically rely on either antibodies raised to a specific structure or mass-spectrometry libraries that can detect agents for which a finger print has been identified and validated. The NIDA would like to promote the development of assays based on pharmacologic activity rather than chemical structure. Examples of such assays would include (but be not limited to) scintillation proximity assays, robust cell-based assays to detect activation of pharmacological pathways, or cells expressing engineered receptors activated solely by synthetic ligands, designed to pick up a range of metabolites. Other examples might include microfluidic surface plasmon resonance devices, which can both concentrate and detect receptor or antibody-bound substances.

Such assays should be:

- Non-invasive and able to detect quantities of illicit materials or metabolites in a range of concentrations typically found biofluids of substance users within a few days of use.

- Ideally assays should be designed with a standard clinical or analytical laboratory in mind, i.e., to be analyzed in a high throughput format by technicians with a moderate scientific training.

- The assays can be either designed to be analyzed with standard existing equipment, or include both the assay and development of analytical hardware, provided that the ultimate system can be commercially viable in a clinical and drug testing market place.

Contact: Aidan Hampson, Ph.D.; 301-443-8039; Email: aidan.hampson@nih.gov

Very strong applications outside of the areas of current strategic interest are accepted and could be funded at the levels of statutory guidelines (not to exceed $150,000 for Phase I and $1,000,000 for Phase II, in total costs, including direct costs, indirect costs and fee).

- Interaction studies, research involving comorbid mental health disorders, investigations of protective and resilience factors, and sex/gender analyses
- Research on the characterization of how abused drugs affect the structure and function of the human central nervous system
- Research on individual differences in neurobiological, genetic, and neurobehavioral factors that underlie increased risk for and/or resilience to drug abuse, addiction, and drug-related disorders
- Development and testing of provider training materials (including mobile and web-based) to help ensure that interventions are delivered appropriately
- Research on transcranial magnetic stimulation for chronic pain and sleep/insomnia in the context of relapse prevention
- IT-based booster treatments or post-treatment support to extend and sustain the behavior change and increase the chances for treatment success
- Research aimed at improving the adoption of evidence-based approaches and treatments in real-world settings
- Research to develop technological devices in the delivery of initial drug abuse treatment or medication adherence interventions with specific emphasis on validated ability of those devices to increase treatment effects and insure that the intervention is delivered with fidelity and at reduced cost and staff time.

Contact: Will M. Aklin, Ph.D., Tel: 301.443.4877; aklinwm@nida.nih.gov

- Research on new and dynamic ways to monitor changes in the legislative landscape of substance abuse, particularly marijuana and prescription drugs, and how those changes impact health at the population level

- Digital and social media technologies that allow for the identification of substance use problems in individuals and populations, the prevention of those problems, and the provision of the resources necessary for providing those with substance use problems with the services they need

- The expansion of HIV, HCV and TB services and testing in the context of drug abuse (particularly injection drug use)

- The implementation of existing evidence-based substance abuse treatment and prevention services among populations at risk for substance abuse, and among underserved or represented populations, such as minorities, criminal justice populations, American Indian and Alaska Native populations, and those suffering from co-morbid psychological disorders

- The use and implementation of developmentally based interventions to prevention and mitigate risk for substance abuse problems, particularly among youth and adolescents

Contact: Matthew Finger, MA; Tel: 301.402.0263; Matthew.finger@nih.gov

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

The NIDCD supports research on the normal mechanisms of, as well as on diseases and disorders of hearing, balance, smell, taste, voice, speech and language. The Institute also supports research related to disease prevention and health promotion. The NIDCD addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders. The NIDCD also supports efforts to create and refine devices, as well as develop cellular-based applications that may replace or substitute for lost and impaired sensory and communication functions. For more information about areas of interest to the NIDCD, please visit our home page at http://www.nidcd.nih.gov/. Potential applicants are encouraged to contact the program staff listed in the following descriptions of NIDCD program areas early in the process of preparing the application.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NIDCD may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II). Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting the application.

Phase IIB Competing Renewal Awards

The NIDCD will accept **Phase IIB SBIR/STTR Competing Renewal grant applications to support research and development that are required to SUPPORT the process of developing products that require approval by a Federal regulatory agency (e.g., FDA, FCC). Such products include, but are not limited to: medical implants, drugs, vaccines, and new treatment or diagnostic tools that require FDA approval.**

Examples of topics of NIDCD interest are presented below:

Hearing and Balance Program

Development of treatment modalities to prevent or lessen the effects of hearing disorders; development of new hearing aids, cochlear implants, and other assistive devices; development of improved screening technologies to assess hearing loss, especially in neonates and infants; development of new or improved power sources for hearing aids or cochlear implants; development of technologies that provide self-fitting, self-adjusting, or other features that increase performance, accessibility, or affordability of hearing aids; development of new outcome measures for assessing the efficacy of treatments for hearing disorders; development of technologies for the study, diagnosis and treatment of tinnitus; development of technologies for the study, diagnosis and treatment of otitis media including non-invasive diagnostics to identify middle ear pathogens, novel antibacterial strategies, and prophylactic anti-microbial strategies; development of technologies for the study, diagnosis and treatment of noise-induced and age-related hearing loss.

Development of technologies for the study, diagnosis and treatment of balance disorders, particularly for the elderly; development of clinical tests and instruments to assess balance/vestibular function; development of instruments and tests measuring head stability and vestibular function during natural stimulation of the vestibular system; development of perceptual reporting techniques and psychological indices for clinical assessment of the balance-disordered patient; development of tests and new outcome measures for assessing the efficacy of physical rehabilitative regimens for balance disorders; and

development of assistive devices for balance disorders, including neural prostheses for the vestibular system.

Development of new research tools to aid in the study of the auditory and/or balance systems that can provide an improved understanding of fluctuating patterns of neural circuit structure and function over time and across large assemblies of neurons; new animal models of impaired function; improved diagnostic tools for inner ear function, including DNA-based assays and biochemical markers of disease. Development of improved tests and instruments for screening and diagnosis of inner ear function; development of technologies to enable gene transfer to the inner ear, including viral vectors; development of cell type specific markers and probes to examine cell lineage in inner ear regeneration.

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National Institute on Deafness and Other Communication Disorders
301-402-3458, Fax: 301-402-0390
Email: millerr@nidcd.nih.gov

Voice, Speech, and Language Programs

Development of technologies for the study, diagnosis and treatment of voice, speech, and language disorders is strongly encouraged, as are projects that focus on determining the nature, causes, treatment and prevention of communication disorders such as stuttering, Specific Language Impairment, spasmodic dysphonia, dysarthria, and aphasia. Emphasis is on research and development of diagnostic measures and intervention strategies for voice, speech, and language disorders; development of communication and other assistive devices for individuals with voice, speech, and language disorders; development of speech and language assessments and interventions for nonverbal individuals with autism; development of new systems for visual communication by individuals who are deaf or severely hearing impaired; development of new systems of communication for individuals with motor speech impairment, including a brain computer interface (BCI) communication prosthesis; development of innovative treatment delivery systems or intervention protocols; design and development of diagnostic measures or materials for early identification of voice, speech and language impairment in children; development of assessments and treatments for childhood and adult voice, speech and language impairment associated with bilingual or multi-cultural populations; development of assessment measures of sign language abilities; development of improved artificial larynges and tracheoesophageal shunts; development of artificial intelligence computer models that simulate normal and disordered voice, speech and language.

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Lana Shekim, Ph.D. [Voice & Speech Program]
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Taste and Smell Program

Development of easily administered diagnostic tools for testing human chemosensory function throughout the lifespan; development of intervention strategies and targeted drugs for the treatment of taste and smell disorders; preventive measures to limit the deleterious effects of infections, airborne toxins, radiation, chemotherapy and other drugs on chemosensory function; novel therapies to stimulate regeneration of mature sensory neurons in damaged and/or aged tissue; development of olfactory biomarkers for neurodegenerative disease; development of tools to facilitate chemosensory research

including mouse models of chemosensory dysfunction and improved neuroimaging, cell labeling, and axonal tracing techniques.

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Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

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For administrative and business management questions, contact:

Mr. Christopher P. Myers
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NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

The NIDCR conducts and fosters research on the etiology, pathogenesis, prevention, diagnosis, and treatment of oral, craniofacial and dental diseases and conditions. For more specific information about areas of interest to the NIDCR, please visit our home page at http://www.nidcr.nih.gov.

NIDCR's small business programs are highly focused on maximizing translational science opportunities – moving rapidly and intentionally toward pushing innovation in basic orofacial biology into useful products.

Special statement regarding clinical trials:

> Projects proposing a clinical trial component in STTR or SBIR applications should consider if the funds available through these awards can adequately support a clinical trial, especially if the trial is testing a drug under an investigational new drug (IND) application or as an investigational device. The cost and time needed to plan and deploy most Phase II and almost all Phase III clinical trials would exceed the support provided under this program. Products originally developed and preliminarily tested with SBIR/STTR support can be studied further with R34/U01 awards that support clinical trials (see http://grants.nih.gov/grants/guide/pa-files/PAR-14-346.html).

Special budgetary notice:

> For FY2015, NIH has received preapproval from SBA for select translational science topics that due to their complexity potentially could require budgets over the 50% statutory limits (greater than $225,000 for Phase I SBIR/STTR awards and greater than $1,500,000 for Phase II SBIR/STTR awards). The topics denoted below with a " ** " fall under this preapproval category. **However, before submitting an application to NIDCR for projects in these topic areas, applicants are strongly encouraged to contact the Dental Small Business Coordinator for guidance and instructions. Any budget request above these limits is expected to be fully justified and commensurate with the scope of work.**

Developmental Biology and Mammalian Genetics

Emphasis is on the understanding of the development of tooth and bone, and on the identification of the genetic and environmental contributions to craniofacial disorders. The objective of this scientific program is to elucidate the underlying causes of craniofacial disorders, thereby advancing the fields of diagnosis, treatment, and prevention. Interests in this area include but are not limited to:

A. Develop early pregnancy genetic tests to screen fetal cells in maternal blood for genetic mutations involved in inherited syndrome and non-syndrome craniofacial defects.

B. Develop instrumentation to improve the diagnosis and treatment of inherited and acquired craniofacial defects.

C. Develop improved appliances to aid suckling by newborn infants with cleft palate and cleft lip.

Infectious Diseases and Immunity

Research relating to the etiology, pathogenesis, prevention, diagnosis and treatment of infectious diseases of the oral cavity is supported by the NIDCR. This includes research on practical ways to effectively use the host immune system to prevent or treat oral infectious diseases and microbial-induced inflammation. Infectious diseases of the oral cavity include caries, periodontitis, candidiasis, peri-implantitis, pulpitis, and various viral, bacterial, and fungal infections of the oral mucosa and research on the diagnosis and prevention of oral manifestations and malignancies of HIV infection and AIDS. Specific examples of technology development needs include but are not limited to:

A. Develop ways to overcome or eliminate the risk of oral infections in persons who smoke or chew tobacco, drink alcohol, or are immunosuppressed, have diabetes, are malnourished, or are psychologically stressed.

B. Explore novel methods or agents to eradicate oral biofilms (dental plaque) on teeth, oral soft tissues, and dental implants without adversely affecting the normal oral flora.

C. Isolate, synthesize or prepare new antibiotics and antimicrobial agents that can overcome bacterial and fungal resistance to current compounds. Formulate combinatorial drug regimens to attack microbes growing in oral biofilms (dental plaque).

D. Develop controlled release systems for local delivery of synthetic peptides, recombinant proteins, or other chemical or immunotherapeutic agents to prevent, control, and/or treat oral infectious diseases, or the oral manifestations of HIV infection.

E. Develop biological response modifiers or other immunological approaches to reduce or eliminate microbial-induced chronic inflammation or the tissue destruction associated with chronic inflammation in the oral cavity.

F. Develop ways to interfere with microbial colonization and growth through the use of antimicrobial agents and chemotherapy.

G. Identify and exploit the structural features of oral biofilms for increased therapeutics delivery.

H. Develop computer programs and apply systems biology approaches to model biologically active peptide regions of oral components that have anti-fungal, anti-bacterial and anti-viral activities.

I. Develop substitutes of naturally occurring chemicals (phytochemicals) known to have a role in controlling opportunistic infections induced by HIV.

J. Develop synthetic peptides and recombinant proteins of oral components with anti-fungal, anti-bacterial and anti-viral activities including those against HIV and oral opportunistic pathogens.

**K. Develop oral topical formulations with combined microbicide, analgesic, and anti-inflammatory activities to enhance oral mucosal defenses and prevent and/or control oral infections and lesions in HIV-infected and/or immunosuppressed subjects.

L. Discover, test, standardize, and validate novel biomarkers present in oral fluids for screening and clinical diagnosis of HIV, and oral opportunistic pathogens infections and AIDS malignancies. Apply similar strategies as listed below for oral, oropharyngeal and salivary gland cancers to AIDS malignancies.

Clinical Research

**A. Develop improved methods to detect and predict progression of dental caries, periodontal disease, reversible pulpitis and irreversible pulpitis.

**B. Improve or develop new methods to enhance oral and craniofacial surgery. This would include both intraoral and extraoral surgery.

**C. Develop improved methods to mechanically repair or treat tooth structure damaged by dental caries or periodontal disease.

Oral, Oropharyngeal and Salivary Gland Cancers

Emphasis is on molecular mechanisms of oral epithelial cell deregulation that lead to oral cancers. Research related to early detection, diagnosis, and prevention, and treatment of oral cancers is of particular interest. Examples include but are not limited to the following areas:

**A. Develop imaging techniques for the early detection, diagnosis and prognosis of pre-malignant lesions.

B. Develop effective pharmacological, immunological and radiological modalities for treatment of pre-malignant and malignant lesions in preclinical models.

C. Develop novel technologies for the genetic and molecular-targeted therapy (e.g. siRNAs, peptide based therapies) in preclinical models.

E. Develop regimens for the alleviation of the oral complications of cancer therapy.

F. Develop animal models to facilitate the testing of therapeutic and chemopreventive agents for oral cancers.

Temporomandibular Joint Disorder and Orofacial Pain

Emphasis on research for chronic disabling painful diseases of the oral-craniofacial-dental areas including chronic pain, neuropathies, and diseases of the temporomandibular joint. NIDCR encourages applications that include but are not limited to:

A. Developing improved techniques for measuring nociceptive, chemosensory, tactile, kinesthetic, or proprioceptive function involving craniofacial structures. Such measures may be useful in screening for deficits, improving diagnosis, or for evaluating responses to orofacial treatments or interventions.

B. Developing improved biomarkers for neuropathic conditions affecting oral-craniofacial tissues or structures.

C. Developing assays facilitating reliable evaluations of relationships between biological and other risk factors as they relate to onset, and exacerbation of pain and for examining the transition from acute pain to chronic pain conditions.

D. **Discovering and developing novel, pharmacological medications for treating chronic orofacial pain disorders, by leveraging results from ongoing genetic studies of chronic pain conditions.

Saliva, Salivary Diagnostics, and Salivary Gland Diseases

Emphasis is on salivary gland physiology and pathophysiology and in the repair and restoration of the damaged gland. Examples include but are not limited to:

**A. Development of viral, non-viral and gene therapy-based approaches to address compromised salivary gland function. Development of cell and tissue-based strategies and technologies for restoration of damaged or destroyed salivary gland function.

**B. Development of novel compounds or materials that protect and preserve salivary glands from head and neck cancer irradiation therapy.

**C. Development of non-invasive methods for the determination of efficacy and safety of artificial saliva, sialogogues, and of their delivery vehicles used in addressing the diminution or lack of saliva (xerostomia) due to Sjögren's Syndrome or head and neck cancer irradiation therapy.

**D. Development of biomarker strategies and technologies for the identification of Sjögren's Syndrome in blood or saliva.

E. Discovery of biomarkers derived from oral fluids that are predictive of the onset, progression and recurrence of oral diseases and conditions, such as periodontal diseases, caries, and oral, oropharyngeal and salivary gland cancers.

F. Development of immunological strategies and immunotherapy-based approaches for addressing xerostomia from Sjögren's Syndrome.

G. Development of enhanced or novel tools for early detection of salivary gland cancers.

Biotechnology, Biomaterials, and Applications for Regeneration and Restoration of Oral, Dental and Craniofacial Tissues

Emphasis is placed on the development of a broad range of technologies targeted at regeneration and restoration of diseased and injured hard and soft tissues of the oral and craniofacial complex and on translating these applications to the clinic. Tissues of interest include craniofacial and alveolar bone, the periodontal ligament, TMJ bone and cartilage, oral mucosa, facial skeletal muscle, vasculature and peripheral nerve. Also of interest are multi-tissue composites and organs, such as vascularized and innervated bone and muscle, salivary gland, tooth, periodontium, bone-periodontal ligament-cementum interface and osteochondral complexes. Specific topics could include but are not limited to:

A. Development of technologies for design, fabrication, and manufacturing of biomimetic and biocompatible biomaterials and scaffolds, including nanomaterials and self-assembling nano-scaffolds, for tissue engineering and regenerative medicine applications. Projects focused on the development of hydroxyapatite or remineralization techniques such biomaterials need to include assessments demonstrating their ability to replicate the mechanical and physical properties of mineralized tissue such as dentin and enamel or bone.

B. Development of cell-based technologies, including stem cell-based technologies. These include, designing strategies for isolation, purification, scaled up production, standardization, comparison and quality control of stem and progenitor cells and their differentiated progenies, derivation of efficient and predictable methodologies for cellular reprogramming, and advancing technologies for reconstruction of stem cell niches for augmenting tissue regeneration.

C. Development of bioreactor systems to facilitate design, fabrication, and manufacturing of soft and hard tissues. Among their capabilities, these bioreactors may be able to mimic biophysical forces, such as mechanical and electrical forces that normally guide tissue morphogenesis *in vivo*.

D. Development of improved dental composite materials, including biomimetic and self-healing materials and adhesive sealants. These include but are not limited to materials to replace Bis-GMA resin-based systems that are suitable for restoring crowns of posterior teeth and exposed roots of the teeth. Any novel dental composite restorative components or systems must include assessments in a physiologically relevant test system that mimics microbial and physicochemical conditions found in the oral cavity.

**E. Development of methods, materials, and devices for orthodontic, prosthetic, and craniofacial applications including those that can be used for craniofacial bone distraction, craniofacial reconstruction, healing, and scarless repair.

F. Development of artificial tissue and organ mimics that can be adapted to high-throughput formats for a broad range of screening applications, such as analysis of biomaterial and tissue function, drug efficacy and toxicology assays, biocompatibility assays, genetic screening and others.

G. Development of mathematical, computational, and bioinformatics approaches for modeling oral and craniofacial tissues and organ function and physiology to address needs of system biology, synthetic biology, and single cell analysis.

H. Development of novel biomolecules, including growth factors, cytokines, small molecules, siRNAs, and others for counteracting diseases and injuries of oral and craniofacial tissues and promoting their regeneration.

I. Development of advanced viral and non-viral based biomolecule delivery technologies that can precisely deliver and release therapeutic proteins, nucleic acids, small molecules, or combinations thereof with predictable temporal kinetics to target specific tissue sites.

**J. Development of imagining diagnostics to accelerate clinical implementation of reliable, reproducible, highly specific and sensitive diagnostic instruments for dental caries, cracked teeth, pulp vitality, bone quality, and periodontal diseases.

K. Development of biosensors for noninvasive, dynamic real-time monitoring of physiological processes in the human body using the oral cavity as the sensing site. These biosensors will be able to assess health and disease states and receive feedback from body fluids and clinical compounds that are found in or pass through the oral cavity and in certain cases, will be able to communicate these outputs wirelessly and remotely.

Clinical and Behavioral Research

Provides support for the development of evidence-based products related to behavioral and social aspects of oral health, oral health prevention or treatment interventions, and other patient-oriented aspects of oral health. This includes support for clinical trials and patient-oriented research to establish safety and initial efficacy of products. NIDCR is especially interested in applications that significantly improve oral health by: 1) being broadly applicable to many populations, 2) contributing to meaningful oral health improvements for a specific population, 3) expediting translation of research findings into oral health improvements, and/or 4) equipping oral health care providers, educators or researchers with tools to improve public oral health. Examples of studies of interest include, but are not limited to, the following:

A. Develop and test devices or methods to improve time-sampled monitoring of behavioral adherence with preventive or therapeutic regimens specifically relevant to oral diseases/conditions. Such devices or methods could be utilized in a variety of settings, including naturalistic settings, within clinical trials, within oral health care delivery systems, etc.

B. Develop and test novel compliance and survey measures or tools to identify the underlying causes of insufficient preventive dentistry for specific underserved populations.

C. Develop, or adapt for use in a new population or setting, novel measures or methods for identifying individual, family, group, or other processes that explain oral health behavior.

**D. Develop and test for safety, efficacy, and/or effectiveness of measures or materials for diagnosing, preventing, or treating oral, dental, and craniofacial conditions and disorders.

E. Develop, or adapt for use in a new population or setting, oral health interventions utilizing technology to improve efficiency of delivery (e.g., management of chronic pain related to temporomandibular joint disorders, etc.).

F. Develop, or adapt for use in a new population or setting, interventions addressing health behaviors highly associated with oral health (e.g., tobacco, alcohol, and other drug use; management of diabetes, HIV infection, or other chronic illnesses; etc.).

G. Develop technologies or modules that utilize existing web-based platforms to improve preventive oral health hygiene for children and adolescents (e.g., social marketing via web-based interaction, virtual reality “worlds”, “massively multiplayer online games”, etc.).

H. Develop and test innovative methods for facilitating collaborations, referrals, and/or ongoing follow-ups between oral health professionals and other health care professionals.

I. Develop and test web-based training or other innovative approaches for oral health care professionals to accelerate accurate translation of new knowledge regarding oral diseases and their effective prevention or treatment into clinical or public health practice.

J. Develop and test the effectiveness of innovative teaching tools to inform oral health professionals or the public regarding oral cancer prevention and early detection. Develop and test for safety and

efficacy methods for diagnosing caries, pulp vitality and / or periodontal diseases that utilize non-ionizing radiation.

K. Develop and test for safety and efficacy methods for diagnosing caries, pulp vitality and / or periodontal diseases that utilize non-ionizing radiation.

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NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

The NIDDK supports research in diabetes, endocrinology and metabolic diseases; digestive diseases and nutrition; and kidney, urologic and hematologic diseases. For additional information about areas of interest to the NIDDK, please visit our home page at http://www.niddk.nih.gov.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, the NIDDK may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. For topics listed in APPENDIX A: National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations, the NIDDK generally will not fund Phase I applications greater than $300,000 total costs or project periods greater than 2 years; or Phase II applications greater than $2,000,000 total costs or project periods greater than 3 years. For all other topics, the NIDDK does not generally fund Phase I applications greater than $225,000 total costs or project periods greater than 2 years; or Phase II applications greater than $1,500,000 total costs or project periods greater than 3 years. Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards

NIDDK will accept Phase IIB SBIR/STTR Competing Renewal grant applications (only) from NIDDK-supported Phase II awardees that propose to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, and 3) continuing refinements to durable medical equipment (DME) designs such as cost reduction, testing for safety, durability, and reliability, and meeting or establishing standards. This renewal grant should allow small businesses to get to a stage where interest and investment by third parties is more likely. Such products include, but are not limited to biological products, devices, drugs, medical implants, etc. related to the mission of the NIDDK. The previously funded Phase II SBIR/STTR grant need not have been submitted in response to a particular solicitation, as long as the research is appropriate to the purpose of this solicitation. Budgets up to $1,000,000 total costs per year and time periods up to 3 years may be requested for this Phase IIB Competing Renewal opportunity. These awards are intended to support completion of research needed to obtain an IND or IDE. Applicants must provide evidence that they have consulted formally with the FDA concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements. Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a timeline related to Federal regulatory approval processes.

Examples of research that would be considered responsive to this announcement are listed below for illustrative purposes and are not exclusive of other appropriate activities.

- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.
- Assessment of devices with regard to performance standards related to the FDA approval process.
- Clinical and toxicology studies in support of an Investigational New Drug Application to the FDA.
- Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.

Final Progress Reports

As detailed in NOT-OD-12-152, the NIH has released new instructions for SBIR/STTR Final Progress Reports.

The NIDDK is interested in tracking the progress of the small business concerns it funds and the products they develop. Funding priority will be given to those small business concerns that show not only their ability to develop products but also their growth as a small business concern towards independence from the SBIR/STTR program.

Additional Programs and Services for NIDDK SBIR Awardees

The NIDDK encourages awardees to apply for the following free programs:

- Phase I: The NIH Niche Assessment Program (https://sbir.nih.gov/nap) provides awardees with an in depth market analysis for their technology.
- Phase II: The NIH Commercialization Assistance Program (https://sbir.nih.gov/cap) will assist awardees in transferring their products to the marketplace.

Diabetes, Endocrinology and Metabolic Diseases

The Division of Diabetes, Endocrinology and Metabolic Diseases supports basic and clinical research on the etiology, pathogenesis, prevention, diagnosis, and treatment of diabetes mellitus and its complications; endocrine diseases; osteoporosis; cystic fibrosis, and other metabolic disorders; as well as research on basic endocrine and metabolic processes. Research topics of potential interest to small businesses include, but are not limited to:

I. SENSORS, HORMONE REPLACEMENT, AND DELIVERY DEVICES:

A. Assessment of non-invasive, minimally invasive or implantable sensors for monitoring blood or interstitial fluid glucose for prevention of hypo- and hyperglycemia in diabetic patients. NIDDK will give priority to research that has already progressed to an *in vivo* model or to be clinically tested.

B. Integration of glucose sensor and insulin delivery systems to create an artificial pancreas.

C. Development of improved insulin and other pancreatic hormone delivery methods or devices.

D. Development of novel insulin and glucagon formulations showing improved kinetics and stability

E. Development of novel and more accurate non-enzymatic based glucose detection technologies.

F. Development of telemedicine approaches that can be incorporated as components/and or adjuvants of an artificial pancreas for better diabetes self-management.

G. Development of technologies that may promote and facilitate adherence/compliance by users of glucose control devices

II. SCREENING TESTS, DIAGNOSTICS AND BIOLOGIC TOOLS:

A. Development of techniques or products useful for predicting, preventing or delaying progression of diabetes, including tests for identifying patients at risk, and methods of monitoring disease progression.

B. Development of diagnostic tools for diabetic foot ulcers. These tests could be used to determine the risk of developing a diabetic foot ulcer or used for choosing treatment strategies.

C. Development of diagnostic tools to measure the autonomic neuropathy that develops in people with diabetes.

D. Development of clinical measures of oxidative stress, advanced glycation end-products and chronic inflammation that result from diabetes.

E. High throughput - Point of care technologies (reliable, accurate, cost-effective, highly sensitive, standardized having rapid turnaround time) for autoantibody detection, T cell –subsets-auto-reactivity and other immune parameters for autoimmune diabetes diagnosis and follow-up.

F. Development of methods to measure changes in the immune status that may be used as markers to follow the immune-modulatory activity and beneficial effect (beta cell mass preservation, reduction of inflammation at the target organ, etc.,) of biologic agents tested in clinical trials for the prevention and/or treatment of T1D.

G. Development of high throughput assays based on biologic pathways likely involved in the pathogenesis of diabetes and its complications that could be used to screen molecular libraries for novel therapeutic agents.

H. Development and validation of surrogate markers to monitor disease progression and potential therapies for diabetic complications.

I. Development and validation of tools for use by health care providers/systems to improve diabetes care and prevention.

J. Development of techniques and tools to identify islet cell progenitors, methods to predict transplant success with recovered islet preparations, and non-invasive imaging as well as other methods for the *in vivo* measurement/ evaluation of pancreatic beta cell mass, function or inflammation after transplantation of pancreatic islet/beta cells.

K. Point of care low cost /portable technologies for diabetes and pre-diabetes diagnosis.

L. Development of innovative technologies to predict and prevent hypoglycemia.

III. INTERVENTIONS AND THERAPIES:

Diabetes

A. Development of immunomodulation/tolerance induction strategies to prevent or slow progression of type 1 diabetes.

B. Development of new therapies or devices to prevent and treat diabetic foot ulcers.

C. Development of new therapies to correct the underlying metabolic defects that result from diabetes, such as reactive oxygen species production and glycation of proteins.

D. Development of methods that protect islet grafts after transplantation, including the evaluation of alternative transplantation sites, minimize the use of immunosuppression through immunomodulation/tolerance induction or immunoisolation/encapsulation of the graft from the host immune system, or support the use of single donors for transplantation.

E. Development of methods that expand the number of human islets during culture while still retaining appropriate functional islet characteristics and the ability to be successfully transplanted.

F. Development of methods utilizing replenishable cell sources, especially stem cells that produce functional islet like cells/tissues that can be successfully transplanted.

G. Development of more reproducible methods that improve yield/viability/function of islets prior to transplantation and the engraftment and long term function of islets after transplantation.

H. Development of educational or psychosocial approaches that increase adherence to recommended diabetes treatment regimens or that reduce co-morbidities and complications (e.g., depression or foot ulcers).

I. Development of novel technologies that may facilitate self -management of diabetes and adherence to treatment.

J. New implantable and easy to replace technologies that may mimic the beneficial effect of gastric bypass/bariatric surgery for the treatment of diabetes without the need of a major invasive surgical procedure.

Other Endocrine and Metabolic Disorders

K. Identification of new ligands for previously unclassified (orphan) nuclear receptors and development of partial agonists or antagonists with therapeutic potential for diseases such as diabetes and osteoporosis, hormone-dependent cancers, and for conditions such as obesity.

L. Development of Selective Receptor Modulators (SRMs) with tissue specificity and profiles that provide beneficial effects without the side effects secondary to therapies based on naturally occurring hormones.

IV. GENETIC TESTING AND GENETIC THERAPIES

A. Development of improved methods for the diagnostic, population or newborn screening or prenatal testing for genetic metabolic diseases.

B. Improvements in the construction of gene therapy vectors to increase transduction efficiency, level and duration of expression, and to improve targeting.

C. Development of improved methods of manufacturing gene therapy vectors that are scalable and improve titer and bioactivity of the vectors.

D. Development of new vector systems that improve the ability to transduce nondividing cells such as hematopoietic stem cells, neurons, hepatocytes or epithelial cells.

E. Development of techniques to achieve efficient homologous integration or site-specific integration of introduced genes.

Digestive Diseases and Nutrition

The Division of Digestive Diseases and Nutrition supports research on the function, diseases and disorders of the digestive tract; the esophagus, stomach, intestine, colon, anorectum, pancreas, liver, gallbladder, and biliary tract; research on nutrition and obesity as well as information transfer in the field of digestive diseases and prevention of obesity. Innovative investigator-initiated projects that are not mentioned below are encouraged. Areas that may be of interest to small businesses include, but are not limited to:

I. DIGESTIVE AND LIVER DISEASES (CLINICAL)

A. Development of assays and new genetic screening methods for detection of biomarkers for genetic predisposition to GI-relevant diseases and liver.

B. Development of improved means for detecting Barrett's esophagus, GERD, and other GI disorders.

C. Development of methods for gastrointestinal endoscopy without the need for sedation.

D. Development of agents to treat motility disorders (e.g., pseudo-obstructive disorder, chronic constipation, and slow bowel transit).

E. Development of surrogate markers and non-invasive imaging methods to quantitatively assess GI and liver disease.

F. Development of non- or minimally-invasive tools that have improved therapeutic capabilities and visualization capabilities for detecting GI disorders (e.g., mucosal abnormalities and pathologies).

G. Development of novel antifibrotic therapies for progressive liver failure.

H. Development of quantitative tests of hepatic “reserve” which would be of use, for example, in assessing the risk of surgery in patients with liver disease.

I. Development of humanized monoclonal antibodies against HCV and HBV to be used for prevention of recurrent disease in liver transplant patients.

J. Development of and validation of therapeutic interventions for treatment and/or progression of pancreatitis and its complications.

K. Development of more accurate and useful approaches to the diagnosis of chronic pancreatitis by functional, radiologic, endoscopic, or pathologic/cytologic means.

II. Digestive and Liver Diseases (Basic)

A. Development of molecular probes for the diagnosis of mucosal dysplasia in inflammatory bowel disease.

B. Development of gut immune-modulators, or non-antigenic gliadin in celiac disease.

C. Development of new techniques, including non-invasive imaging, to measure motility/intestinal transit at various sites within the gastrointestinal tract.

D. Development of techniques for the preservation and transplantation of the liver, small intestine, and pancreas.

E. Development of novel proteomic or metabolomic technologies designed to study digestive and liver diseases, and their complications.

F. Development of a test for determining the hepatotoxic potential of drugs, agents or additives that is more sensitive than testing in mice and reflects the human response to the test compound.

G. Development of animal models to study hepatotoxic agents.

H. Development of non-invasive techniques to detect liver disease.

I. Creation of artificial organs or development of effective xenographic techniques for liver transplantation.

J. Development of biomarkers that quantitatively assess the degree of cold and warm ischemia injury in donor liver organs.

K. Development of non-invasive measures of pancreatic exocrine function.

L. Development of humanized mouse models of multi-allelic diseases.

M. Development of measurements to quantitate phenotypic or metabolic markers of disease progression in animal models, thus reducing the numbers of animals needed.

III. Nutrition, Obesity, and Eating Disorders

A. Development of novel methods and tools to accurate evaluate nutritional status, physical activity, and energy expenditure.

B. Development of a non-invasive breath or blood test to accurately measure dietary intake.

C. Development of better means to detect food borne pathogens with the goals of (1) preventing their inclusion in foodstuffs and (2) better treatment of acute infections.

D. Development of safe drugs that inhibit appetite or increase energy expenditure.

Kidney, Urologic and Hematologic Diseases

The Division of Kidney, Urologic, and Hematologic Diseases supports research into basic mechanisms of the organ and tissue function, and the diseases of the kidney, urologic and hematologic systems. Projects are expected to help develop an understanding of the physiology, pathophysiology, and related diseases of the kidney, urinary tract, and blood and blood forming systems so that rational treatments, prevention strategies, and/or arrest of diseases may be devised. Support for advances in the technology of cell and molecular biology that will enhance research in kidney, urologic and hematologic diseases is encouraged. Research opportunities of interest to small businesses include, but are not limited to:

I. Development of a Genomic Toolbox for Study of Kidney, Prostate, Bladder, or Red Cells, which would include:

A. Library generation and gene identification from whole organ or rare compartments in normal, developing, or injured tissues.

B. Antibodies or phage libraries that will facilitate the prospective identification and purification of renal cell types.

C. Strategies to deal with the anatomical complexity, increase the representation of low abundance transcripts, or decrease the redundant sequencing of over-represented or known genes.

D. Bioinformatics tools.

E. Flexible databases useful for designing organ-specific databases and web sites.

F. Techniques for visualizing RNA distribution within cells or tissues.

G. New methods to acquire material from archival samples.

II. Application of Proteomics and Metabolomics to Kidney, Urologic and Hematologic Diseases

A Identification of surrogate markers in the plasma, serum, or urine that correlate with acute or chronic kidney disease, urologic diseases of the prostate or bladder, or dysregulation of iron metabolism or other hematologic diseases (not leukemia), such as hemoglobinopathies or thalassemia.

B. Identification or development of novel proteomic or metabolomic technologies designed to study kidney, urologic, or hematologic diseases.

III. Kidney

A. Development of antibodies or phage libraries specific for the individual cell types of the kidney.

B. Development of both data and cell banks of diabetic kidney disease families and autosomal and recessive polycystic disease families for use by the research community.

C. Development of pharmacological agents that might be used to intervene in acute or chronic renal disorders and in disorders of renal hemodynamics, blood pressure, electrolyte metabolism, and extracellular volume regulation.

D. Means to improve physiologic homeostasis in maintenance dialysis therapy through the:

1. Improvement of blood access to permit continuous access to the circulation with minimal inflammation.
2. Development of means to provide for continuous anticoagulation.
3. Development of reliable, non-invasive, online hemodialysis monitoring systems assessing real-time treatment parameters such as blood volume, access flow, and urea clearance.

E. Studies to improve the efficiency of maintenance dialysis:

1. Development of innovative methods to produce more efficient and less morbid forms of renal dialysis (e.g., GI dialysis, artificial kidney, implantable dialyzers).
2. Studies on biocompatibility of artificial kidney membranes, in surface sensitive proteins, complement, and clotting mechanisms.
3. Development of new agents for sterilizing dialysis membranes and methods / agents to reduce hemodialysis or peritoneal dialysis catheter-related infections.
4. Studies on improved biomaterials for hemodialysis and peritoneal dialysis catheters to decrease the foreign body response, biofouling and bacterial biofilm formation.

F. Improved techniques for preservation and storage of kidneys intended for transplantation.

G. Development of material(s) for construction of urinary catheters that may reduce the incidence of infection in the urinary tract, and materials that decrease uretheral and bladder inflammation due to foreign body.

H. Development of improved renal imaging techniques, differential renal function assessments and diagnostic assessment of non-malignant parenchymal diseases.

I. Development of early diagnostic tools, preventative measures, and treatment modalities for acute kidney injury.

J. Identification of mediators of kidney injury (acute or chronic) and pharmacological means to block these effects.

K. Development of new non-invasive methods for measuring kidney function:

1. Reliable, non-invasive, non-radioactive methods of measuring glomerular filtration rate (GFR).
2. Identification of serum factors released by damaged kidney cells.
3. Characterization of changes in kidney hormonal function in kidney disease at various stages of severity.
4. Development of new biomarkers for early detection of kidney dysfunction, prediction of progression, and early indication of recovery.
5. Development of rapid, accurate, and cost effective means of quantifying urine albumin.

L. Development of new technology to improve and optimize data collection of real-time observations (e.g., biomarkers, diet, physical activity, vital signs, psychological parameters, environmental factors), reporting of patient outcomes, interventions and adherence (e.g., diet, medicine) for clinical studies.

IV. UROLOGY

A. Analyses of factors responsible for initiation, fluctuation and progression of symptoms of lower urinary tract dysfunction (LUTD) leading to the development of a diagnostic tool. Development of animal, computer, or in-vitro models for the study of benign prostatic hyperplasia (BPH).

B. Development of diagnostic modes to clinically non-invasively or minimal-invasively measure bladder obstruction before and after surgical or pharmaceutical intervention and/ or treatment devices for bladder outlet obstruction.

C. Prevention, diagnostic, or treatment modalities for urinary tract infections.

D. Kinetics of renal stone formation, such as characterization of growth and dissolution, or crystal growth inhibition, and definition of reliable biochemical profiles of stone forming patients. Development of diagnostic device for biochemical profiling of stones either in-vitro or in-vivo.

E. Development of localization methods through imaging or non-invasive methods or instrumentation using minimally-invasive methods to access stones for therapy. Methods to directly improve access to difficult stones.

F. Development of additional therapeutic agents and methods for prevention and/or treatment of urolithiasis.

G. Development of more real-time diagnostic assessment of lower urinary tract function using non-invasive, remote or minimally invasive measures, which can include neuro-pharmacological/neuro-physiological assessments in urodynamics.

H. Objective and diagnostic measurement devices or methods for assessment of urinary voiding and storage disorders, including stress, urge, and mixed incontinence, both in adults and children.

I. Development of non-invasive or minimally invasive treatment methods or pharmacological for urinary incontinence and/or bladder instability.

J. Non-invasive or minimally invasive methods to diagnosis bladder inflammation or bladder epithelial and/ or bladder wall changes of non-cancerous origin.

K. Non-invasive, reduced or non-radiological diagnostic methods for evaluating vesico-ureteral reflux in children and infants.

L. Methods for determining inflammatory cytokines, histamines, or other factors in voided urine, as markers for lower urinary tract inflammatory processes or other urologic disorders, including chronic and acute urologic pain disorders.

M. Development of simple diagnostic kits for evaluating growth factors in urine in a clinical laboratory.

N. Development of new or enhanced methods to derive synthetic or semi-synthetic biological matrices or other tools to treat urologic disease and/or augment the functionality of urologic tissues and organs.

O. Studies on improved biomaterials for indwelling, urethral catheters to decrease foreign body response, biofouling, and bacterial biofilm formation.

P. Development of tools for elucidating the role of urinary and gut microbiome in urinary stone disease and other benign urological symptomatic disorders.

V. HEMATOLOGY

A. Development of methods and equipment for routine high volume isolation of highly purified hematopoietic stem and progenitor populations.

B. Identification of new methods to assay hematopoietic stem and progenitor cells with short- and long-term repopulation models amenable to serial examination.

C. Development of chemically defined reagents that support hematopoietic stem cell proliferation and differentiation.

D. Definition of culture conditions using serum-free medium that will support the ex vivo expansion of hematopoietic stem and progenitor cells.

E. Development of new approaches for identifying, isolating, and genetically analyzing fetal erythrocytes in the maternal circulation.

F. Development of novel methods for the delivery of DNA, proteins, and other compounds to hematopoietic stem cells.

G. Development of rapid, high throughput microarrays for accurate assessment of gene expression profiles of hematopoietic stem cells.

H. Development of non-invasive systems for monitoring the total hemoglobin and hematocrit, suitable for use with adults or neonates.

I. Application of nanotechnology to the measurement of blood parameters and diagnosis of blood disorders.

J. Development of new methods for the non-invasive or minimally invasive measurement of body iron.

K. Adaptation of MRI technology for the non-invasive measurement of body iron:

1. Develop appropriate MR measurement method(s).
2. Optimize RF coils for the body region of interest (primarily heart, liver, and pancreas).
3. Develop magnets of the appropriate magnetic field strength(s).
4. Develop a reliable method for calibrating, validating, and standardizing organ specific iron concentration measurements as detected by magnetic resonance imaging.
5. Determine the most appropriate magnetic resonance method for determining relaxation times and susceptibility.
6. Develop indicator materials for direct MR measurement of iron concentration.

L. Design of therapeutic drugs for inducing fetal hemoglobin synthesis.

M. Development and validation of a sensitive, specific, reproducible, quantitative, and clinically applicable assay method for measuring serum hepcidin levels, as well as cellular hepcidin and ferroportin expression levels.

N. Design and validation of novel therapeutic agents that modulate hepcidin and cellular ferroportin expression and/or activity *in vivo*.

Other Research Topic(s) Within the Mission of the Institute

For additional information on research topics, contact:

DIABETES, ENDOCRINOLOGY AND METABOLIC DISEASES

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DIGESTIVE DISEASES AND NUTRITION

Ms. Christine Densmore
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KIDNEY, UROLOGIC AND HEMATOLOGIC DISEASES

Kidney

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Urology

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Hematology

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For administrative and business management questions, contact:

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NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

The mission of the National Institute of Environmental Health Sciences www.niehs.nih.gov is to discover how the environment affects people in order to promote healthier lives, with a vision of providing global leadership for innovative research that improves public health by preventing disease and disability. NIEHS achieves its mission and vision through a multidisciplinary biomedical research program, prevention and intervention efforts, and a communication strategy that encompasses training, education, technology transfer and community outreach. www.niehs.nih.gov/sbir

Join our listserv for program announcements https://list.nih.gov/cgi-bin/wa.exe?SUBED1=sbir-niehs&A=1.

I. Exposure Assessment Tools

http://www.niehs.nih.gov/research/supported/dert/programs/exposure/ The NIEHS Exposure Biology and Exposome Program studies the totality of the exposures that a person experiences from conception to death along with the associated biological responses. Validated tools are needed that measure, analyze, and predict a substantial range of internal and external exposures and health outcomes across diverse geographic populations. These tools should be designed fit for purpose in collaboration with the purchasers and end-user populations (e.g., community outreach programs, citizen scientists, disaster response personnel, population-based epidemiologists, or clinical researchers). Examples include:

- Integrated systems and/or computational models that leverage information from existing databases (*e.g.*, EPA ExpoCast) and devices (sensors, biomonitors, satellites, etc.) linking exposure at the point of contact, internal dose, and biological response, where the cumulative personal exposures can be used to simulate and predict population-scale effects. Individual personal privacy protection must be addressed.

- Sensors
  - Technologies to assess personal exposure in population studies using networks of fixed site and wearable monitors
  - Personal, wearable, real-time detection measurements across multiple stressors and scales (*e.g.*, time, space, route of exposures, distribution), with emphasis on high sensitivity and specificity and/or low cost devices

- Biomonitors
  - Personal monitoring technologies that can detect multiple toxicants in biospecimens using non- or minimally invasive approaches
  - Devices that can continuously monitor and report exposures in real-time
  - New strategies for detecting analytes not currently measured in CDC NHANES, including replacement chemicals or emerging chemicals

- Technologies that can assess multiple exposures in archived biological samples
- New approaches to integrate smart device technologies into exposure assessment
- Untargeted discovery or annotation of environmental analytes in metabolomics studies

II. Nano Environmental Health and Safety

http://www.niehs.nih.gov/research/supported/dert/programs/nanohealth/ The NIEHS Nano Environmental Health and Safety (Nano EHS) program is interested in the detection of engineered nanomaterials in the environment, in products, and in biological samples; and technologies that can predict toxicity potential. High priority engineered nanomaterials of interest are those with a potential for human exposure.

Examples include:

- Sensors that can detect engineered nanomaterials in air, water, and consumer products, and provide a contextual assessment on the toxicological potential

- Biomonitoring technologies that can detect engineered nanomaterials for personal monitoring of biospecimens using non- or minimally invasive approaches
- In vitro assays to evaluate biological responses to engineered nanomaterials, beyond cytotoxicity

III. Toxicity Screening, Testing, and Modeling

The National Toxicology Program http://ntp.niehs.nih.gov/ at NIEHS is interested in technologies to improve predictivity in toxicology testing to support the goals and initiatives of Tox21 http://ntp.niehs.nih.gov/results/hts/index.html. Phase III of Tox21 is focused on expanding biological endpoints and human relevance with increased focus through the following efforts:

Improved or expanded testing methods for toxicity screening
These should include the development of physiologically relevant cell-based systems or phylogenetically lower order animal models. *In vitro* approaches should reflect *in vivo* effects in animals and humans, and may be used to reduce or replace *in vivo* animal use. High priority areas are the development of metabolically competent *in vitro* screening systems that are predictive of xenobiotic metabolism in humans, and the incorporation of genetic variation in *in vitro* or animal models to understand susceptibilities. Examples include:

- Data rich *in vitro* approaches that incorporate mid- to high-throughput -omics or high content imaging
- Enhanced lower organism models (*e.g.,* zebrafish or C*. elegans*) for mid- throughput toxicant screening
- Stem cell assays (both embryonic and iPS cells) for effects of toxicants on cell differentiation, with multiple functional endpoints
- Screening systems that incorporate genetic diversity into toxicology testing (*e.g.,* panels of human iPS cells or rodent models for genetic diversity)
- Improved human organotypic models that more accurately predict *in vivo* function, which may include microfluidic approaches. Specifically, mid-throughput systems to evaluate the effects of xenobiotics on functional endpoints or pathway changes in liver, kidney, gastro-intestinal, lung or brain tissue. Other target tissues are also acceptable.
- *In vitro* assays to model inflammatory responses to xenobiotics
- Short-term tests, assays, or systems that reduce or replace animal studies, or increase predictivity of *in vivo* animal models of acute toxicity (oral or inhalation), reproductive or developmental toxicity (*e.g.,* from endocrine-disrupting xenobiotics), carcinogenicity, or ocular toxicity
- Improved identification and characterization methods for untargeted, high-throughput metabolomics analysis of xenobiotics

Computational approaches for predictive toxicology

- New computational systems and tools for integrating toxicity data that analyzes and visualizes data across different screening systems, as well as *in vivo* data
- Improved experimental and computational tools for *in vitro* to *in vivo* extrapolation of xenobiotic exposures across a range of assay types
- Technologies for pre-market identification of problem xenobiotics through *in vitro* and computational tools (*e.g.,* development of an integrated testing strategy for green chemistry)
- Computational tools for modeling detoxification and metabolic activation

Other technologies for enhanced toxicology testing

- High-throughput, low cost approach to measure global gene expression in a cell simultaneously

- Improved methods for fixing and preserving tissues that maintain cellular structure for histopathology while minimizing degradation of nucleic acids (RNA, miRNA, DNA, methylated DNA) so that archival tissue blocks can be better used for molecular analysis.
- Alternatives or improvements to formalin fixation, paraffin embedding (FFPE) of tissues are sought for improved molecular or genome-wide analysis for better use of tissue archives.
- *In vivo*, real-time, and tissue-specific detection of oxygen radicals in experimental animals

IV. Biomarkers

NIEHS supports the development and validation of biomarkers that can distinguish reversible from irreversible changes in target organs of toxicity as a result of individual responses to environmental stressors (*e.g.,* air pollution components, pesticides, toxic metals, endocrine-disrupting compounds, and other industrial chemicals).

Biological pathways of interest include:

- Oxidative stress
- Inflammation
- DNA damage response
- Immune function
- Mitochondrial function
- Epigenetic regulation

High priority human biomarkers include, but are not limited to:

- Inflammation biomarkers
- Plasma or serum-based markers using altered RNA or protein expression or altered metabolite profiles.to determine response to environmental exposures
- Markers developed in exhaled breath, buccal cells, or other easily accessible, non-invasive biological samples that characterize alterations in key pathways associated with environmental stressors
- Urinary biomarkers for DNA adducts, metabolites, or other cellular markers
- miRNA or exosome biomarkers for exposure assessment to environmental toxicants (*e.g*., drug induced liver injury)

V. Superfund Research Program

http://www.niehs.nih.gov/research/supported/dert/programs/srp/ The NIEHS Superfund Research Program (SRP) is interested in applying new engineering, bioengineering, and biotechnology approaches to develop novel strategies to characterize, monitor, and remediate hazardous substances at contaminated sites.
Topics of interest include, but are not limited to:

Monitoring, Detection, and Site Characterization

- Real-time, on-site monitoring: soil, surface water, groundwater, subsurface, sediments, air (such as volatile releases from sites) etc.
- Nanotechnology-based sensors and probes, biosensors, and miniaturized analytical probes
- Non-targeted or multi-analyte field sampling tools or kits
- Products that allow for rapid sample clean-up/preparation for analysis of environmental samples
- Devices to detect chemical mixtures in environmental media
- Self-contained miniaturized toxicity-screening kits for detecting contamination hotspots
- Assays or devices to determine the extent to which a contaminant is bioavailable

- High throughput assays or toxicity screening products for use in ecological risk assessments

Examples of specific environmental monitoring, detection, and site characterization needs:

  - Devices to detect and measure vapor intrusion or to detect non-aqueous phase liquids (NAPLs) and dense non-aqueous phase liquids (DNAPLs) in the subsurface
  - Site characterization techniques and strategies for complex geology (fractured, karst and heterogeneous layered deposits)
  - Short-duration tests or methods to improve identification of reasonable worst case vapor intrusion condition in a building
  - Technologies for rapid extraction or processing of soil for incremental sampling methodologies (ISM)
  - Technologies for automated fiber counting for asbestos samples

Remediation

- Novel technologies for *in situ* remediation of contaminated sediments, soils, and groundwater
- Technologies to remediate chemical mixtures in environmental media
- Portable adsorption systems for removing chlorinated VOCs from indoor air to achieve risk-based indoor air standards
- Nano-enabled structures, electrochemical methods, photocatalytic processes, thermal treatments, or filtration-based methods of remediation.
- Bioremediation and phytoremediation technologies including development and culturing/propagation of plants, bacterial strains, or fungal species optimized for bioremediation.
- New strategies for delivery of reagents for groundwater remediation: *in situ* chemical oxidation ISCO), zero valent iron (ZVI), and hydraulic fracturing (note: this excludes gas exploration)
- New strategies for delivery of reagents for recovery/extraction of contaminants in groundwater

Information Technology to Support Monitoring and Remediation

- Computational, geographical information system-based, or modeling products for predicting fate and transport of contaminants, rates of remediation, or for identifying contamination sources
- Miniaturized data analysis tools

SRP encourages applicants to develop green / sustainable detection technologies and remediation approaches that improve energy efficiency and reduce waste generation. Proposals must demonstrate that the proposed detection and remediation technologies are relevant to Superfund. For more information about the types of hazardous substances found at Superfund sites: http://www.niehs.nih.gov/research/supported/dert/programs/srp/hwaerp/index.cfm

VI. Education/Outreach

http://www.niehs.nih.gov/research/supported/dert/programs/peph/ As part of its Partnerships for Environmental Public Health (PEPH) Program, NIEHS is interested in developing tools that build capacity, improve environmental health literacy, and support citizen science endeavors. These approaches or resources should be fit for purpose to meet the needs of the following audiences: community members, health care and public health professionals, educators, and students of all ages. Approaches may include:

- Mobile applications that contextualize environmental health information about exposures of concern in food, air, water, or consumer products

- Devices for collecting and reporting information on exposures in environmental samples for educational purposes in schools or communities
- Systems that can utilize public and voluntary population data from sensors, activity trackers, GIS enabled devices, social communications, and surveillance cameras; for example, to assist disaster response and communication
- STEM education resources related to environmental health in school settings or community education programs
- Continuing medical education classes related to environmental health
- Documentaries, short films, and television shows on environmental health science topics with accompanying discussion guides, lessons, or activities to facilitate broader use of the programming

VII. Worker Training Program

http://www.niehs.nih.gov/careers/hazmat/about_wetp/
The NIEHS Worker Training Program (WTP) is interested in Advanced Training Technology (ATT) products for the health and safety training of hazardous materials (HAZMAT) workers, skilled support personnel, and emergency responders in biosafety response and cleanup, community and citizen preparation and resiliency, and for ATT tools to assist in research into the acute and long-term health effects of environmental disasters. ATT as defined by WTP includes, but is not limited to, online training, virtual reality, serious gaming, and tools that complement all aspects of training from development to evaluation including advance technologies that enhance, supplement, improve, and provide health and safety training for hazardous materials workers. WTP accepts solicitations via requests for applications (RFA). Please contact Kathy Ahlmark ahlmark@niehs.nih.gov for information on the next solicitation date, which differs from the standard receipt dates of this NIH omnibus.

VIII. NIEHS DOES NOT Fund

× Technologies for the detection and remediation of pathogens in the environment - contact EPA or DoD for information on SBIR funding opportunities for this topic

IX. Other Topics within the Mission of the Institute

For additional information on research topics, contact:

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For information on the Hazardous Substances Detection and Remediation Program, contact:

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For administrative and business management questions, contact:

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Morrisville, NC 27560

NATIONAL EYE INSTITUTE (NEI)

The NEI supports research with respect to eye diseases, visual disorders, mechanisms of normal visual function, preservation of sight, and the special health problems and requirements of individuals with impaired vision. Applications for all areas of vision research are encouraged. Examples that may be of interest to small businesses are provided below, but this list is not meant to be exhaustive.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NEI may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. For topics listed in APPENDIX A: National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations, NEI does not generally fund Phase I applications greater than $300,000 total costs or project periods greater than 2 years; or Phase II applications greater than $2,000,000 total costs or project periods greater than 3 years.

Phase IIB Competing Renewal Awards

The NEI will only accept SBIR Phase IIB Competing Renewal grant applications from Phase II SBIR awardees to continue the process of developing technologies that ultimately require federal regulatory approval or require extraordinary time and effort in the Research and Development phase. Such technologies include, but are not limited to, pharmacologic agents, biological products, and devices. These technologies should be clearly related to the mission of the NEI. This renewal grant should allow small businesses to reach a stage in the project where interest and investment by third parties is more likely. The Competing Renewal application must be a logical extension of a previously completed Phase II (R44) SBIR grant. NEI grantees seeking SBIR Phase IIB Competing Renewal funding must submit an application within a period no later than the first six receipt dates following expiration of the previous Phase II budget period. Budgets not to exceed $750,000 total costs per year and time periods up to two (2) years may be requested for this SBIR Phase IIB Competing Renewal opportunity.

Potential applicants are strongly advised to contact Dr. Jerome Wujek (contact information provided below) before beginning the process of putting an application together.

The following topics are meant for illustrative purposes only and are not exclusive of other appropriate activities.

General Research and Development Topics

NEI is interested in providing support for the development of new technologies, strategies, research tools, reagents and methods that can be applied to basic and translational research which will benefit vision health. This encompasses research and development of innovative enabling technologies in areas of genomics, proteomics and nanotechnology. More specific topics include drug and high throughput assays; drug delivery systems; gene therapy, cell-based therapy and regenerative medicine; development of *in vitro* and *in vivo* disease models; surgical devices and materials; telemedicine, mobile health, and health education; and design/fabrication of new or improved ophthalmic instruments for diagnosis and treatment of eye disorders.

Specific Research and Development Topics

RETINAL DISEASES

New therapeutic approaches for inflammatory and degenerative diseases and for inhibition of abnormal angiogenesis in the retina and choroid; Better methods of diagnosing and treating diabetic retinopathy and other vascular diseases; Non-invasive techniques for early diagnosis of macular degeneration and

other retinal degenerative diseases; Instruments and procedures for improved surgical management of retinal detachments; Retinal prostheses to help restore visual function; Better methods for cell or tissue transplantation.

CORNEAL DISEASES

New diagnostic tools, therapeutic agents and drug delivery methods for the treatment of corneal injury, infection, dry eye, ocular pain, and other ocular surface disorders; New biomaterials for corneal prostheses and corneal transplants; Instruments and procedures for correcting the refractive power of the cornea and/or measuring the cornea's optical properties or other physiological properties.

LENS AND CATARACT

New approaches in the post-operative management of cataract surgery; New surgical instruments for cataract extraction and new biomaterials for replacement of the natural lens; Design/fabrication of accommodative intraocular lenses.

GLAUCOMA AND OPTIC NEUROPATHIES

New therapeutic agents, instruments, and procedures for the diagnosis and treatment of glaucoma; Non-invasive methods to measure changes in the optic nerve head and retinal fiber layer.

STRABISMUS, AMBLYOPIA, AND REFRACTIVE ERROR

New approaches to detect and treat strabismus, amblyopia, and myopia; New tools and techniques for vision screening; New or improved methods and materials for correcting the refractive power of the eye and/or measuring the eye's optical properties or other physiological properties; New materials and manufacturing processes for eyeglasses and contact lenses.

VISUAL IMPAIRMENT AND BLINDNESS

Instruments and methods to better specify, measure, and categorize residual visual function; New or improved devices, systems, or programs that meet the rehabilitative and everyday living needs of blind or visually-impaired persons.

Additional Information

The NEI's programs are described in more extensive detail in documents which are available from the Institute. For additional information about the research programs of the NEI, please visit our home page at http://www.nei.nih.gov.

For more information on research topics, contact:

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NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

The NIGMS supports research and research training in the basic medical sciences and related natural and behavioral sciences and in specific clinical areas (i.e., clinical pharmacology, trauma and burn injury, sepsis, wound healing, and anesthesiology). The four divisions that support research of potential interest to small businesses and their collaborators include:

Division of Cell Biology and Biophysics

Division of Genetics and Developmental Biology

Division of Pharmacology, Physiology, and Biological Chemistry

Division of Biomedical Technology, Bioinformatics, and Computational Biology

Division of Training, Workforce Development, and Diversity

For additional information about areas of interest to the NIGMS, please visit our home page at http://www.nigms.nih.gov. This site includes staff contact information by program area (http://www.nigms.nih.gov/about/pages/contactbyarea.aspx). It also includes links to program announcements that highlight NIGMS areas of special emphasis (http://www.nigms.nih.gov/Research). In some cases, these announcements specifically mention the SBIR and STTR grant mechanisms, in most cases they do not. However, it is clear that small businesses could make contributions to the research objectives described in these announcements.

Limited Amount of Award

According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II and Phase IIB awards. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50% ($225,000 for Phase I and $1,500,000 for Phase II and Phase IIB, a hard cap). NIGMS will not accept applications with budget requests exceeding this hard cap with the exception of projects fitting within the list of SBA-approved topics for awards over the statuary budget limitations; the entire list for NIH (including NIGMS) may be found in Appendix A of this document.

If considering a project with a budget exceeding the hard cap, applicants are strongly encouraged to contact NIGMS program officials prior to submission, and preferably earlier during application preparation. In all cases, applicants should propose a budget that is reasonable and appropriate for completion of the research project.

Phase IIB Competing Renewal Awards

NIGMS will accept Phase IIB SBIR-only Competing Renewal grant applications to continue the process of developing products that ultimately require 1) clinical evaluation, 2) approval by a Federal regulatory agency, or 3) continuing refinements that include but are not limited to cost reduction, testing for performance, safety, reliability and/or durability, and meeting or establishing standards, particularly for basic or clinical research instrumentation or durable medical equipment (DME) designs. This renewal grant should enhance the likelihood that small will attract interest and investment by third parties. Such products include, but are not limited to research equipment, biological products, devices, drugs, medical implants, etc. related to the mission of the NIGMS. Budgets for this Phase IIB Competing Renewal opportunity must follow the guidelines for Phase II applications (described above). For awards that are intended to support completion of research needed to obtain an IND or IDE, applicants must provide evidence that they have consulted formally with the FDA concerning the research needed for the development of a drug, biologic or medical device and that the proposed research will address these regulatory requirements. Such evidence should include FDA correspondence from a pre-IND meeting for an IND application or a pre-IDE meeting for an IDE application, and the status of the project in a timeline related to Federal regulatory approval processes.

Prospective applicants considering a Phase IIB Competing Renewal application are strongly encouraged to contact either the Program person of record for the Phase II award or NIH staff listed at the end of this NIGMS topics announcement.

To assist NIGMS in planning for Phase IIB applications, it is helpful for prospective applicants to submit to the NIGMS SBIR/STTR Coordinator (listed below) a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Phase II grant number
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Funding Opportunity Announcement Number

The letter is non-binding and does not enter into the review process. It is anticipated that only a small number of NIGMS SBIR Phase II awards would be eligible for a Phase IIB Competing Renewal award.

Division of Cell Biology and Biophysics

Research on membrane synthesis, structure, and function; membrane models; membrane transport; cell division; cell organization; cell motility; and biophysics of proteins, nucleic acids, and biological assemblies, including viral entry, packaging, maturation, and release, as well as the development of instrumentation, components, and methods for the analysis of cellular components and macromolecules by imaging, spectroscopy, and diffraction analysis.

SBIR and STTR applications on the application of cell biology, biophysics, biochemistry, physics, mathematics, and chemistry to biomedical problems, and the development of instrumentation to facilitate research in cell biology and biophysics, such as, but not limited to, the topics listed below are welcome.

A. Development and improvement of methods for the expression, solubilization, and purification of milligram quantities of regulatory, cellular, and membrane associated proteins, as well as for the preparation of specifically labeled macromolecules and the recovery of proteins from inclusion bodies.

B. Development of novel ligands, inhibitors, and other probes for spectroscopic and microscopic analysis of cellular assemblies and viral structures, macromolecules and components, their localization and function *in vivo* and at a single molecule level.

C. Development of instrumentation, devices, and methods for detecting in real time, analyzing, and separating biologically important compounds, macromolecules, and their interactions.

D. Development of new methods and materials directed toward the solution of biological macromolecule structures, including membrane proteins, assemblies and complexes by, but not limited to, x-ray diffraction, electron diffraction, NMR and mass spectroscopy.

E. Imaging probes and sensors, other reagents and methods, instrumentation, software for microscopy, spectroscopy, and single molecule analysis of molecules, cells, tissues, embryos and small model organisms. Technologies for applications of microscopy, spectroscopy and single molecule analysis in basic biomedical research, including but not limited to light, electron, X-ray and scanning probe microscopy and fluorescence, magnetic and electron paramagnetic spectroscopy. NOT included are small animal and preclinical imaging and high throughput platforms for diagnostic and clinical applications.

F. Computational methods for analysis, prediction, and improving methods for determination of macromolecular structures and structure-function relationships.

Development of computerized tools that might be used in the presentation of the concepts of cell and structural biology to audiences at a variety of levels

Division of Genetics and Developmental Biology

Research on developing a better understanding of fundamental processes and mechanisms of development and inheritance in health and disease. Support of basic topics in genetics and developmental biology, including nucleic acid chemistry, the structure of genetic material, the mechanisms of transmission and expression of genetic information, cellular regulation of growth and differentiation, and population genetics. Areas that may be of interest to small businesses include, but are not limited to:

A. Development of computer software for the analysis of the primary and secondary structures of nucleic acids as these relate to genetic problems.

B. Improvement in procedures for the separation and analysis of nucleic acids and proteins as these relate to genetic problems.

C. Improvement of methodology (technology) for genetic analysis (e.g., gene expression, probes).

D. Development of probes for detection of human genetic polymorphisms, including disease genes.

E. Development of improved procedures for cytogenetics and diagnostic array technology.

F. Improvement in procedures (statistical, computational, laboratory) for the analysis of gene flow and gene dynamics in human populations.

G. Development of improved vectors for gene transfer.

H. Development of valid animal models for genetic diseases and birth defects.

I. Development of quantitative approaches to the analysis of complex biological systems.

J. Development of tools and technologies to detect and monitor complex human phenotypes or traits.

K. Development of technology to derive and expand pluripotent cell populations from non embryonic sources, for example, induced pluripotent stem cells (iPS).

L. Development of improved technology to scale up the growth of induced pluripotent stem cells in culture and to regulate their differentiation state

M. Development of markers, reagents and tools to characterize the unique properties of iPS cell lines and to distinguish them from adult stem cells and more differentiated cells.

N. Development of existing human embryonic stem cell lines and new or existing iPS cells as a model system for drug discovery.

O. Development or improvement of methodology for generation of antibodies or other affinity reagents for proteins and other small molecules in non-mammalian genetic model systems.

P. Improvement in procedures (statistical, computational, laboratory) for the high- and medium-throughput analysis of gene expression patterns and regulatory networks.

Q. Development or improvement of methods for high throughput detection of epigenomic changes.

R. Development or improvement of methods for characterizing the metabolic interactions of complex communities of microorganisms particularly those involved in host-microbe interactions.

S. Development of improved or novel methodology for structure/function analysis of very large macromolecular complexes involved in transmission or expression of genetic material.

Division of Pharmacology, Physiology, and Biological Chemistry

Research related to the actions of therapeutics, including anesthetics, and the development of biotechnological methods for their production and investigation. Research on cell signaling molecules and signaling intermediates, particularly those related to G-protein coupled receptors. Research in the field of glycomics, especially tool and methods development for this emerging field. Research on pain management as it relates to anesthesia and the perioperative period. Research on responses to traumatic injury, including burn injury, and methods to mitigate these responses. Research on wound healing and tissue repair. Research on the causes and treatments for common complications of critically ill patients (sepsis, systemic inflammatory response syndrome, multiple organ failure), especially directed towards the role of the inflammatory and innate immune responses. Research leading to new knowledge of physiological functions at the molecular, cellular, and organ systems levels. Research on the structure, function, and biosynthesis of cellular components and cellular metabolism, bioenergetics, and mechanisms of enzyme action, regulation, and inhibition. Research leading to the synthesis of new chemical entities or development of new chemical methods to probe biological phenomena or to alter the behavior of biological systems. Examples include, but are not limited to:

A. Methods for isolation, characterization, and production of natural and bio-engineered products.

B. Development of synthetic methodology to improve the efficiency (broadly defined) of discovery and production of bio-medically relevant compounds.

C. Development of enzymes, catalytic antibodies, ribozymes, artificial enzymes, and host molecules as drugs or synthetic tools.

D. Isolation, characterization, and development of factors and strategies, methods, or treatments involved in tissue repair, wound healing, sepsis, and traumatic injury, emergency, peri-operative, or critical care conditions, and associated pain management.

E. Improved systems for collection, processing, and analysis of real time physiological data from injured or critically ill patients. Application of systems biology or complexity theory approaches towards understanding the physiology of injured and critically ill organisms. Development of tools, software, algorithms, etc. needed to link clinical, demographic, physiological, genomic, proteomic or other datasets of injured or critically ill organisms.

F. Metabolomics/metabonomics of injury and/or critical illness.

G. Development of strategies, methods, or new technologies to improve the delivery, monitoring, safety and efficacy of anesthesia.

H. Research to improve drug design and delivery.

I. Research to improve drug bioavailability by improved understanding of factors that influence absorption, metabolism, transport, or clearance of therapeutics and underlying mechanisms. Application of pharmacokinetic and pharmaceutical principles to the study of large biomolecules, such as proteins, polypeptides, and oligonucleotides.

J. Research to discover, detect, and understand the genetic basis of individual differences in drug responses (pharmacogenomics).

K. Development of novel in vivo and in vitro methods to predict the safety and toxicities of pharmacologic agents.

L. Development of bioinformatic, mathematical, and/or computational approaches/resources and/or pharmacokinetic modeling programs which utilize ADME parameters of drugs and pharmacogenomic information of individual patients or patient populations to reduce adverse drug reactions in individual patients.

M. Development of ontologies and modules useful for combining and mining databases containing genotype and phenotype information in order to discover correlations for drug effects, either therapeutic or adverse.

N. Development of technologies, including instrumentation, software, reagents, and methods for proteomics, including but not limited to robotics, sample preparation and pre-fractionation, analytical separations, mass spectrometry, intelligent automated data acquisition, and improved informatics technologies.

O. Development of technologies, including instrumentation, software, reagents, and methods for glycomics, including but not limited to development of: specific glycan structural databases, methodologies for synthesis of robust glycan libraries, glycan labeling reagents and glyco-enzyme inhibitors, and analytical tools for determining carbohydrate structure and biological function.

P. Development and application of methods and materials for the elucidation of membrane protein structures at or near atomic resolution.

Q. Development of high-throughput methods for sequencing and re-sequencing of mitochondrial genes and relevant nuclear genes and for proteomic and/or functional profiling of mitochondria in diagnosis of mitochondrial diseases.

R. Development of new metal ion chelators and other tools to probe and/or alter the localization and concentration of metal ions in cells and in whole organisms. Research to exploit metal metabolism and metal-regulated cellular control and cell-cell signaling processes to probe and/or alter cell function. Research to develop investigational and therapeutic applications of metal-complexes and to understand the factors governing their pharmacology and toxicology.

S. Development of high-throughput methods and strategies to characterize the function of proteins and enzymes and/or define the functional interrelationships of proteins and enzymes.

T. Development of research tools to promote scientific collaboration in any of the above areas of research. For example, applications software for secure peer-to-peer networking to facilitate the exchange of scientific data and research materials or to construct a searchable distributed database.

U. Development of tools to characterize oxidative stress and oxidative stress related molecules (NO, peroxynitrite, hydrogen peroxide, lipoxidation products modified proteins, DNA modifications, etc.) including the extent and/or localization (by organ/tissue/cell/organelle) of oxidative stress.

Division of Biomedical Technology, Bioinformatics, and Computational Biology

This Division enables the development of research tools in two broad areas: (1) New or improved instruments, devices, and related methodologies to facilitate biomedical or behavioral research. Instrumentation includes, but is not limited to mass spectrometry, nuclear magnetic resonance, optical or laser spectroscopies, X-ray absorption/diffraction/scattering, detectors, electron or confocal microscopies, electrophoresis and other separation techniques, bioreactors, centrifugation, and flow cytometry. (2) New or innovative tools and methods in bioinformatics and computational biology, including social, population, and behavioral modeling research. Example areas that may be of interest to small businesses include, but are not limited to:

A. **Technology for Systems Biology:** Development of novel technologies for proteomics, glycomics, metabolomics, and other aspects of systems biology for discovery and clinical applications, (e.g., sample handling, separations, mass spectrometry, and computational tools for protein identification, data curation and mining, and for integrating genome variation, pathways and networks with biological function).

B. **Technology for Microscopy and Imagining:** Development of new or improved microscopic techniques, instruments, and supporting software that measures the location and dynamics or molecules in situ, organelles, cells, or tissues on the nano- and micro-scale.

C. **Technology for Structural Biology:** Development of tools including but not limited to detectors, cameras, light sources, optics, and automated data collection and analysis systems, for studying the structures of biomolecules and biospecimens in the size range of peptides to cells, using diffraction, microscopy and/or spectroscopy techniques,.

D. **Bioinformatics and Computational Biology:** Development of information and communication technology from computer and other quantitative sciences in support of biomedical or behavioral research, that apply best practices and proven methods for software design, construction and implementation to promote adoption by a broad biomedical research community. These may include:

1. Development of tools and methods for the modeling, simulation or analysis of complex biological systems.

2. Development of tools and methods for behavioral and social modeling, including mobile and other computer technologies to collect and validate data or to implement more effective broad-based behavioral interventions.

3. Development and enhancement of databases and data formats for biomedical research activities.

4. Development of collaborative environments and technologies to translate Big Data to knowledge, including but not limited to development of knowledge environments, research commons, data and metadata curation methods, and tools that address data security and privacy issues.

5. Development of tools and methods to collect, interpret, analyze and visualize scientific data through integration and interoperability of different data types.

6. Design and development of software and hardware for improving the effectiveness of computational approaches in biomedical research.

Development of computational biology software packages for integrative analysis of biomedical data, especially ones relevant to genomics, imaging, and clinical data

Division of Training, Workforce Development, and Diversity

Research toward development of products or services to market discoveries derived from a broad research base and for science literacy or research capacity, focusing at the post-high school level and beyond, and particularly to enhance diversity of the scientific workforce. Other Research Topic(s) Within the Mission of the Institute

Other Research Topic(s) Within the Mission of the Institute

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NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

For the most up-to-date information, please visit the NHLBI SBIR/STTR website (http://www.nhlbi.nih.gov/funding/sbir/index.htm) and subscribe to our listserv. You can also follow us on Twitter @NHLBI_SBIR

NHLBI plans, conducts, and supports research, clinical trials, and demonstration and education projects related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, and sleep disorders. It also supports research on the clinical use of blood and all aspects of the management and safety of blood resources. The NHLBI SBIR/STTR programs foster basic, applied, and clinical research on all product and service development related to the mission of the NHLBI. The NHLBI has four extramural program divisions, described below.

Cardiovascular Sciences

The Division of Cardiovascular Sciences (DCVS) supports basic, clinical, population, and health services research on the causes, prevention, and treatment of cardiovascular diseases. The research programs of the Division encompass investigator-initiated research, targeted research, Institute-initiated research in targeted areas of research need and scientific opportunity, specialized centers of research focused on selected research topics, and clinical trials. Research supported by the Division is concerned with the etiology, pathogenesis, prevention, diagnosis, and treatment of coronary artery disease and atherothrombosis; structural heart disease; heart failure and arrhythmias; and hypertension and vascular diseases. A broad array of epidemiological studies is supported by the DCVS to describe disease and risk factor patterns in populations and to identify risk factors for disease. Also supported are clinical trials of interventions to prevent and treat disease; studies of genetic, behavioral, sociocultural, and environmental influences on disease risk and outcomes; and studies of the application of prevention and treatment strategies to determine how to improve clinical care and public health.

Lung Diseases

The Division of Lung Diseases (DLD) supports research on the causes, diagnosis, prevention, and treatment of lung diseases and sleep disorders. Research is funded through investigator-initiated and Institute-initiated grant programs and through contract programs in areas including asthma, bronchopulmonary dysplasia, chronic obstructive pulmonary disease, cystic fibrosis, respiratory neurobiology, sleep-disordered breathing, critical care and acute lung injury, developmental biology and pediatric pulmonary diseases, immunologic and fibrotic pulmonary disease, rare lung disorders, pulmonary vascular disease, and pulmonary complications of AIDS and tuberculosis.

Blood Diseases and Resources

The Division of Blood Diseases and Resources (DBDR) supports research on the causes, prevention, and treatment of nonmalignant blood diseases, including anemias, sickle cell disease, and thalassemia; premalignant processes such as myelodysplasia and myeloproliferative disorders; hemophilia and other abnormalities of hemostasis and thrombosis; and immune dysfunction. Research supported by the Division encompasses a broad spectrum of topics ranging from basic biology to medical management of blood diseases. The Division has a major responsibility for research to improve the adequacy and safety of the nation's blood supply. It also plays a leading role in transfusion medicine and blood banking, including research to evaluate blood donation screening, manufacturing, and processing technologies. The Division also has a major responsibility supporting research in hematopoiesis and stem cell biology and disease. It also supports hematopoietic stem cell transplantation research, and the application of stem cell biology findings to the development of new cell-based therapies to repair and regenerate human tissues and organs.

Center for Translation Research and Implementation Science

The Center for Translation Research and Implementation Science (CTRIS) plans, fosters, and supports an integrated and coordinated program of research to understand the multi-level processes and factors that are associated with successful integration of evidence-based interventions within specific clinical and public health settings such as worksites, communities, and schools; identifies and makes readily available to implementation and dissemination practitioners emergent knowledge about the late phases of translation research, especially the "T4" phase, for rapid and sustained adoption of effective interventions in real world settings; leads the NHLBI effort in the rigorous, systematic evidentiary reviews and subsequent NHLBI participation in the collaborative model for clinical practice guidelines development; supports training and career development of personnel in "T4" translation research and health inequities relating to heart, lung, and blood diseases; provides a focal point for advice and guidance on matters pertaining to minority health, health inequities and minority participation in research; represents the NHLBI to other governments, other Federal Departments and agencies, international organizations, and the private sector on global health issues; and provides data analytics and portfolio analysis to evaluate and inform future directions of implementation research programs.

The NHLBI encourages applications through this Omnibus solicitation proposing innovative technologies related to any area within the NHLBI mission.

The NHLBI maintains a list of topics of special interest (http://www.nhlbi.nih.gov/funding/sbir/funding/omnibus_grant_solicitation.htm) to the Institute. Instructions for submitting applications in response to these topics are posted on the web page. The list is revised throughout the year, so please check regularly for updates. For more information, contact Jennifer Shieh (nhlbi_sbir@mail.nih.gov) or the Division contact associated with your technology area listed at the end of the NHLBI section.

Phase II Applications

The NHLBI strongly encourages applicants to include a robust regulatory strategy with corresponding milestones in Phase II applications. Applicants are also encouraged to include letters of support or other evidence documenting their regulatory strategy. The NHLBI will consider the strength of the regulatory plan when making funding decisions. For assistance regarding regulatory strategy, explore the “Small Biz Hangout” series on the NHLBI YouTube channel and contact Chris Sasiela (nhlbi_sbir@mail.nih.gov) with specific questions.

For assistance regarding the commercialization plan, watch the “Small Biz Hangout” for advice on *Writing Your Phase II Commercialization Plan* (http://bit.ly/Ph2CommPlanHangout) and contact Gary Robinson (nhlbi_sbir@mail.nih.gov) with specific questions.

NHLBI-Supported Funding Opportunity Announcements (FOAs)

In addition to this Omnibus program announcement, the NHLBI releases targeted Funding Opportunity Announcements (FOAs) throughout the year. Sign up for the listserv to be notified of new FOAs.

These FOAs are listed to inform potential applicants about other funding opportunities to which they can apply; applications submitted in response to this Omnibus program announcement are not limited to research and development areas described in the following targeted FOAs. The NHLBI also encourages mission-aligned applications for innovative technologies outside these targeted areas.

(Funding Opportunity Announcements can be released or expire at any time throughout the year; please refer to the NHLBI SBIR/STTR web site for active announcements supported by NHLBI.)

- NHLBI SBIR Phase IIB Bridge Awards to Accelerate the Commercialization of Technologies for Heart, Lung, Blood, and Sleep Disorders and Diseases (SBIR): http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-16-009.html
- Small Market Awards: SBIR Phase IIB Competing Renewals for Heart, Lung, Blood and Sleep Technologies with Small Commercial Markets (SBIR): http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-012.html
- Onsite Tools and Technologies for Heart, Lung, and Blood Clinical Research Point-of-Care (SBIR/STTR): http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-011.html
- Bioreactors for Reparative Medicine (SBIR/STTR): http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-15-008.html
- Human Cellular Models for Predicting Individual Responses to Cystic Fibrosis Transmembrane Conductance Regulator (CFTR)-Directed Therapeutics (SBIR/STTR): http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-15-027.html
- Stem Cell-Derived Blood Products for Therapeutic Use: Technology Improvement (SBIR/STTR): http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-15-030.html
- Developing a Point-of-Care Device for the Diagnosis of Sickle Cell Disease in Low Resource Settings (SBIR): http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-010.html
- Developing Improved Assessments of Tissue Oxygenation (SBIR Phase II only): http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-15-019.html
- Development of Highly Innovative Tools and Technology for Analysis of Single Cells (SBIR): http://grants.nih.gov/grants/guide/pa-files/PA-13-140.html
- Safe and Effective Instruments and Devices for Use in Neonatal and Pediatric Care Settings (SBIR/STTR): http://grants.nih.gov/grants/guide/pa-files/PAR-13-090.html
- New Technologies for Viral Hepatitis (SBIR/STTR): http://grants.nih.gov/grants/guide/pa-files/PA-15-077.html

SBIR Phase IIB Awards

The NHLBI does not accept applications for Phase IIB SBIR competing renewal awards through this Omnibus solicitation; however, the NHLBI offers Phase IIB opportunities through the NHLBI Phase IIB Bridge Awards and the NHLBI Phase IIB Small Market Awards using separate funding opportunity announcements (Bridge Award: RFA-HL-16-009; http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-16-009.html. Small Market Award: RFA-HL-14-012; http://grants.nih.gov/grants/guide/rfa-files/RFA-HL-14-012.html). The purpose of the NHLBI Bridge and Small Market Awards is to accelerate the transition of SBIR/STTR Phase II projects to the commercialization stage by promoting partnerships between SBIR/STTR Phase II awardees and third-party investors and/or strategic partners. The Small Market Award is designed to support technologies addressing rare diseases or pediatric populations. The Bridge and Small Market Awards encourage business relationships between applicant small business concerns and third-party investors/strategic partners who can provide substantial financing to help accelerate the commercialization of promising new products and technologies that were initiated with SBIR/STTR funding. In particular, applicants are expected to leverage their previous SBIR/STTR support, as well as the opportunity to compete for additional funding through the NHLBI Bridge Award or Small Market Award programs, to attract and negotiate third-party financing needed to advance a product or technology toward commercialization. Development efforts may include preclinical R&D needed for regulatory filings (e.g., IND or IDE) and/or clinical trials.

An SBIR Bridge Award or Small Market application must represent a continuation of the research and development efforts performed under a previously funded SBIR or STTR Phase II award. The NHLBI welcomes applicants previously funded by any NIH Institute or Center or any other Federal agency, as

long as the proposed work applies to the NHLBI mission. Applications may be predicated on a previously funded SBIR or STTR Phase II grant or contract award. Applicants with Phase II contracts or awards from another Federal agency must contact the NHLBI to ensure their application can be received.

Applicants are strongly encouraged to contact Jennifer Shieh at 301-496-2149 or jennifer.shieh@nih.gov for additional information.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, the NHLBI may not fund an application or may decrease the length of an award and/or the budget recommended by a review committee. NIH has received a waiver from SBA, as authorized by statute, to exceed the statutory budget limitations of $225,000 for Phase I and $1,500,000 for Phase II for specific topics relevant to the NHLBI that can be found below. Generally, the NHLBI does not fund Phase I applications greater than $300,000 total costs or project periods greater than 2 years. In addition, the NHLBI does not generally fund Phase II applications greater than $2,000,000 total costs or project periods greater than 3 years. **Applicants with budget questions or considering requesting a budget greater than these amounts are strongly encouraged to contact Jennifer Shieh (**nhlbi_sbir@mail.nih.gov**) before submitting an application**.

NHLBI Topics for Awards over Statutory Budget Limitations

A. Biomedical technologies (medical devices, instruments, pharmaceuticals, drugs, therapeutics, vaccines, diagnostics and biologics) for heart, lung, blood, and sleep related diseases and disorders requiring Federal regulatory approval (FDA) or clearance to be commercialized.

B. Small and large animal testing of products of tissue engineering and regenerative medicine, drugs, medical devices, therapeutics, and biologics and studies involving *in vivo* animal experiments for heart, lung, blood, and sleep related diseases and disorders.

C. Clinical trials and other experiments involving human subjects for heart, lung, blood, and sleep related diseases and disorders.

D. Therapeutics (drugs, devices, or biologics) development for heart, lung, blood, and sleep related diseases and disorders.

E. Device development for heart, lung, blood, and sleep related diseases and disorders Development for heart, lung, blood, and sleep related diseases and disorders.

F. Investigation of biomarkers and biosignatures of heart, lung, blood, and sleep related diseases and disorders.

G. Technologies to enhance clinical research for heart, lung, blood, and sleep related diseases and disorders.

H. Advanced instrumentation and high throughput tools for biomedical research in heart, lung, blood, and sleep related diseases and disorders.

I. Tools and platforms to improve the dissemination and implementation of evidence-based interventions for heart, lung, blood, and sleep related diseases and disorders.

Final Progress Reports

As detailed in NOT-OD-12-152, the NIH has released new instructions for SBIR/STTR Final Progress Reports.

The NHLBI is interested in tracking the progress of the small business concerns it funds and the products they develop. Funding priority will be given to those small business concerns that show not only their ability to develop products but also their growth as a small business concern towards independence from the SBIR/STTR program.

Programs and Services for NHLBI Small Business Awardees

The NHLBI offers free assistance to applicants and awardees regarding regulatory approval, commercialization, and business plan development. Please contact nhlbi_sbir@mail.nih.gov for more information and note what specific topic(s) you would like advice on:

- Chris Sasiela, Ph.D., RAC - Regulatory Specialist
- Gary Robinson, Ph.D. - Business Development Advisor

The NHLBI hosts "Small Biz Hangouts" - a free educational series covering the basics of biomedical technology development. Previous Hangouts are archived on the NHLBI YouTube channel: http://bit.ly/NHLBI-YouTube

Sign up for the NHLBI listserv to learn about upcoming live events. Learn more about available resources at http://www.nhlbi.nih.gov/about/org/dera/otac/resources.

The NHLBI encourages awardees to apply for the following free programs:

- Phase I: The NIH Niche Assessment Program (http://sbir.nih.gov/nap) provides awardees with an in depth market analysis for their technology.
- Phase II: The NIH Commercialization Assistance Program (http://sbir.nih.gov/cap) will assist awardees in transferring their products to the marketplace.

For additional information on research areas, please contact:

CARDIOVASCULAR SCIENCES

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LUNG DISEASES AND SLEEP DISORDERS

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BLOOD DISEASES AND RESOURCES

Phyllis Mitchell
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CENTER FOR TRANSLATION RESEARCH AND IMPLEMENTATION SCIENCE

Uchechukwu Sampson

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NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

The National Human Genome Research Institute (NHGRI) has been guided, since the inception of the Human Genome Project in 1990, by a sequential series of plans, each of which has been developed with considerable input from the scientific community. These plans have always laid out ambitious goals and measurable objectives to gauge progress. NHGRI initiated its most recent planning process in 2008 and concluded with the publication in February 2011 of its newest strategic plan, Charting a Course for Genomic Medicine from Base Pairs to Bedside (Nature, 10 February 2011; Volume 470). The phenomenal advances that have marked genomics and have allowed genomic applications to transform many important fields made it an opportune time for the Institute to take a new look at genomics and its future.

The purpose of this document is to provide information to investigators about the breadth of research falling within NHGRI's mission. When appropriate, NHGRI will publish Requests for Applications that will be used to stimulate research in specific areas, to fill gaps in research knowledge, or to generate community resources that will further the mission of genomics or ELSI research.

The following are areas of high program relevance for investigator-initiated applications; they are not listed in priority order.

Technology and Methods Development

Technology development in DNA sequencing and genotyping are examples of activities that have changed the nature of what scientific research questions are practical to address, have enabled new approaches, and have facilitated the development of new community resource data sets. Many areas of critical importance to the realization of the genomics-based vision for biomedical research require continued technological and methodological developments before pilots and then large-scale approaches can be attempted. Accordingly, the NHGRI will continue to support the development of new, fundamental technologies in all areas of genomics. Important areas in which technology development applications would be responsive to this Program Announcement include (but are not limited to) analyses of gene expression and other molecular phenotypes, discovery and characterization of genetic variation; identification of the genetic contributions to health, disease, and drug response; statistical analytic methods for understanding human genomic variation and its relationship to health and disease; and chemical genomics. There is also continued need to support technology development for the comprehensive discovery of functional elements in the human and model organism genomes, and new DNA sequencing technology. Many of these assays would benefit from the ability to work with very small amounts of starting material, to the limit of single cells, along with minimally-invasive human specimens that are easy to collect, handle, and store. As these technologies mature, emphasis should be on high throughput, cost-effective methods that consistently produce very high quality data.

The Institute also places high priority on contributing selectively to the development of new and needed technology in related areas, such as proteomics and systems biology research, when NHGRI funding can be used to further a truly unique development that will have a significant impact on the field.

Bioinformatics and Computational Biology

The development of new sequencing technologies has dramatically increased the amount of data produced for genomics. NHGRI encourages new computational applications for the production, processing, secure sharing, and analysis of data from these new sequencing platforms. The NHGRI has also supported the generation of many other large-scale genomic data sets such as haplotype maps, genetic variants, transcriptome measurements, functional elements, and protein interactions,. NHGRI also encourages the development of new computational methods and tools to enable the analysis of these and other large datasets, and to extract useful biological information from them. These applications would include better computational methods for storage, access, compression and transfer of large genomic

datasets by biomedical researchers along with better analysis methods to interpret these data and integrate them with other data types. Methods that are fast and computationally efficient are highly desirable.

Where possible, existing community data standards and methods for data exchange should be used in the development of these new methods and tools. Further information on programs related to genomic databases and computational biology is available at this web site: http://www.genome.gov/10001735.

Genomic databases are essential resources for the biological and biomedical research communities. The creation and maintenance of effective databases are as important a component of research funding as is data generation. NHGRI has been a primary source of support for several major genetics/genomics-oriented databases and will continue to foster technology improvements to develop effective methods for integrating, displaying, and providing access to genomic information. Projects developing new database and data science technologies to improve the utility of genome information would be appropriate as applications

Some genomic data analysis and display tools have been developed that already are used in the community that would benefit from additional work to support broader dissemination, for example making them efficient, reliable, robust, well-documented, and well-supported. NHGRI will support projects to extend the support for these informatics tools to make them readily adopted by any biomedical research laboratory that wishes to use genomic technologies to address biological questions.

Population Genomics and Genomic Medicine

Population genomics applies genomic technologies, such as genome-wide association testing and sequencing, to population studies to identify genes or variants that affect common etiologically complex conditions and predict individual risk. Genomic medicine is an emerging discipline that investigates the value of applying genomic methods in clinical care for the diagnosis, treatment, and prevention of complex diseases. The research scope of Population Genomics and Genomic Medicine at NHGRI includes: developing resources and statistical methods for observational studies and clinical trials incorporating advanced genomic technologies; conducting proof-of-principle studies that apply genomic technologies to epidemiologic and clinical research; developing research methods and infrastructure needed for future epidemiologic and clinical studies of genetic and environmental contribution to disease; assessing phenotypic manifestations of genetic variants through electronic medical records (EMRs); integrating genomic results and clinical decision support into EMRs, and assessing the impact of genetic information on health outcomes and delivery of care. For additional information about Genomic Medicine NHGRI, please visit this web site: http://www.genome.gov/27550079.

Ethical, Legal and Social Implications

NHGRI, through the ELSI Research Program, supports research studies that examine issues and, where appropriate, develop policy options regarding the ethical, legal and social implications of genomics. These studies may focus on issues associated with genomic research, genomic medicine or broader societal effects of genomic information and technologies. More detailed information on specific ELSI research priorities within each of these broad areas is available on the ELSI Research priorities web site: http://www.genome.gov/27543732.

Other Research Topics Within the Mission of the Institute

Individuals interested in any of the above listed areas are encouraged to contact the NHGRI staff listed below. For more specific information about areas relevant to NHGRI's mission, please visit our home page at http://www.genome.gov/Grants/

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

The mission of the National Institute of Mental Health (NIMH) is to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. Mental disorders constitute an immense burden on the U.S. population, with major depression now the leading cause of disability in the U.S., and schizophrenia, bipolar disorder, and obsessive-compulsive disorder ranked among the ten leading causes of disability. NIMH also takes a leading role in understanding the impact of behavior on HIV transmission and pathogenesis, and in developing effective behavioral preventive interventions. The NIMH conducts a wide range of research, research training, research capacity development, as well as public information outreach and dissemination to fulfill its mission.

For the Institute to continue fulfilling this vital public health mission, it must foster innovative thinking and ensure that a full array of novel scientific perspectives are used to further discovery in the evolving science of brain, behavior, and experience. In this way, breakthroughs in science can become breakthroughs for all people with mental illnesses.

The NIMH SBIR/STTR programs support small businesses to develop technologies that can advance the mission of the Institute, including in basic neuroscience research relevant to mental disorders, translational and clinical research of mental disorders, clinical diagnosis or treatment of mental disorders, and dissemination of evidence-based mental health care. The NIMH Strategic Plan (http://www.nimh.nih.gov/about/strategic-planning-reports/index.shtml) and the National Advisory Mental Health Council's workgroup report "From Discovery to Cure" http://www.nimh.nih.gov/about/advisory-boards-and-groups/namhc/reports/fromdiscoverytocure_103739.pdf present key scientific priorities across these domains, and describe the need for tools to realize these priorities. Research priorities for the NIMH further include aspects of HIV/AIDS prevention, treatment, and care, in accordance with the Trans-NIH Plan for HIV-Related Research (http://www.oar.nih.gov/strategicplan/).

For additional information about areas of interest to the NIMH, please visit our home page at http://www.nimh.nih.gov.

Also visit the NIMH SBIR/STTR home page: http://www.nimh.nih.gov/research-funding/small-business/index.shtml.

Important notes:

1. It is very helpful for potential SBIR/STTR applicants to contact NIMH prior to submitting an application, to ensure the application is of priority/interest to NIMH. Please see the contacts section.
2. An additional criteria that the federal government considers in supporting a small business with SBIR funds, is past commercialization performance. It is expected that small businesses who have received previous SBIR grants, have had success in commercializing their previously supported technologies. Small businesses that are mostly interested in research and development (and not commercialization) should consider other grant mechanisms at NIH, rather than the SBIR program. Program staff at NIMH can help identify the most appropriate grant mechanism to use.
3. The NIH has received a waiver from the SBA, regarding the funding cap. The technology areas that are included in this waiver can be found in the topic list located in Appendix A of this document. The technologies listed in the Appendix A (under NIMH) are of priority to this institute.

Phase IIB Competing Renewal Awards

The NIMH will accept Phase IIB SBIR Competing Renewal grant applications in two categories: 1) to continue research and development of technologies that ultimately require federal regulatory approval,

and 2) to continue research and development of complex instrumentation, clinical research tools, or behavioral interventions and treatments.

Technologies in the former category (those that ultimately require federal regulatory approval) include, but are not limited to: pharmacologic agents and drugs, biological products, medical devices, vaccines, etc., related to the mission of the NIMH. Phase IIB SBIR Competing Renewal grants for such technologies should allow small businesses to get research and development to a stage where interest and investment by third parties is more likely.

Companies that are developing technologies that do not focus on drug development, but that require federal regulatory approval prior to commercialization, may be eligible to submit a Phase IIB Competing Renewal application.

For both technology areas, Phase IIB applications may be submitted through the Omnibus SBIR funding opportunity announcement. For this opportunity, budget limits of $3 million total costs and time periods up to 3 years may be requested. These budget allowances have been approved by the SBA through a waiver.

The following examples would make appropriate topics for proposed NIMH SBIR Phase IIB Competing Renewal projects. These are meant for illustrative purposes only and are not exclusive of other appropriate activities:

- Preclinical studies, including pharmacology and toxicology, beyond those conducted under the Phase I (R43) and initial Phase II (R44) grants. Some *in vivo* or *in vitro* studies would be expected to have been carried out in Phase I or the initial Phase II grant.
- Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.
- Studies in normal healthy volunteers to determine a drug's safety profile, metabolism, etc.
- Assessment of devices with regard to performance standards related to the FDA approval process.
- Safety and effectiveness studies of novel medical devices.
- Evaluation of novel imaging approaches for diagnostic purposes.
- Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.

Although technologies in the latter category listed above (complex instrumentation, clinical research tools, or behavioral interventions/treatments) may not require federal regulatory approval, extraordinary time and effort is needed for their research and development. Therefore, NIMH supports Phase IIB Competing Renewal awards of existing Phase II grants for such technologies. The Phase IIB Competing Renewal award for these would provide up to an additional three years of support at total cost funding levels of up to $$2.4 million for the project. These budget allowances have been approved by the SBA through a waiver.

Please contact the Program Director in the appropriate Division or Dr. Margaret Grabb (listed below) before beginning the process of putting an application together. In addition, prospective applicants are encouraged to submit to the program contact a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions

- Funding Opportunity Announcement (e.g. PA-11-133).

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows NIH staff to estimate the potential review workload and plan the review. It is expected that only a portion of NIMH SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

Division of Neuroscience and Basic Behavioral Science (DNBBS)

The Division of Neuroscience and Basic Behavioral Science provides support for research programs in the areas of basic neuroscience, genetics, basic behavioral science, research training, resource development, technology development, drug discovery, and research dissemination. The Division has the responsibility, in cooperation with other components of the Institute and the research community, for ensuring that relevant basic science knowledge is generated and then harvested to create improved diagnosis, treatment, and prevention of mental and behavioral disorders.

In this Division, the SBIR and STTR programs support research and the development of tools related to basic brain and behavioral science, genetics, and drug discovery and development relevant to the mission of the NIMH. Such tools include: software (such as informatics tools and resources and tools for analyzing data); hardware (such as the development of instrumentation or devices); wetware (such as the use of iRNAs or other bioactive agents as research tools or molecular imaging agents or genetic approaches to label neural circuits or modify circuit functions); and drug discovery related technologies such as high throughput screening (HTS) or computational pharmacology approaches.

AREAS OF EMPHASIS

- Novel imaging probes to study brain structure and function at all levels, from the molecular to the whole organ, using any imaging modality (PET, fMRI, optical, etc.).
- Drug discovery/drug development of novel compounds which act on molecular pathways (receptors, enzymes, second messengers, etc.) that are not typically targeted with currently available psychiatric drugs, and that have a strong biological justification as a novel mechanism for treatment of psychiatric disorders.
- Novel screening assays for high throughput acquisition and analysis of data about behavior and the brain, from the level of genes to the level of behavior.
- Novel technologies that would enable researchers to study how populations of neural cells work together within and between brain regions, in order to understand how changes in neural activity contributes to mental disorders.
- Develop informatics tools to facilitate the sharing of data between laboratories. This could include common data element efforts, but is not limited to that area.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

Division of Translational Research (DTR)

The Division of Translational Research plans, supports, and administers programs of research, research training, and resource development aimed at understanding the pathophysiology of mental illness and hastening the translation of behavioral science and neuroscience advances into innovations in clinical care. The Division supports a broad research portfolio, which includes studies of the phenotypic characterization and risk factors for major psychiatric disorders; clinical neuroscience to elucidate etiology and pathophysiology of these disorders; and psychosocial, psychopharmacologic, and somatic treatment

development. In addition, the Division supports an integrated program to clarify the psychopathology and underlying pathophysiology of psychiatric disorders of late life and to develop new treatments for these disorders.

In this Division, the SBIR and STTR Programs support research aimed at facilitating the validation and commercialization of new methods of assessing psychopathology and measuring treatment response to therapeutic agents. In addition, the SBIR and STTR Programs support the clinical development of novel pharmacologic treatments and technology development used to deliver novel psychosocial approaches to the treatment of mental illness in adults, pediatrics and geriatrics.

AREAS OF EMPHASIS

- Develop valid measures of the various constructs in the Research Domain Criteria (RDoC) matrix (see http://www.nimh.nih.gov/research-funding/rdoc/index.shtml), e.g., neurocognitive tasks, psychometrically sophisticated questionnaires, measures of behavior, and biomarkers, into a commercial product.
- Conduct early stage, proof of concept clinical trials to advance the development of novel therapeutics. The clinical trials are expected to include biological/behavioral data to assess target engagement and to help determine potential success or failure of the compound before moving on to larger clinical trials (see NOT-MH-11-015 http://grants.nih.gov/grants/guide/notice-files/NOT-MH-11-015.html).
- Develop, test and validate reliable and stable biomarkers that can identify at-risk individuals prior to disease onset, improve diagnosis, predict treatment response, or to measure disease progression. Biomarkers are also needed in clinical trials to identify dose ranges, to identify a specific subpopulation of subjects to enroll in a treatment trial, or to measure efficacy or toxicity/side effects.
- Development of novel diagnostic tools and innovative measures of treatment response and disease progression, preclinical or clinical efficacy testing, or toxicity measures for drug development.
- Development of hardware and software tools to enable refined physiological and behavioral assessment of normal and atypical infant and child development.
- Web-based tools to enhance prevention, early identification and treatment of pediatric mental disorders by various educational and health professionals.
- Development of hardware and software tools to support operations of multi-site clinical trials.
- Development of novel methods to enhance efficiency of early phase clinical trials.

Prospective applicants are strongly encouraged to contact Dr. Margaret Grabb (listed below) with questions about the relevance of their interests to the mission of this division.

Division of AIDS Research (DAR)

The NIMH DAR supports scientific research to understand and alleviate the consequences of HIV infection on the central nervous system, and research to strengthen the provision and outcomes of HIV/AIDS prevention and treatment. High-priority research areas for SBIR/STTR applications are described below.

- Develop and test novel, non-invasive diagnostic approaches (instrumentation, imaging, biomarkers, central nervous system [CNS] cell-based *in vitro* models) to detect neurocognitive

dysfunction associated with HIV-1 infection and innovative technologies to study the mechanisms involved in HIV-1 associated neuropathogenesis and persistence of HIV-1 in the CNS. or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy

- Design and test novel therapeutic strategies aimed at amelioration of HIV-1 associated neurocognitive disorders (HAND) and eradication of HIV-1 from CNS reservoirs or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy.
- Discover and develop innovative technologies for targeting therapies to the brain, including antiretroviral drugs, nanotechnology, imaging tools to study HIV-aging interactions or HIV-related neurodegeneration and neuroprotective strategies with improved capability to cross the blood-brain barrier for amelioration of HAND.
- Design new strategies to reduce adverse effects of anti-retroviral drugs such as neuropsychiatric side effects and drug-drug interactions.
- Develop or adapt neurological/neuropsychological/neurobehavioral assessments to evaluate HIV-1 associated abnormalities in adults or children in resource poor environments that are adaptable to different cultures and languages.
- Develop innovative approaches to improve the scientific assessment of HIV sexual risk behavior through remote sensing devices, biomarkers, or other novel methods.
- Develop and test tools, curricula, and strategies that seek to reduce documented racial/ethnic, gender, and age-related disparities in HIV infection or in HIV treatment adherence and treatment outcomes.
- Develop novel tools and approaches to identify, recruit, enroll, and/or retain those most vulnerable to HIV/AIDS (e.g., African-American MSM, adolescents) in HIV prevention research and/or initiatives.
- Develop and test tools, curricula, or other approaches designed to facilitate the effective implementation of emerging biomedical HIV prevention methods (e.g., pre-exposure prophylaxis, microbicides, circumcision, etc.), including but not limited to approaches that address behavioral aspects of biomedical prevention (e.g., provider knowledge and training; patient uptake, adherence, HIV screening, and risk-reduction counseling; adverse event monitoring, etc.).
- Develop or adapt and evidence-based HIV sexual risk reduction, psychosocial coping, or treatment adherence interventions for delivery through the internet or mobile devices, with the aim of expanding intervention access, fidelity of delivery, and/or intervention tailoring.
- Develop novel tools and approaches designed to improve HIV treatment outcomes by rapidly linking individuals diagnosed with HIV to primary medical care, enhancing patient readiness for initiation of antiretroviral medications, improving and sustaining patient adherence to antiretroviral medications, and/or improving patient retention in medical care.
- Develop innovative approaches designed to improve the quality of HIV testing, (including rapid home based HIV antibody tests), HIV counseling, prevention, and treatment services by strengthening patient-provider communication and/or modifying the decision-making processes and practice behaviors of health care providers.
- Develop innovative approaches designed to improve the uptake and understanding of rapid home based HIV antibody tests by key populations at higher risk for HIV as well as innovative interventions that can be paired with home test kits to increase linkage and engagement in HIV care for those testing positive.

- Develop novel information technology tools designed to improve dissemination of evidence-based interventions and assist healthcare providers, community-based organizations, and professional or advocacy organizations in identifying, adopting, and implementing proven HIV prevention and treatment interventions.

Prospective applicants are strongly encouraged to contact Dr. Rebecca DelCarmen-Wiggins (listed below) with questions about the relevance of their interests to the mission of this division.

Division of Services and Intervention Research (DSIR)

The Division of Services and Intervention Research (DSIR) supports two critical areas of research:

- Intervention research to evaluate the effectiveness of pharmacologic, psychosocial, somatic, rehabilitative and combination interventions on mental and behavior disorders-including acute and longer-term therapeutic effects on functioning across domains for children, adolescents, and adults.

- Mental health services research to improve the access, cost, quality and outcomes of mental health care, as well as improve the dissemination and implementation of effective interventions in clinical and community settings.

The intervention research addresses the effectiveness of treatment and preventive interventions in usual practice and community settings with the purpose of informing clinicians, patients, families, and health policy makers on evidence based practices. In funding decisions, special emphasis is placed on the potential clinical impact of the research activities and on the implications of the research findings for improving community practice and health outcomes. Types of interventions include the full range of behavioral, psychotherapeutic, pharmacologic, and non-pharmacologic somatic or alternative interventions, as well as rehabilitation or other adjunctive services, e.g., integrated approaches to chronic mental illness. Examples of areas of interest are:

- Randomized clinical trials evaluating the effectiveness of known efficacious interventions.

- Analyses of naturalistic databases to evaluate the effectiveness of known efficacious interventions.

- Identifying moderators and mediators of intervention effects as a step to design and test personalized interventions.

- Evaluating the combined or sequential use of interventions.

- Determining the optimal length of intervention, establishing the utility of continuation or maintenance treatment (that is, for prevention of relapse or recurrence).

- Evaluating the long-term impact of efficacious interventions on symptoms, functioning, and quality of life.

Services research covers all mental health services research issues across the lifespan and disorders, including but not limited to:

- Services organization, delivery (process and receipt of care), and related health care financing at the individual, clinical, program, community and systems levels in specialty and non-specialty mental health, general health, and other delivery settings (such as the workplace).

- Interventions to improve the quality and outcomes of care.

- Enhanced capacity for conducting services research.

- The clinical epidemiology of mental disorders across all clinical and service settings.
- The dissemination and implementation of evidence-based interventions into service settings.

In this Division, the SBIR and STTR Programs support research and development of novel tools related to clinical trials (including preventive, treatment, and rehabilitative interventions alone and/or in combination), methodology, clinical epidemiology, services research, effectiveness research, health disparities (including rural populations) and the dissemination and implementation of evidence-based treatments/research into clinical and community settings in areas directly related to the mission of the NIMH. Such tools may include applied behavioral science and technology, software, hardware and associated technologies. Collaboration with NIMH supported researchers for the development of software for new analytic techniques and/or decision-making algorithms is encouraged. Also supported is research and the development or adaptation of tools and technologies to be used to enhance the training and development of new generations of researchers and practitioners and to keep established researchers and practitioners up-to-date on the findings, implementation, and methods of interventions and services research.

Prospective applicants are strongly encouraged to contact Dr. Adam Haim (listed below) with questions about the relevance of their interests to the mission of this division.

Program Contacts

Margaret Grabb, Ph.D. (general questions about the NIMH SBIR program, Phase IIB program, DNBBS, DATR, DDTR divisional interests)
National Institute of Mental Health
6001 Executive Boulevard, Room 7201, MSC 9645
Bethesda, MD 20892-9645
Rockville, MD 20852 (for express/courier service)
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Rebecca DelCarmen-Wiggins, Ph.D. (DAR divisional interests)
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Gregory K. Farber, Ph.D. (general questions about technology development)
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Email: farberg@mail.nih.gov

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

The mission of NIMHD is to lead scientific research to improve minority health and eliminate health disparities. To accomplish this, NIMHD plans, reviews, coordinates, and evaluates all minority health and health disparities research and activities of the National Institutes of Health; conducts and supports research in minority health and health disparities; promotes and supports the training of a diverse research workforce; translates and disseminates research information; and fosters innovative collaborations and partnerships.

The Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program enable the Nation's small businesses to apply their unique research and development capabilities toward accomplishing NIMHD's mission.

Through small business Phase I, Phase II, and Fast-track awards, NIMHD supports multi- and trans-disciplinary research and development leading to novel and or improved products capable of contributing to NIMHD's mission. Research and development may proceed and or be initiated at the molecular, cellular, individual, community or population level. Funding support for focus groups, phase I/II clinical trials, and other studies as needed to develop and test the proposed product may be requested. Additionally, NIMHD seeks innovative strategies that engage, collaborate, or partner with health disparity communities for designing and delivering innovative products and services to improve minority health and eliminate health disparities.

An overarching objective of NIMHD's investments in SBIR/STTR programs is to ensure that health disparity populations benefit equally from innovations in health promotion and prevention, biotechnology, imaging technologies, technologies for computational biology and informatics, including for example, systems, and structural biology; and technologies designed to advance personalized medicine, electronic health records and systems, etc. New or improved instruments, devices, and related methodologies to facilitate biomedical or behavioral research and efforts that seek to redesign or design new instruments, devices, and methods likely to increase access, reduce costs, and improve quality are of special interest.

Disparities in Health Outcomes

Disparities in health outcomes are believed to result from complex interactions between many factors such as environmental exposures and genetic traits, and/or the accrual over time of stable phenotypic traits and lifestyle behaviors that contribute to but are insufficient individually to cause the onset of disease or illness. Innovations leading to improved health outcomes are of interest. Examples include, but are not limited to:

1. Multidisciplinary basic research approaches that lead to biological probes and starting points for therapeutic interventions;
2. Innovative high-throughput screening approaches to identify compounds that are active in target- and phenotype assays and to use these approaches to develop bioactive probes for application in clinical settings;
3. Methodological and technological innovations that will integrate behavioral and social science with biomedical research, including gene related and environmental components;
4. Differential pharmacologic drug metabolism;
5. Impact of dietary decision making in diverse populations and effect on health disparity outcomes; and
6. Innovations in mobile health (mHealth) and telehealth/telemedicine technologies for communication, diagnosis, monitoring, evaluation, medical management, tracking, training, and treatment in underserved community settings and rural and remote locations.

Health Promotion and Prevention Research in the Health Disparities Communities

High priority is given to activities designed to empower health disparity communities to achieve health equity through health education, disease prevention, and partnering in community-based hypothesis, outcomes- and problem-driven research. Examples of such activities include, but are not limited to:

1. Efficacy of therapies in local populations;
2. Motivating positive behavioral changes in diverse populations;
3. Health outcomes related to health seeking, lifestyle, risk taking, protective behaviors and/or socioeconomic status;
4. Incorporating research into health promotion and disease prevention initiatives, applying new knowledge in a culturally appropriate manner in intervention/disease prevention initiatives;
5. Distribution of health structures and adverse health effects, and the sufficiency of healthcare frameworks in accommodating diverse social, cultural, political and economic factors; and
6. Development and/or refinement of culturally appropriate survey instruments, tools and databases to promote community based research engaging minorities, rural and other medically underserved populations; and culturally appropriate, evidence-based health promotion and disease prevention/intervention educational media such as software, videos, printed materials for health disparities populations and disadvantaged communities.

Innovations in Health Disparities Research

Studies that promote and advance evidence-based transformations in medical decision-making and health policy; demonstration projects that implement evidence-based, culturally sensitive intervention/disease prevention therapies and diagnostics; and activities designed to build capacity for health disparities research are of high priority. Examples of such studies include, but are not limited to:

1. Development of health disparity group-specific methodologies and diagnostics;
2. Development of technologies targeted for health disparity groups (i.e., gene chips, other novel assay systems, diagnostics, animal models, specialized instruments, etc.);
3. Demonstration projects that build capacity for health disparities research (e.g., regional hospital-based registries for disease areas of emphasis, etc.) or implement the translation/application of research results in a culturally sensitive manner; and
4. Innovative technologies that enable use of electronic health record (EHR) systems and personal health records (PHR) for health disparities research. Elements could include interoperability and mapping among disparate technologies and data sets for multi-site interdisciplinary studies, innovations to enhance and accelerate participant recruitment for clinical studies, and security systems to protect storage and transmission of confidential medical data.

Development of Innovative Software and Tools for Science and Health Education

Funding support is available for the development of educational software and the application of educational technology and tools to facilitate learning of science or health science topics that target K-12 students, families, students from community, tribal, undergraduate colleges and the general public, including health service providers. Topics can range from basic biological, behavioral, social and physical sciences to specific human diseases, disorders, and conditions. Examples include but are not limited to obesity, nutrition, regenerative medicine, bioengineering, and how different parts of the body work across the lifespan, healthy living and lifestyle, mental health, health services research, health promotion, and disease prevention. Development of software, technology, or tools may be directed towards new products or adaptation of existing products designed to be more efficient, more accessible, cost-effective, more

culturally appropriate, and user-friendly in promoting interactive learning, dissemination and promotion of health science to diverse populations. This effort is intended to yield efficient and user-friendly, culturally appropriate and effective educational units that can be extended to enhance the health science literacy of the general public or segments of the general public.

Examples of suitable topics include:

1. Web-based, stand-alone computational tools, instructional software or other interactive media for dissemination of science education;
2. Curriculum materials, Interactive teaching aids, models for classroom instruction, and teacher education workshops;
3. Development of health promotion and disease prevention/intervention materials such as informational videos and/or print materials and programs which are culturally appropriate for diverse populations and special communities;
4. Development and/or refinement of culturally appropriate survey instruments, tools and databases to promote community-based research engaging minorities, and rural and other medically underserved populations;
5. Development of methodologies, diagnostics, technologies, equipment, assay systems and portable devices that can be used in community settings, such as health centers, neighborhood clinics, doctors' offices, public schools, libraries, and rural and remote locations to facilitate biomedical and behavioral research;
6. Development of culturally appropriate educational materials for health promotion and disease prevention/intervention such as: software, videos, printed material to facilitate translation and dissemination of evidence-based health information; and
7. Innovative applications of health information technology, including telemedicine/telehealth tools and technologies, to facilitate electronic health information exchange, enable clinical research at the point of care, and improve access to quality health care for hard to reach populations.

For additional information about the areas of interest to the NIMHD, please visit our home page at http://www.nimhd.nih.gov/.

For additional information on research topics, contact:

Mr. Vincent A. Thomas, Jr., MSW, MPA
Program Manager
National Institute on Minority Health and Health Disparities, NIH
6707 Democracy Blvd.
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Bethesda, MD 20892-5465
301-402-2516, Fax: 301-480-4049
Email: vt5e@nih.gov

For administrative and business management questions, contract:

Ms. Priscilla Grant, J.D., C.R.A.
Grants Management Officer
National Institute on Minority Health and Health Disparities, NIH
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NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

The mission of NINDS is to reduce the burden of neurological disease—a burden borne by every age group, by every segment of society, by people all over the world. To this end, the Institute supports and conducts research on the healthy and diseased brain, spinal cord, and peripheral nerves. The NINDS SBIR/STTR program funds small business concerns to conduct innovative neuroscience research and/or development (R/R&D) that has both the potential for commercialization and public benefit. NINDS is committed to helping small business concerns commercialize their technologies through its grant funding, technical assistance program participation, and outreach at meetings. NINDS encourages all Phase II applicants to apply to the NIH Commercialization Assistance Program (CAP) to gain assistance in transferring their products to the marketplace. The CAP program is open to all Phase II grants that were active in the past five years. NINDS is increasingly tracking the progress of its funded small business concerns and the products they develop. Funding priority will be given to those small business concerns that show not only their ability to develop products but their growth as a small business concern towards independence from the SBIR/STTR program.

Limited Amount of Award

For budgetary, administrative, or programmatic reasons, NINDS may decrease the length of an award and/or the budget recommended by a review committee, or not fund an application. According to statutory guidelines, total funding support (direct costs, indirect costs, fee) normally may not exceed $150,000 for Phase I awards and $1,000,000 for Phase II awards. With appropriate justification from the applicant, Congress will allow awards to exceed these amounts by up to 50%. Applicants considering a requested budget greater than $225,000 for Phase I and $1,500,000 for Phase II (total funding support) are strongly encouraged to contact Stephanie Fertig (fertigs@ninds.nih.gov) before submitting an application.

NIH has received a waiver from SBA to exceed the hard cap for specific topics that can be found in APPENDIX A: National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations and only these specific topics can apply and receive awards over the hard cap. NINDS specific waiver topics are listed below. Generally, NINDS does not fund Phase I applications greater than $700,000 total funding support, with no more than $500,000 total cost in any year or project periods greater than 2 years. In addition, the NINDS does not generally fund Phase II applications greater than $3,000,000 total funding support, with no more than $1,500,000 total cost in any year, or project periods greater than 3 years. Again, applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

For all other funding opportunities, applications should follow the guidelines in the Award Budget section of those announcements carefully.

Phase IIB Competing Renewal Awards

NINDS only accepts Phase IIB SBIR/STTR Competing Renewal applications through specific opportunities that focus on the commercialization of SBIR and STTR developed technologies. These opportunities can be found on the NIH SBIR webpage: http://www.ninds.nih.gov/funding/small-business/small_business_funding_opportunities.htm. Contact Stephanie Fertig at 301-496-1779 or fertigs@ninds.nih.gov for additional information.

Research Topics of Interest to NINDS

General Areas of Interest

The NINDS accepts a broad range of small business applications that are significant, innovative, and relevant to its mission. Examples of research topics within the mission of NINDS are shown below. This list is not all inclusive and some research areas fall into multiple categories.

1. Therapeutics and Diagnostics Development for Neurological Disorders, including biomarker and diagnostic assays, therapeutics (drugs, biologics, and/or devices) for treatment of neurological disorders, and technologies/methodologies to deliver therapeutics to the nervous system.
2. Clinical and Rehabilitation Tools, including intraoperative technologies for neurosurgeons, rehabilitation devices and programs for neurological disorders, and brain monitoring systems
3. Technology and Tools, including technologies to image the nervous system, neural interfaces technologies, and tools for neuroscience research and drug development.

In addition to the research topics listed, NINDS also encourages applications in specific program areas. For additional information about NINDS funding opportunities, please visit our small business home page at: http://www.ninds.nih.gov/funding/small-business/.

Within the general areas of interest, the following specific topics fall under the SBA waiver and may require additional funds above the hard budget caps:

A. *In vivo* animal testing required for therapeutics and diagnostics development.

B. Drug and biologics preclinical discovery and development activities for regulatory submission, such as lead identification/optimization, preclinical efficacy testing, IND-enabling studies, and manufacturing for clinical trials.

C. Device preclinical discovery and development activities for regulatory submission, such as hardware prototyping, device/software verification, biocompatibility/sterilization testing, pre-clinical efficacy testing, large animal GLP safety testing, and preparing material/devices for human testing.

D. Clinical testing of therapeutics (drugs, devices, or biologics), diagnostics, clinical and rehabilitation tools (i.e. intraoperative technologies, rehabilitation devices and programs, and brain monitoring systems), and technologies for clinical research. This would include clinical research studies to test scientific hypothesis that are not feasible or practical to conduct in animal models but would inform a final device design.

E. *In vivo* animal testing of technologies for animal research and development of animal models for drug development and neuroscience research.

F. Research that requires special facilities to contain hazardous or infectious materials.

Clinical Trials

The NINDS is committed to identifying effective treatments for neurological disorders by supporting well-executed clinical trials. NINDS will not accept unsolicited SBIR/STTR applications that include clinical trials under the Omnibus solicitation. A clinical trial is a prospective biomedical or behavioral research study of human subjects designed to answer specific questions about safety, tolerability, efficacy and/or effectiveness of pharmacologic, behavioral, biologic, surgical, or device (invasive or non-invasive) interventions. NINDS accepts and supports SBIR and STTR clinical trial applications through specific opportunities, which can be found on the NINDS SBIR webpage: http://www.ninds.nih.gov/funding/small-business/small_business_funding_opportunities.htm. Other human subjects research, including the development of diagnostics or clinical research tools, can be submitted through the Omnibus solicitation and NINDS may decline funding of any application that includes human subjects for programmatic or administrative reasons. SBIR applicants considering projects involving human subjects research are

strongly encouraged to contact Stephanie Fertig or Joanne Odenkirchen (contact information provided below) well in advance of submission.

Joanne Odenkirchen, M.P.H.
Clinical Research Project Manager, Office of Clinical Research
301-496-3104
Email: jo21x@nih.gov

Countermeasures Against Chemical Threats

NINDS manages the NIH Countermeasures Against Chemical Threats (CounterACT) program. CounterACT supports research and development on new and improved therapeutics or diagnostic technologies to prevent or mitigate the toxic effects from exposure to chemical threats, defined as toxic chemical agents that could be used in a terrorist attack against civilians, or those that could be released at toxic levels by accident or natural disaster. This includes the development of new (or support of existing) partnerships between small business and not-for-profit laboratories engaged in this research. The scope of research supported includes early screening for compounds with the desired biological activity, advanced preclinical and efficacy testing, through clinical research with promising candidate therapeutics. For more information on this program, including specific program announcements, please see: www.ninds.nih.gov/counteract. Applicants are strongly encouraged to consult with Dr. David Jett to determine the programmatic relevance of their proposed research.

David A. Jett, Ph.D.
Program Director, NIH CounterACT Research
301-496-6035
Email: jettd@ninds.nih.gov

For additional information on research topics, contact:

Ms. Stephanie Fertig, M.B.A.
Research Project Manager, Small Business Programs
301-496-1779, Fax: 301-402-1501
Email: fertigs@ninds.nih.gov

For administrative and business management questions, contact:

Ms. Tijuanna Decoster
Chief, Grants Management Branch
301-496-9231, Fax: 301-402-4370
Email: decostert@mail.nih.gov

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

The National Institute of Nursing Research (NINR) supports research focused on biological and behavioral aspects of critical health problems that confront the Nation. Rapid advances in technology and genomic science, as well as significant changes in demographics and health care policies and practice, have placed pressing demands on nursing to find fresh approaches and interventions that improve health outcomes. Emphasis is on seeking ways to reduce the burden of illness and disability by understanding and easing the effects of acute and chronic illness, improving health-related quality of life by preventing or delaying the onset of disease or slowing its progression, establishing better approaches to promote health and prevent disease, and improving clinical environments by testing interventions that influence patient health outcomes and reduce costs and demand for care.

For additional information about areas of interest to the NINR, please visit our home page at http://www.ninr.nih.gov/, and also at http://www.ninr.nih.gov/researchandfunding.

Research and Development of Technologies for Health Promotion, and Alleviation, and Management of, or Adaptation to Symptoms

A. Technologies to be used in the hospital, long-term care, hospice, assisted living facility, or home setting that improve symptom diagnosis, evaluation and management in persons with chronic conditions.

B. Devices that improve the acceptance and use of assistive and monitoring devices.

C. Technologies to assist in health promotion and prevention activities across the lifespan.

D. Devices to assist in providing palliative care for patients with serious life-limiting illnesses through the disease trajectory whether in active treatment or at the end of life.

Research and Development of Technologies to Enhance Self Care and Clinical Care

A. Technologies to assist patients to adhere to medical regimens, including medical devices to enable providers and or research scientists to monitor successful adherence to complex medication regimens.

B. Devices that improve delivery of care to persons who have restricted or impaired movement.

C. Technologies that monitor short and long term self-management behavior changes.

D. Biological and behavioral monitoring devices for patients in at-risk and underserved populations in rural and frontier areas that will enhance access to clinical care.

E. Telehealth and mHealth technologies to improve patient outcomes through increasing quality, type, and speed of health information sharing.

F. Technologies to disseminate research information (i.e., biobehavioral responses, communication of risk, bioethics) to nurses practicing in emergency settings and in the community.

G. Develop and creatively apply new and existing knowledge to the implementation of health information technology, and access to and use of electronic health records.

Research and Development of Technologies for End-of-Life and Palliative Care

A. Web-based information and communication technologies for data collection on hospice and palliative care symptoms and need of care to improve the effectiveness and efficiency of patient report data and integration into appropriate hospice/palliative care

B. Use of Health Information technology for data collection, management and care integration across the spectrum of hospice and palliative care

C. Technologies (e.g., telecommunications) to provide support mechanisms of caregivers of hospice/palliative patients

D. IT implementation across the spectrum of palliative and hospice settings that highlight the potential of informatics to improve palliative and hospice care

E. Home-based tele health applications for individuals and family caregivers in palliative and hospice care

F. Technologies to enable healthcare providers at clinical sites to communicate with hospice and palliative care patients at their home---'virtual visit" technologies.

For additional information on research topics, contact:

Dr. Augie Diana
Program Director
National Institute of Nursing Research (NINR)
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NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

The mission of the National Center for Advancing Translational Sciences is to catalyze a generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions. NCATS is committed to supporting small business Phase I, Phase II, Fast-track and Phase IIB Competing Renewal awards through the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Programs (STTR). For additional information, please visit http://www.ncats.nih.gov.

Limited Amount of Award

For budgetary, administrative or programmatic reasons, NCATS may decide not to fund an application or may decrease the length of an award and/or the budget recommended by a review committee. Generally, NCATS will not fund:

- Phase I applications greater than $225,000 total costs or project periods greater than 2 years
- Phase II applications greater than $1,500,000 total costs or project periods greater than 3 years

For certain topical areas (Appendix A), the Small Business Administration has approved an NIH SBIR/STTR Topic Waiver list for which the NCATS generally will not fund:

- Phase I applications greater than $325,000 total costs or project periods greater than 2 years
- Phase II applications greater than $2,000,000 total costs or project periods greater than 3 years

Applicants considering a requested budget greater than these limits are strongly encouraged to contact program staff before submitting an application.

Phase IIB Competing Renewal Awards

Occasionally, NCATS may accept Phase IIB SBIR Competing Renewal grant applications of NCATS supported Phase II awards to continue research and development of products that have a potential to address bottlenecks in the translational process, and where additional time and effort is needed to reach a stage where interest and investment by third parties would be likely. Such products are expected to have broad applicability and be consistent with the mission of NCATS.

Topics of interest to NCATS– Grant Funding Opportunities

Areas of current interest of the NCATS SBIR and STTR programs include:

Drug Discovery and Development

- Small molecule and biologics analytical characterization
- Accelerate bioengineering approaches to the development and clinical application of biomedical materials, devices, therapeutics and/or diagnostics
- Technologies to determine alternative uses for existing therapeutic interventions
- Protein-protein interaction assays for high-throughput screening of rare disease related projects
- Tools and technologies to enable assaying of compound activity on currently “non-druggable” targets

- Innovative platforms for identification and prioritization of targets for therapeutic intervention with clear clinical impact
- Fluorescence probes to replace antibodies for determination of cellular protein translocation
- Co-crystallization high-throughput screening techniques
- Tools and technologies that increase the predictivity or efficiency of medicinal chemistry, biologic or other intervention optimization
- Use of continuous flow manufacturing technology to address therapeutics shortages
- Interventions that target molecular pathways or mechanisms common to multiple diseases
- Development of novel alternative biologics technologies (e.g., inhalation/transdermal technologies for biologics)
- Methodologies and technologies to substantially lower the cost of manufacturing biologics
- Development of novel technologies for enzyme replacement therapies (e.g., new cell culture/expression system) to solve a major bottleneck in rare disease research
- Development of non-AB biologics, cell-based therapies and gene therapy discovery amid technology development

Diagnostics and Devices

- Small autonomous devices for real-time detection of metabolites involved in metabolic and endocrine disorders
- Phenotypic assay development, including stem cell technology platforms for human “disease-in-a-dish” applications and the evaluation of toxicity
- Tools and technologies that increase the efficiency of human subjects research, including development of technologies that facilitate rapid diagnosis and/or clinical trial recruitment and subject tracking, IRB evaluation, and/or regulatory processes
- Development of patient-friendly devices able to measure metabolites in blood for the management of hyperammonemia and hyperaminoacidemias
- Development of high-throughput imaging technologies that focus on making translational research more efficient

Bioinformatics / Information Technology

- Searchable access to information about research resources, facilities, methods, cells, genetic tests, molecules, biologic reagents, animals, assays, technologies with links to their use in published research studies
- Tools for meaningful sharing of research data with low barrier for provision and user-friendly access
- Novel platforms, technologies and tools to enable clinical and translational research, particularly those with mechanisms for inclusion of patient-reported data
- Software development to provide integration of patient data collected from multiple devices and diverse clinical studies

- Development of personalized phenotypic profiling (as well as personalized intervention) based on patient-centered integration of data from multiple data sources, including social media

Clinical Research

- Increased efficiency of clinical research conduct including, but not limited to, regulatory decision support, appropriate study site selection, patient eligibility analysis, and recruitment tracking
- Educational tools for clinical and translational research
- Computational or Web-based health research methods including:
    - Platforms for generally applicable and scalable multi-disease registries and natural history studies
    - Clinical trial designs and analyses (e.g., for pragmatic clinical trials)

Clinical Trials

NCATS will not accept SBIR/STTR applications that include clinical trials under the current Omnibus solicitation. A clinical trial is a prospective biomedical or behavioral research study of human subjects designed to answer specific questions about safety, tolerability, efficacy and/or effectiveness of pharmacologic, behavioral, biologic, surgical, or device (invasive or non-invasive) interventions.

Other human subjects research may be submitted through the Omnibus solicitation and NCATS may decline funding of any application that includes human subjects for programmatic or administrative reasons. SBIR applicants considering projects involving human subjects research are strongly encouraged to contact Lili Portilla or NCATS Program staff.

For additional information on research topics, please contact:

Ms. Lili M. Portilla, MPA
Director of Strategic Alliances and SBIR Program Manager
Phone: 301-217-2589, Fax: 301-480-3661
Email: NCATS-SBIRSTTR@mail.nih.gov

For administrative, business management and grant policy questions, please contact:

Mr. Long T. Nguyen
Grants Management Officer
Phone: 301-402-6737, Fax: 301-480-3777
Email: nguyen1@mail.nih.gov

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH (NCCIH)

The mission of the National Center for Complementary and Integrative Health (NCCIH) is to define, through rigorous scientific investigation, the usefulness and safety of complementary and alternative medicine interventions and their roles in improving health and health care. For a detailed description of NCCIH mission, please see http://nccih.nih.gov/about/plans/2011/.

The following narrative indicates the scope of projects suitable for the SBIR/STTR program that fit within the mission of NCCIH. For additional information about areas of interest to NCCIH and a listing of NCCIH's currently funded applications, please visit http://www.nccih.nih.gov/research. Business concerns interested in exploring SBIR/STTR grant opportunities with NCCIH are encouraged to contact NCCIH Program Officers prior to submitting an application.

Topics of Interest to NCCIH

NCCIH encourages innovative technological research and development of commercializable CAM products that would fulfill the mission of NCCIH. The application may include basic, pre-clinical, and early phase clinical studies. The areas of interest to NCCIH include but are not limited to development and validation of:

- technology for standardization and characterization of biologically active ingredients in natural products;
- technologies for taxonomic identification of botanical raw materials or detection of adulterants;
- methods for standardization and characterization of active components of mind-body medicine interventions;
- tools for the analysis of polysaccharides and polyphenols;
- botanical or botanically derived products with useful therapeutic potential including symptom management;
- technologies for the identification and characterization of bioactive metabolites derived from oral consumption of natural products;
- methods for the sustainable production of low yield natural products of commercial interest;
- biomarkers which correlate with efficacy of CAM therapies;
- standardized, reliable and economical tools that correlate with brain imaging in response to CAM treatment;
- technical imaging tools or instruments for studying manual therapies;
- CAM-based tools for pain management;
- tools, technology and instruments, including gaming technology, for the accurate assessment of adherence and/or fidelity to the use of CAM practices, interventions, and products;
- tools to improve patient-reported outcome measures of CAM clinical investigations;
- tools to improve biological and physiological outcome measures of CAM clinical investigations;
- tools to promote adoption of healthy behaviors through the use of CAM interventions;

- tools to assess the effects of CAM on healthy behaviors.

Topics That Are of Less Interest to NCCIH

The NCCIH Office of Communications is responsible for disseminating CAM information to the public. Therefore applications addressing software development or educational materials and courses (including Continuing Medical Education courses or CD's) will not be considered relevant to the NCCIH SBIR/STTR program. Also not eligible for support are applications seeking to develop cookbooks for special diets or instructional materials for clinical practice. NCCIH does not fund clinical practice other than as a component of funded clinical research.

Although applications to support the development of databases are not widely encouraged, these proposals will be considered if they are limited to aiding the taxonomic and phytochemical characterization of medicinal plants/fungi. Applicants are encouraged to contact the appropriate NCCIH Program Officer before submitting any SBIR proposals related to database development.

Other Research Topic(s) Within the Mission of the Center

For additional information on research topics, please contact:

Dr. John Williamson
Program Officer & Branch Chief
6707 Democracy Blvd.
Suite 401, MSC 5475
Bethesda, MD 20892-5475
301-496-2583, Fax: 301-480-1587
Email: williamsonjs@mail.nih.gov

For administrative, business management, and grant policy questions, please contact:

Ms. Shelley Carow
Grants Management Officer
6707 Democracy Blvd.
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NATIONAL LIBRARY OF MEDICINE (NLM)

The National Library of Medicine (NLM) offers support for research and development projects in biomedical informatics. NLM defines biomedical informatics as the science of optimal organization, management, presentation and utilization of information relevant to medicine and biology. The informatics projects of interest to NLM involve the application of computer and information sciences to information problems in a biomedical domain. For additional information about areas of interest to NLM and a listing of NLM funded applications, please visit http://www.nlm.nih.gov/ep. Business concerns interested in exploring SBIR/STTR grant opportunities with NLM are encouraged to contact the NLM representatives prior to submitting an application.

NLM's SBIR/STTR grant programs are focused on areas of particular interest from small business. The following narrative indicates the scope of projects suitable for the SBIR/STTR program that fit within the mission of NLM. They are not listed in priority order.

- New Technologies that facilitate utilization of electronic health records systems in clinical practice and public health
- Explore the use of social media to track disease outbreaks, pandemics, or assist patients in chronic disease management
- Tools for exploring climate and environmental effects on human health
- Tools and systems for applying research data to clinical problems
- Tools for disaster information management
- Tools and approaches for integrating large heterogeneous data sets

Other Research Topic(s) Within the Mission of the Center

For additional information on research topics, contact:

Dr. Jane Ye
Program Officer
Division of Extramural Programs
National Library of Medicine
301-594-4882, Fax: 301-402-2952
Email: yej@mail.nih.gov

For administrative and business management questions, contact:

Mr. Dwight Mowery
Grants Management Officer
Extramural Programs Division
National Library of Medicine
301-496-4221, Fax: 301-402-0421
Email: moweryd@mail.nih.gov

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI), OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS (ORIP)

ORIP supports high-quality, disease-free animal models and specialized animal research facilities to help meet the needs of biomedical researchers to understand, detect, treat, and prevent a wide range of human diseases. This support enables discoveries at molecular, cellular, and organ levels that lead to animal-based studies which then are translated to patient-oriented clinical research, aiming to find treatments to cure or ameliorate common and rare diseases. Through the small business Phase I, Phase II, Fast-track and Competing Renewal awards, ORIP is especially interested in funding research to develop biomedical methods and technologies that improve animal models of human diseases, and the care, use, and management of laboratory animals. ORIP also encourage the development and implementation of technologies to directly benefit the welfare of research animals and to directly improve animal facilities that support biomedical and behavioral research.

A list of some potential ORIP program topics follows the description of our Phase IIB Competing Renewal Awards. For additional information, please visit our home page at http://dpcpsi.nih.gov/orip/index.

Phase IIB Competing Renewal Awards

ORIP will accept Phase IIB SBIR Competing Renewal grant applications to continue research and development of methods, tools and devices for basic or translational research where extraordinary time and effort is needed for completion of these projects. The Phase IIB Competing Renewal award is intended to allow small businesses the opportunity to reach a stage where interest and investment by third parties would be more likely. Such products are expected to have broad applicability, consistent with the mission of ORIP. Budgets that do not exceed $1 M per year in total costs (for up to 3 years), may be requested for this Phase IIB Competing Renewal opportunity; although it is expected that, in most cases, the requested budget would not exceed the final year budget of the applicant's previous Phase II award. This opportunity is available for the SBIR program only.

Please contact your Program Officer before beginning the process of preparing a Phase IIB Competing Renewal application. In addition, prospective applicants are strongly encouraged to submit to the Program Contact (listed after each section), a letter of intent that includes the following information:

- Descriptive title of the proposed research
- Name, address, and telephone number of the Principal Investigator
- Names of other Key Personnel
- Participating organizations
- Funding Opportunity Announcement Number (e.g., PA-12-XXX)

A letter of intent is not required, is not binding, and does not enter into the review of a subsequent application. It is expected that only a few of ORIP SBIR Phase II awards will be eligible for a Phase IIB Competing Renewal grant.

Research Topics of Interest to ORIP

RESEARCH AND DEVELOPMENT IN COMPARATIVE MEDICINE

A. Development of improved reagents and cost-effective methods to accurately screen and diagnose selected diseases of laboratory animal, and to perform overall assessments of animal quality and health status. An urgent need currently exists for the development of improved methods for detection of active tuberculosis in nonhuman primates.

B. Development of improved reagents and techniques to isolate and propagate embryonic and somatic stem cells from laboratory animals. Improvement of the *in vitro* and *in vivo* methods to efficiently generate induced pluripotent stem cells and to reprogram the differentiated cells to other lineages.

C. Development of technology to identify molecular phenotype of a single stem cell or induced pluripotent stem cell from laboratory animals.

D. Development of improved reagents, techniques, and equipment for genomic and transcriptomic analysis and data-mining from tissue or cells of laboratory animals and animal models of human diseases.

E. Development of new technologies to rapidly phenotype large number of animals.

F. Development of technologies to identify biomarkers for clinical diagnostics in well validated disease models.

G. Development of vaccines and new therapeutic agents to prevent and/or control selected laboratory animal diseases. One high priority need is to develop methods to control and prevent Herpes virus B in nonhuman primates.

H. Identification, development, and characterization of spontaneous and engineered vertebrate animal models for studies of various human diseases, excluding most random mutagenesis projects performed on rodents. Applications primarily focused on cancer should typically be directed to NCI. A need exists for a small animal model of Hepatitis C virus infection in humans. Methods to produce genetically engineered mice susceptible to HCV replication, without the requirement for individual colonization with transplanted organs or cells in each experimental subject, are encouraged.

I. Identification, development, and characterization vertebrate animal models for studies of various human diseases and for use in training.

J. Development and refinement of high throughput technologies and devices for the cryopreservation, long-term maintenance, and monitoring of stem cells, biological samples and laboratory animal embryos, gametes, and their predecessors.

K. Development of technologies for improved embryo transfer within a single animal species or of intraspecific embryo transfer to allow preservation of rare, unique, or endangered animal species that may have unique value as animal models for human disease.

L. Development of improved reagents, techniques, and equipment to perform, analyze, capture and process data gathered in “omics” studies (genomics, transcriptomics, phenomics, proteomics, glycomics, epigenomics, metabolomics) in normal and disease-condition animal models.

M. Development of biological tools and reagents for reconstruction, remodeling, repair and regeneration of tissues damaged by injury or disease. Development of the technologies and procedures to test efficacy and safety of these experiments in animal models. Approaches to detect and track the implanted cells and tissues *in vivo*.

N. Development of new technologies in animal/cell models to study the function (activation/silencing) of noncoding DNA or RNA regions in the development of diseases.

O. Development of *in vitro* animal cell culture techniques and computational methods to reduce the number of animals used in studies and replace certain tests conducted in animal models with new complementary methods.

P. Development of acellular biomaterials, biosensors and reagents to promote, detect and track reconstruction, remodeling, repair and regeneration of tissues damaged by injury or disease.

Q. Development of reagents, including antibodies, that will facilitate research using zebrafish or xenopus as animal models of disease or for understanding basic aspects of development, physiology, or genetics.

R. Development of reagents and biological tools to characterize naturally occurring disease conditions in cats and dogs that can inform or be used for the assessment of parallel disease states in human.

S. Development of rapid and sensitive technology for the accurate detection and diagnosis of polymicrobial infections in biomedical laboratory animal models, including those agents involved in vertical transmission of diseases into embryos and larvae.

T. Technologies for improved sex determination of embryos, neonatal, and juvenile stages of animals, with one high priority need being nonmammalian species.

Miguel Contreras, Ph.D.
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RESEARCH AND DEVELOPMENT IN SCIENCE EDUCATION

Development of Innovative and Inquiry-Oriented Software and Gaming Resources for Science and Health Education

Funding opportunities are available for the development of discovery-oriented educational software, Serious STEM Gaming and the application of educational technology and tools for health science topics that target pre-kindergarten to grade 12 (P-12) students, teachers and families, and the general public, particularly those from underserved communities. Topics can range from basic biological science to specific human diseases. Examples include; but are not limited to diet and exercise, infectious disease, bioengineering, the clinical trials process, how different parts of the body work across the lifespan, healthy living and lifestyle, mental health, and prevention of obesity, heart disease, diabetes, and other chronic diseases. Development of software, gaming technology, or other educational tools may be directed towards new products or adaptation of existing products designed to be more efficient, cost-effective, and user-friendly in promoting problem solving, interactive learning, dissemination and promotion of health science. This effort is intended to yield efficient and user-friendly, culturally appropriate and effective educational resources that can be extended to enhance the health science literacy and the health of the general public. A rigorous evaluation plan and broad dissemination are strongly encouraged.

Examples of responsive applications may include but are not limited to:

A. Web-based, stand-alone computational tools, instructional software or other interactive media for dissemination of science education;

B. Curriculum materials, interactive teaching aids, models for classroom instruction, and teacher education workshops;

C. Serious Science, Technology, Engineering and Mathematics (STEM) gaming resources;

D. Development of health promotion and disease prevention/intervention materials such as informational videos and/or print materials and programs which are culturally appropriate for populations and special communities.

Projects that target the following constituencies are strongly encouraged:

E. P-12 students, teachers and parents;

F. Students of community colleges, tribal colleges, undergraduate colleges and minority-serving institutions;

G. Patients and families with health conditions that disproportionately affect minorities and other medically underserved populations, including members of disadvantaged urban and rural communities.

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OTHER RESEARCH TOPIC(S) WITHIN THE MISSION OF THE OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS

The Science Education Partnership Award (SEPA) program, http://nihsepa.org/, supports and fosters health-related research and development projects designed to promote research career capacity at minority serving institutions and in underserved communities. These programs support a wide variety of medical research, including workforce development tools to reduce health disparities experienced by disadvantaged groups and medically underserved populations. Applications involving partnerships with Research Centers in Minority Institutions (RCMI) Program Institutional Development Awards (IDeA)-eligible institutions are strongly encouraged as are collaborative projects with Clinical and Translational Science Award (CTSA) institutions. Topics of special interest include:

A. Development and/or refinement of culturally appropriate survey instruments, tools and databases to promote community based research engaging minorities, rural and other medically underserved populations;

B. Development of methodologies, diagnostics, technologies, equipment, assay systems and portable devices that can be used in community settings, such as health centers, neighborhood clinics, doctor offices, public schools, libraries, and rural and remote locations to facilitate biomedical and behavioral research;

C. Development of culturally appropriate educational materials for student, teacher and community health literacy and disease prevention/intervention such as: software, videos, printed material to facilitate translation and dissemination of evidence-based health information; and

D. Innovative applications of health information technology, including telemedicine/telehealth tools and technologies, to facilitate electronic health information exchange, enable clinical research at the point of care, and improve access to quality health care for hard to reach populations.

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RESEARCH AND IMPROVEMENT IN ANIMAL WELFARE AND ANIMAL FACILITIES

The Division of Construction and Instruments supports the development and implementation of technologies to directly benefit the welfare of research animals and to directly improve animal facilities that support biomedical and behavioral research. In particular, the areas being supported include research on tools and equipment, their use to improve and ease care, and to facilitate monitoring of healthy animals. Another area of interest encompasses research to improve laboratory equipment to maintain the environmental conditions and to upkeep the infrastructure of animal facilities. Of special importance is the employment of green technologies. Examples of topics of special interest include (but are not limited to) research leading to the development of better, more reliable, and more efficient:

A. Equipment such as vacuum cleaners, air filters, hoods, snorkels, autoclaves for animal research facilities, for barrier facilities, and other facilities with special needs and requirements;

B. Equipment to distribute water and food, and monitor their intake by research animals;

C. Equipment to increase the quality of life and prevent injuries of research animals and research staff and investigators;

D. Equipment to monitor and protect the well-being of animals;

E. Equipment and its use for maintenance of disease-free colonies and healthy animals;

F. Equipment to disinfect devices, furnishings, and other apparatus in animal facilities such as aquaria, cages, tunnels, and racks;

G. Cost-effective husbandry and colony management techniques, equipment, and/or new approaches to improve laboratory animal welfare and assure efficient and appropriate research use;

H. Specialized equipment and caging for laboratory animals to permit optimal environmental control and operational efficiency, including improvements in caging and remote monitoring in animal facilities.

Research for the development of equipment and protocols for specific research needs is not within the scope of the ORIP mission.

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CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

CDC will accept SBIR grant applications on the September 5, 2015, January 5, 2016 and April 5, 2016 submission dates.

CDC's Mission: CDC works 24/7 to protect America from health, safety and security threats, both foreign and in the U.S. Whether diseases start at home or abroad, are chronic or acute, curable or preventable, human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same.

CDC increases the health security of our nation. As the nation's health protection agency, CDC saves lives and protects people from health threats. To accomplish our mission, CDC conducts critical science and provides health information that protects our nation against expensive and dangerous health threats, and responds when these arise.

CDC Role:

Taking the health pulse of our nation
Detecting and responding to new and emerging health threats
Tackling the biggest health problems causing death and disability for Americans
Putting science and advanced technology into action to prevent disease
Promoting healthy and safe behaviors, communities and environment
Developing leaders and training the public health workforce, including disease detectives

Those functions are the backbone of CDC's mission. Each of CDC's component organizations undertakes these activities in conducting its specific programs. The steps needed to accomplish this mission are also based on scientific excellence, requiring well-trained public health practitioners and leaders dedicated to high standards of quality and ethical practice.

To keep pace with emerging public health challenges and to address the leading causes of death and disability, the CDC has begun an effort to quickly achieve measurable impact in a few targeted areas. The term "Winnable Battles" describes public health priorities with large-scale impact on health and with known, effective strategies to intervene. The charge under Winnable Battles is to identify optimal strategies and to rally resources and partnerships to accelerate a measurable impact on health.

CDC has identified these winnable battles based on the scope of the burden and our ability to make significant progress in improving outcomes. These priority areas include:

- Food Safety – Foodborne diseases affect millions of people and kill thousands in the U.S. each year.
- Global Immunization – CDC is implementing global immunization programs to eradicate polio, prevent measles and rubella, end the meningitis epidemic in Africa, accelerate the introduction of pneumococcal and rotavirus vaccines, and strengthen countries' own immunization systems.
- Healthcare-associated Infections – HAIs affect patient lives and add to our growing healthcare costs.
- HIV in the U.S. – There are more than 1 million people living with HIV in the U.S.
- Lymphatic Filariasis in the Americas – CDC and its partners are working to eliminate lymphatic filariasis (LF) from the areas of the Americas where the disease still exists.

- Mother-to-Child Transmission of HIV and Syphilis Globally – CDC works with Ministries of Health and other partners to prevent HIV and syphilis from passing from mothers to babies, thus reducing the number of babies who suffer early death and/or chronic illness caused by these infections.
- Motor Vehicle Injuries – Motor vehicle-related injuries are the leading cause of death in the first three decades of life.
- Nutrition, Physical Activity, and Obesity – Excess weight contributes to many of the leading causes of death in the United States, including heart disease, stroke, diabetes, and some types of cancer.
- Teen Pregnancy – In 2009, the number of births to teenage mothers was 409,840 – a birth rate of 39.1 per 1,000 women aged 15 to 19.
- Tobacco – Tobacco use remains the leading preventable cause of disease and death in the United States.

By identifying priority strategies and clear targets and by working closely with our public health partners, we can make significant progress in reducing health disparities and the overall health burden from these diseases and conditions.

In addition to the topics listed below by CDC Center, CDC encourages investigator-initiated applications that focus on support for **Ebola Safety and Response** with a focus on virus transmission, disease prevention and control, public health preparedness, and vaccine development. The 2014 Ebola response is the largest international outbreak response in CDC's history. Progress has been made in the year since CDC first responded to the Ebola outbreak in West Africa, but CDC's and the world's efforts must continue with a goal of getting to zero new cases and, just as important, keeping them at zero. CDC is currently involved in multiple ground-breaking activities, such as research on safe, more comfortable personal protective equipment; whole genome sequencing and analysis; monitoring for mutation patterns or changes in virus transmission; and supporting field trials to help identify a safe and effective vaccine for Ebola. To learn more about Ebola and CDC's efforts, visit http://www.cdc.gov/vhf/ebola/.

For additional information about CDC, please visit our home page at http://www.cdc.gov.

Questions of a general nature about the CDC SBIR program should be directed to:

Sean David Griffiths, MPH
Science Policy Advisor, Office of Science Quality
Office of the Associate Director for Science
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop D-72
Atlanta, GA 30329
404-639-4641; Fax: 404-639-4903
Email: SGriffiths@cdc.gov

or

Diana Bartlett, MPH, MPP
Health Scientist, Office of Technology and Innovation
Office of the Associate Director for Science, Office of the Director
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop D-72
Atlanta, GA 30329
404-639-4938; Fax: 404-639-4903

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CENTER FOR SURVEILLANCE, EPIDEMIOLOGY AND LABORATORY SERVICES (CSELS)

Please visit their web site at: http://www.cdc.gov/ophss/csels/ .

Helping Patients to Understand Laboratory Test Results

Background: In February of 2014, HHS issued the final rule of the Direct Access Rule. The rule allows patients or their representative's direct access to laboratory test reports after having their identities verified, without the need to have the tests sent to a health practitioner first. This rule is intended to empower the patient, to allow the patient to act as a partner with their healthcare provider and take a more active role in their healthcare decisions. Having ready access to test results, however, places the patient in a position of greater responsibility. They may encounter complex test results on laboratory reports and will need to recognize that there is a context in which providers use results to make treatment decisions. This may require that the patient educate themselves about their test results in order to understand their purpose and meaning.

The Winnable Battle Campaign initiated by the Centers for Disease Control and Prevention (CDC) was designed to create strategies to accelerate measurable impact on health outcomes. One focus area of the Winnable Battle Campaign identified by the CDC is nutrition, physical activity, and obesity. Two efforts under this initiative are the Million Hearts Campaign and the Control of Diabetes. Tracking laboratory test results for cholesterol and blood sugar may help the patient understand how to manage these conditions. Efforts that add support for evidence-based, cost-effective strategies that can be implemented now, will have a significant impact on our nation's health. In recent years, mobile phones have become an increasingly important platform for the delivery of health interventions. Smartphones are useful for accessing health data (specifically lab testing data) because of people's tendency to carry their phones with them everywhere. A study found that in 2006 individuals were within arm's reach of their phones on average 58% of the time (Patel et al). The fact that smartphones are in close proximity with the owner, this allows for the potential to increase laboratory test report literacy.

Specific Research Areas of Interest: CDC's Division of Laboratory, Programs, Standards, and Services is highly interested in the dissemination and evaluation of laboratory education targeted specifically from the perspective of the patient. Since patients now have the capability of accessing their test results directly from the laboratory, comprehension of these results may require additional information. Advancement of real-time technologies that assist with understanding live test results can have a major impact in fostering the bond between patient and healthcare provider. Developing an application that will help the patient comprehend laboratory test results by adding a knowledge base component to an existing provider and/or laboratory application portal is a step in the right direction. The CDC Community Health Improvement (CHI) Navigator may be used as a model for application retrieval of health information for users seeking health interventions. CHI Navigator is designed to provide support for the advancement of healthcare by encouraging collaborations with not only hospitals but housing authorities, primary care practices, and community health services. One feature not yet offered through CHI navigator is the ability for patients to obtain their laboratory results via any testing facility. Having the capability to import one's own test results regardless of the laboratory is a real need.

The goal of this project's aim is to address the concept of using person-centered smartphone technology to support patient engagement via patient literacy. Our end result is an educational application or application extension that will be value added to all other laboratory testing and healthcare apps that are already in existence. The applicant will design and develop an information portal that will allow for the comprehension of laboratory test results on a mobile device, ultimately enabling increased patient understanding. Conceptually, the application would be assessable from both the patient-user and healthcare provider perspectives.

Impact and Commercialization Potential: Patients having the ability to obtain copies of their medical test results directly from the testing facility come with the potential of having an education gap. For this reason, it is logical to assume that many patients would still prefer to receive their test results from their healthcare practitioner. However, individuals interested in learning and becoming more aware of their health could benefit from having an application that is designed to facilitate understanding of test results by querying relational databases that houses information on laboratory test results and their interpretation. A web/mobile app portal that provides information to help the patient understand their laboratory test results has vast commercial potential. With ready access to laboratory test reports, it's expected that there will be an education gap and this projects aims to alleviate that. The use of this application could be used as a wrapper tool (an add-on to a pre-existing application) with potential to link to the laboratory portal for delivery of test results, the provider portal for sharing of information that impact's the patient's health or the patient's portal. The developer of this web/mobile app portal could sell to healthcare organizations and health laboratories to be used on their portal.

Visit the CSELS homepage for more information on CSEL's research program areas
http://www.cdc.gov/ophss/csels/

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NATIONAL CENTER FOR HEALTH STATISTICS (NCHS)

For additional information about NCHS, please visit their web site at: http://www.cdc.gov/nchs/.

Developing and testing biomarker/physical health measures for survey use

Background: Surveys are increasing including biologic and physiologic measures to complement the self-reported measures traditionally found in survey research. Many of the current technologies need to be administered by trained medical professionals and used in medical office or laboratory settings. The specimens that are obtained can require special handling with time constraints on storage and delivery. In the typical household survey, the collection of biological or physiological data would be conducted by a trained interviewer who would not have a medical background or even by the survey participant him or herself. Improved and simplified techniques can enhance collected data and provide cost savings over some of the techniques currently available. Non-invasive in-home measurement devices are needed for a

wide range of biologic and physical markers such as cortisol, electrolytes, cotinine, blood pressure, vision and hearing, as well as a variety of others. The ability to collect biological and physiological data would wide greatly expand the usefulness of the self-report data in the surveys. While some technologies may currently be available, they need testing within a survey environment and the reliability and validity determined. NCHS is interested in projects that would develop and/or test techniques for collecting biologic and physiologic data in the context of household surveys.

Specific Research Areas of Interest:

Examples of projects appropriate for support include:

1) The development and refinement of innovative techniques for measurement of biomarkers in survey research conducted in households or other non-clinical settings including the collection of biological specimens such as urine or blood, measuring heart rate, or measuring senses;
2) The development of kits for collecting biomarkers that can be used in survey research conducted in households or other non-clinical settings;
3) The validation of biomarkers collected via nontraditional measures, such as filter paper and saliva, with those collected using traditional measurement techniques;
4) The use of wearable technologies to record physiologic measures;
5) The development of scanning devices to scan labels on prescription and/or over-the-counter drugs;
6) The adaptation of current technologies for use in surveys, such as glucose testing without blood, retinal imaging, sweat sensors, etc.

Impact and Commercialization Potential: The technologies developed could be used not only for NCHS/CDC surveys but across a wide range of surveys sponsored by NIH, SAMHSA, USAID and other government agencies and foundations. When determined to be reliable and valid, they could be used as a lower cost alternative in clinic-based studies. They could be invaluable in international in data collection efforts where medical professionals are unavailable and storage and transportation of specimens are challenging. Some technologies may be developed for use by individuals who would like to monitor their own health in-home.

Visit the NCHS homepage for more information on NCHS's research program areas
http://www.cdc.gov/nchs

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NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL (NCIPC)

For additional information about NCIPC, please visit their web site at: http://www.cdc.gov/injury/index.html. Only applications that address the topics below will be considered for funding by NCIPC.

Technological Innovations to Reduce Prescription Drug Overdose

Background: Overdose from opioid pain relievers is a growing public health concern. In 2011, there were 16,000 opioid-related overdose deaths nationwide. In 2010, for every one overdose death, there were approximately 26 emergency department visits for misuse or abuse. Although the cause of death from prescription opioids is a complicated picture, overdose deaths can be linked to prescriptions from medical providers. Patients who overdose from opioid pain relievers disproportionately have a history of high dose prescriptions and prescriptions obtained from multiple providers. It is important that providers and pharmacists have the tools available to assist them in prescribing and dispensing controlled substances so that overdose of opioids is reduced while safe and effective pain treatment is provided. A large proportion of opioids are prescribed by primary care physicians who are not often trained in appropriate pain management; these providers need technological tools that can improve decision making about opioid prescribing and dosing. Pharmacists, nurses, and others working with in the ambulatory care setting could also benefit from technological tools that improve opioid prescribing. Computerized clinical decision support systems and electronic health record advancements that assist providers with the critical aspects of prescribing can help improve clinical care and patient health outcomes, and reduce the risk of overdose.

Specific Research Areas of Interest: The goals of this project include developing innovative technology that will facilitate healthcare providers' prescribing of opioid pain relievers; in particular, prescribing the appropriate dose. For example, a tool embedded within the electronic health record (EHR) could assist providers, such as primary care physicians (who are responsible for the greatest number of opioid prescriptions) in entering the type of opioid pain reliever(s) (e.g., Codeine, Fentanyl, Hydrocodone, Methadone), strength, and quantity prescribed to a patient, and calculating the total daily morphine milligram equivalents (MME). This calculator could also assist providers when transitioning a patient from one opioid to another, modifying drug duration regimens, or titration (raising or lowering drug strength). In this way, a provider could better ensure that the patient is being prescribed a safe dose. Such technology enhancements would call special attention to a patient's overdose risk, and improve quality of care. Limited technology currently exists, such as the New York City Morphine Milligram Equivalent calculator; however, this calculator is available online and is not integrated easily into provider systems and available at the point of care (e.g., within the electronic health record). Similarly, expansion of computerized clinical decision support tools within physician and community pharmacy dispensing software could allow for safer medication use and decrease over-prescribing. Upon entering a prescription into the pharmacy information system, a program can generate an automated query of the Prescription Monitoring Program or encourage a pharmacist to check before dispensing opioids. This prompt is activated when certain measures of risk arise (overlapping benzodiazepines, barbiturates, etc., history of psychotropic prescriptions, or elevated MME dose) and provides recommendations for communicating directly with the prescribing provider or counseling patients about proper use, storage, and disposal of controlled substances.

Impact and Commercialization Potential: Research on the prescription drug overdose epidemic has shown a connection between inappropriate opioid prescribing and increases in opioid misuse, abuse, and overdose. Addressing this driver of the epidemic is a priority for CDC. With the progress of health information technology, such as meaningful use of electronic health records and development of interoperable systems frameworks, market conditions are currently favorable for the development of technology that could be embedded within EHR or dispensing systems.

Innovations in Electronic Health Record (EHR) Systems to Share Injury-related Data

Background: Unintentional injury is a leading cause of preventable death, occurring from events such as car crashes, drug overdoses, and falls. In 2010, almost 121,000 people died from unintentional injuries in the US, and 1 in 10 people experienced a nonfatal unintentional injury serious enough to require an emergency department visit. Healthcare providers can help prevent, treat, and manage injury through provision of clinical preventive services and referral to community programs for supportive assistance. The electronic health record (EHR) is a tool that can support physicians in providing these clinical services (e.g., through clinical decision support), as well as through private sharing of health information (e.g., providing patients with a copy of their health information, exchanging clinical information with other providers, and providing patient-specific education resources).

Prevention efforts could be enhanced if secure information sharing capabilities were expanded, allowing data to be provided electronically to the EHR by users other than the physician about injury-related events (for example by community-based programs or schools that the patient is enrolled in). For example, if an older adult was referred by a clinician to a community-based exercise program to improve strength and balance and reduce fall risk, and the program could submit attendance records to the EHR, the clinician could better monitor patient adherence and assess future fall risk. If a child in a high school sports game suffered a concussion and was removed from play, and the school could submit information about the “return-to-play” and “return-to-learn” protocols as well as observed and reported symptoms to the EHR, the clinician could better diagnose and manage the traumatic brain injury. The current method often requires health care professionals to manually enter information that is provided by school or community partners into the EHR. This is time consuming and does not allow for rapid or efficient data access. There needs to be a fast and secure method to transfer data from the field back to any EHR (without having to build a direct interface for each EHR). Sharing of data in this way would allow greater collaboration and communication between providers, patients, and community organizations invested in patient health. Clinical care could be enhanced, improving patients’ health outcomes. Such data sharing could also enrich the data available in the EHR for research purposes to allow for more in depth evaluation of public health injury prevention efforts that interface with clinical medicine.

Specific Research Areas of Interest: The goals of this project include developing an innovative product or tool or platform architecture that will facilitate secure data sharing between providers, patients, and organizations in the community within the EHR. This would include the development of a product or tool or platform architecture that enables injury-related data to be sent directly to the EHR. Given the variation in EHR systems developed by multiple vendors, the product structure and protocol would need to allow users to securely send data to <u>any</u> certified EHR. The tool would enable use by patients, health care providers, school personnel, and community organizations to securely send structured data (e.g., concussion information, injury prevention program compliance information) to a single source for decision making. The structure and protocol should also attend to the type of information that would be useful for research purposes in evaluating injury prevention activities within healthcare systems. For optimal use and impact, communication and data transfer would be two- way (i.e., from schools or community organizations to the EHR and back); however, dual transfer would necessitate appropriate data sharing protocols and more complicated privacy and security protections to ensure compliance with required privacy protections.

Impact and Commercialization Potential: Innovation in health information technology has great potential for enhancing integration of injury prevention within health systems. Enhancing the degree to which injury risk factors are assessed and prevention strategies are coordinated through health information technology can increase the public health impact of injury prevention practice. With the progress of meaningful use requirements and development of interoperable systems frameworks, market conditions are currently favorable for the development of modules that can easily interface with EHR technology.

Developing a Fall Detection System for Older Adults

Background: Among older adults, falls and their associated injuries are a growing public health concern—responsible for over 20,000 deaths and 2.3 million emergency department visits nationwide, and costing over $30 billion annually. Older adults who fall often restrict their activities and social contacts, which can impair their quality of life. Technological systems have been developed to broadcast an alert when an older adult falls – discriminating between a fall event and the normal activities of living. Systems can use environmental sensors (e.g., cameras, floor sensors) and/or wearable devices (e.g., accelerometers with electronic sensors on clothing). Using such systems can increase older adults' confidence and independence. There are opportunities to advance technologies by integrating sensors into commonly used devices such as smartphones, and by enhancing detection algorithms. Such refinements could increase the performance, usability, and acceptance of these devices, as well as provide better real-time data about fall events.

Specific Research Areas of Interest: The goals of this project include developing or enhancing innovative assistive technology that can facilitate detecting older adult falls. The technology must advance previous applications by integrating the technology into devices used routinely (e.g., smartphones; wearable technology such as health and fitness monitoring devices), enhancing the fall detection algorithm, or facilitating integration with electronic health records (e.g., communicate fall events to the health provider through the electronic medical record system). Developers must include older adults in the development process and also include procedures for protecting older adults' privacy. The technology should be amenable to testing with older adults in realistic settings and for extended time periods to evaluate real-world applicability. Consideration must be paid to reducing the number of false alarms as well as inappropriate alerts, so as to increase the likelihood of adoption in geriatric practice (e.g., by encouraging patient use).

Impact and Commercialization Potential*:* Preventing fall-related injuries and deaths among older adults is a CDC Injury Center priority and growth area. Research on technology can that enhance the identification of falls in older adults and provide critical information to healthcare providers could enhance providers' ability to assess, treat, and refer older adults to appropriate community-based services and reduce the health burden of falls. With the popularity of smartphone applications and wearable devices that provide real-time health feedback to users, as well as a new focus on transmitting health information to providers for improved decision making at the point of care, market conditions are currently favorable for the development of fall detection system prototypes.

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NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH (NIOSH)

For additional information about NIOSH, please visit their web site at:
http://www.cdc.gov/niosh/programs.

HIGH RISK INDUSTRIAL SECTORS IN NIOSH

Exposure assessment, engineering controls, and personal protective technologies (PPT) are needed to manage exposures to occupational hazards in high risk industrial sectors. These include manufacturing, services, mining, agriculture and construction sectors. Workers in the manufacturing sector, comprising an estimated 14 million paid workers in 2005, face risks that include machinery, repetitive motion, over-exertion, chemicals, nanomaterials, noise and shift work. In the services sector, work environments vary widely and these varied, and often uncontrolled, environments may put the estimated more than 65 million workers at risk of workplace injury, illness and death. The mining sector, comprised of over 300,000 paid workers in 2005 (not counting those in the oil and gas extraction sub-sector), face risks that include noise-induced hearing loss, falling materials, explosions, fires, powered haulage, overexertion, electrical equipment, and exposure to particulates and dusts including diesel emissions, coal dust and silica dust. Agriculture ranks among the most hazardous industries. Farmers are at high risk for fatal and nonfatal injuries, work-related lung diseases, noise-induced hearing loss, skin diseases, and certain cancers associated with chemical use and prolonged sun exposure. Farming is one of the few industries in which the families (who often share the work and live on the premises) are also at risk for injuries, illness, and death. Each day, construction workers face injury hazards from falls, machines, electricity, motor vehicles, and other equipment and circumstances. Health hazards posed by construction work can include dusts, fumes, noise, and chemicals. Research is needed to develop control strategies, PPT, exposure assessment methods and interventions to reduce motor vehicle injuries and deaths in all these high risk industrial sectors.

The following research areas are of particular interest to NIOSH:

Control Technology and Personal Protective Equipment for High Risk Occupations

Background: Personal protective equipment (PPE) protects workers from death and disabling injuries and illnesses as well as from the specific threats of exposures to certain airborne biological particles, chemical agents, nanomaterials, splashes, noise exposures, fall hazards, head hazards, and fires. It is estimated that 20 million workers use PPE on a regular basis to protect them from job hazards and a total of 135,000 workers potentially could benefit from the use of PPE (Worker Health Chartbook 2004). Engineering controls include substitution of a safe material for a hazardous one, design changes to equipment, or modification of work methods to eliminate or reduce hazards. Research is needed to develop and evaluate control strategies and personal protective equipment for specific hazards and to assure their practicality and usability in workplaces in all the high risk industrial sectors.

For additional information about NIOSH PPE and Engineering control programs, please visit their web site at: http://www.cdc.gov/niosh/programs/ppt/ and http://www.cdc.gov/niosh/programs/eng/.

Examples of specific research areas of interest include, but are not limited to:

Conduct research on the ability of existing containment and control strategies to prevent releases and potential human exposures to engineered nanomaterials.

Conduct research to evaluate the effectiveness of personal protective equipment (PPE) in protecting workers against exposure to engineered nanomaterials. Provide data to fill knowledge gaps and support guidance for the selection and use of gloves and protective garments to prevent exposures. Respiratory protection research needs to be extended to a broad range of engineered nanomaterials.

Develop a heads-up display coupled with a personal noise exposure monitoring system. Personal noise alert "badges" and personal noise dosimeters exist, but do not have an effective way to alert the user immediately when a noise hazard occurs. A system that displays a warning within the user's visual field (via lights on protective eyewear, hardhat, etc.) would facilitate hazard recognition.

Develop an inexpensive hand-held earplug test device based on the NIOSH QuickFit concept. Studies of hearing protector users have shown repeatedly that average protection values are much lower than the labeled Noise Reduction Ratings (NRR) determined in laboratories. A QuickFit test system would help workers determine if their hearing protection is giving them at least 15 decibels of attenuation.

Develop innovative engineering control approaches and technologies for reducing asphalt exposures in roofing, and skin exposures and disease in construction workers.

Conduct research to understand PPE integration and interoperability issues. In most cases, individual PPE are currently used without consideration for their ability to function together. Research is needed to test interfaces among different PPT and components. Current interfaces do not provide seamless integration of PPT components resulting in reduced comfort, fit, usability, and protection for the wearer as well as logistical challenges for safety managers and employers.

Develop innovative educational and professional training materials suitable for today's diverse workplace on the role of PPT in occupational safety and health. This is especially critical for high risk occupations. Innovative methodologies including social media should be explored and evaluated to demonstrate their effectiveness at improving workplace safety and health. For example, to what extent can mobile application media be focused on worker safety and health to provide up-to-date PPT information to a diverse range of employers and employees' through portable communication devices?

Impact and Commercialization Potential: The impact of the proposed research will prevent work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technologies (PPT). Potential products include technical methods, processes, techniques, tools, and materials that support the development and use of personal protective equipment worn by individuals to reduce the effects of their exposure to a hazard. NIOSH will continue its collaborative efforts in partnership with labor, industry, government, and other stakeholders.

Exposure Assessment Methods for High Risk Occupations

Background: Exposure assessment provides multi-disciplinary strategies and methods to anticipate, recognize, evaluate, control, and confirm effective management of occupational health stressors,

exposures to those stressors, and resulting health risks. Major gaps in current approaches include: (1) the lack of practical methods for hazard identification and measurement that can be applied at reasonable cost in many workplaces where health stressors may exist, (2) the lack of validated, noninvasive biological methods for monitoring relevant exposure and resulting dose, and (3) the lack of strategies and methods for epidemiologic studies to demonstrate either a dose-response effect or a conclusion of no association between the agent and disease in the complex environments of today's workplaces.

For additional information about NIOSH Exposure Assessment programs, please visit their web site at: http://www.cdc.gov/niosh/programs/expa/.

Examples of specific research areas of interest include, but are not limited to:

As the rapidly emerging new approach to material science, two areas of research are needed to support effective assessment of worker exposure to engineered nanomaterials. 1. Real-time sensors capable of reliably detecting nanoparticles and providing information on size distribution and count, and that can be used for personal monitoring; and 2. Development of methods that can detect and quantify the presence of engineered nanomaterials in samples collected for the purpose of characterizing exposures. These methods need to be cost-effective and available to the OS&H practitioner community. Broader application to general public health assessments should be factored into the research.

Develop new or improved methods to measure occupational health stressors such as psychological and ergonomic factors, noise, chemicals, particles and fibers, physical agents, non-ionizing radiation, or mixtures of stressors in the work environment. Enhanced measurement performance and functionality can include sensitivity, selectivity, size and weight considerations, ease of use, and capabilities to measure multiple analytes simultaneously.

Develop or adapt easy-to-use, direct-reading instruments and test kits to rapidly and inexpensively measure exposures in a variety of workplaces. Critical applications include routine monitoring, evaluating the success of control technologies, and supporting epidemiological studies. For example develop a sound level meter to monitor worker noise exposure that can be used in underground coal mines.

Improve the measurement of low concentrations of chemicals and biomarkers in biological specimens such as blood, urine, saliva and sweat so that such concentrations can be linked to internal dose at the target organs, work tasks and workers can be categorized according to hazard bands and exposure bands, and at-risk workers can be identified and protected.

Develop a computerized system that can be used to predict worker noise exposure from mining machine noise emissions. The system would include an acoustic model of mining environments and algorithms to characterize exposure based on noise source characteristics. The main application for this technology would be for mining machine manufacturers to evaluate the potential effects noise controls during the design process. If the impact of design changes on exposure reduction can be accurately predicted without the need for extensive field measurements, innovative noise controls can reach implementation much more quickly.

Impact and Commercialization Potential: This research will lead to the development of practical solutions and prevention activities to address complex problems that cause occupational diseases, injuries, and fatalities and that will lead to reductions in occupational injuries and illnesses among all workers. NIOSH is committed to building and maintaining collaborative partnerships with international organizations in labor, industry, and government, as well as with other interested stakeholders. Research to Practice (r2p): This research will lead to the development and translation of exposure assessment methods and research findings into prevention practices and products that will be adopted in occupational settings.

Work-related Injuries from Motor Vehicle Crashes

Background: The risk of injury associated with on-the-job operation of motor vehicles affects millions of U.S. workers. Motor vehicle-related incidents are consistently the leading cause of work-related fatalities in the United States. Of over 43,000 work-related fatalities reported by the Bureau of Labor Statistics between 2003 and 2010, 15,396 (36%) were associated with motor vehicles. The public health toll for 2003-2010 included:

10,202 deaths in single- or multiple-vehicle crashes on public roadways
2,487 deaths in crashes that occurred off the highway or on industrial premises
2,707 pedestrian worker deaths as a result of being struck by a motor vehicle

Over the same period, workers incurred nearly 400,000 lost-workday injuries due to these incidents. Crash-related fatalities and serious injuries have a devastating impact on workers and their families, and on the economic health and productivity of American businesses. In some instances, e.g., the operation of heavy trucks, work vehicles also have an impact of the safety of the motoring public.

The virtual NIOSH Center for Motor Vehicle Safety coordinates the CDC/NIOSH response to this pressing worker safety issue. Many NIOSH programs include motor vehicle crashes among their top injury prevention priorities: Traumatic Injury; Transportation, Warehousing, and Utilities; Wholesale and Retail Trade; Oil and Gas Extraction; Public Safety; and Global Collaborations.

Examples of specific research areas of interest include, but are not limited to:

The highest priority is to develop, implement, and evaluate interventions in an effort to build the scientific evidence base to guide prevention of work-related motor vehicle crashes and resulting injuries. This may be achieved by developing new design concepts and standards for use by national standard-setting organizations in updating or developing design standards for specialized work vehicles, enhancing effective interventions for driver training and assessment to reduce work-related motor vehicle crashes, evaluating the effectiveness of technology- or management-based intervention strategies to reduce the incidence or severity of work-related motor vehicle crashes, and enhancing engineering controls for preventing work-related crashes and injuries.

Impact and Commercialization Potential: Application of evidence-based interventions is expected to have a large impact on reducing the incidence and severity of work-related motor vehicle crashes. This will yield substantial public health benefits, and will positively affect workers' compensation and health insurance premiums and costs. CDC/NIOSH has well-established working relationships with employers, their trade associations, and standards-setting organizations, and is therefore strongly positioned to communicate findings and guidance to potential users. CDC/NIOSH also has strong infrastructure to facilitate the transfer of technology-based interventions to the marketplace. Given the extremely short induction period between exposure and injury occurrence, CDC can make a measurable difference in a very short period of time (< 4 years).

Visit the NIOSH homepage for more information on NIOSH's research program areas http://www.cdc.gov/niosh/homepage.html.

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FOOD AND DRUG ADMINISTRATION (FDA)

FDA will accept SBIR grant applications on the September 5 2015, January 5, 2016 and April 5, 2016submission dates.

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get accurate, science-based information they need to use medicines and foods to improve their health.

For additional information about areas of interest to the FDA, please visit our home page at http://www.fda.gov.

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH (CBER)

CBER is responsible for ensuring the safety, efficacy, potency and purity of biological and related products intended for use in the treatment, prevention or cure of diseases in humans as well as the safety of the nation's supply of blood and blood products. The primary responsibility of CBER is to review the quality, safety and efficacy of vaccines, blood products, certain diagnostic products and other biological and biotechnology-derived human products.

CBER's activities include: evaluating the quality, safety and effectiveness of biological products before marketing, and monitoring the pre-clinical and clinical testing of new biological products; licensing biological products and manufacturing establishments, including plasmapheresis centers, blood banks, vaccine and biotechnology manufacturers; AIDS program and policy activities, including research on AIDS therapeutic products, diagnostic tests and vaccines; research to establish product standards, develop improved testing methods and assess the safety of biological products; compliance, lot release program and post market surveillance; meeting PDUFA goals, new research programs, and new regulatory initiatives (managed review process for all products).

CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)

CDER develops FDA policy with regard to the safety, effectiveness, and labeling of all drugs for human use; evaluates new drug applications and investigational new drug applications; develops standards for the safety and effectiveness of all over-the-counter drugs; monitors the quality of marketed drugs through product testing (bioavailability/bioequivalence testing), post marketing surveillance, and compliance programs; develops guidelines on good manufacturing practices; conducts research and develops scientific standards on composition, quality, safety, and efficacy of human drugs.

Drug regulatory research as conducted in CDER is directed at the discovery of new knowledge relevant to drug development, post marketing drug experience (patterns of drug use and safety), and drug regulation to enhance FDA regulatory decisions. These drug regulatory decisions impact on the development of regulations, guidelines and guidance for the regulated industry and provide clarity and consistency in application of CDER regulatory requirements. These drug regulatory decisions also impact public health by ensuring that marketing drugs are safe and efficacious and that their risk: benefit profile remains acceptable during the market life of a drug. Specific areas of research conducted by the Center include: Pharmacology/toxicology, microbiology/virology, clinical pharmacology, pediatric issues in drug therapy, post marketing drug safety, evaluation of effectiveness of regulatory actions, patterns of drug use, including off-label, signal detection methodologies (e.g., data mining techniques), epidemiologic

studies of therapeutics using population-based data, regulatory compliance, product quality, and active surveillance methods.

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

A. Develop a system for gathering real-time data on physician prescribing behavior, understanding and compliance with drug product labeling and frequency of off-label prescribing.

B. Develop and evaluate the effectiveness of new methods and tools for managing the known risks of marketed drug products (e.g., communicating newly identified risks to health care practitioners and patients).

C. Develop methods for timely active surveillance of newly approved drug products in large populations to identify both expected and unexpected outcomes.

D. Develop methods for actively collecting information on all cases of classically drug-associated events (e.g., acute liver failure, blood dyscrasias, severe desquamating skin disorders) to augment the FDA's current passive surveillance system.

E. Develop improved clinical markers and methods with potential for bed-side application for detection of the early onset of adverse drug events.

F. Develop surrogate potency methods for biotech drug products to replace traditional animal testing.

G. Development of psychochemical and in-vitro biological tests to evaluate pharmaceutical equivalence of complex drug substances and drug products.

H. Research into approaches to handle informative missing patient data in clinical trials, including innovations in study designs and statistical methods of analysis.

I. Statistical and computational methods and strategies for the design, analysis and interpretation of microarray, genomic and proteonomic data.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION (CFSAN)

The FDA is responsible for the safety of the vast range of food Americans eat; about 80 percent of all food sold in the United States. This includes everything except for the meat, poultry, and processed egg products that are regulated by the USDA. Consequently CFSAN seeks research designed to complement and accelerate efforts aimed at the detection, prevention, and control of contamination that may be responsible for illness or injury conveyed by foods, colors, and cosmetics. CFSAN conducts research, and develops regulations, guidance and standards related to the composition, quality, nutrition, and safety of food, food additives, colors, and cosmetics. The Center evaluates FDA's surveillance and compliance programs relating to foods, colors, and cosmetics; reviews industry petitions, and develops regulations for food standards to permit the safe use of color and food additives.

CFSAN maintains an active research program that is focused on the following priorities; ensuring the safety of food, dietary supplements and cosmetics; improving nutrition; and promoting the security and integrity of the food supply. The Center's research activities are intended to; support the FDA's regulatory activities; reduce the incidence of foodborne illness by improving our ability to detect and quantify foodborne pathogens, toxins, and chemicals that could jeopardize the safety and security of the food supply; find new and improved ways to control these agents; and safely produce, process, and handle food and food products. FDA is committed to reducing the incidence of foodborne illness to the greatest extent feasible while at the same time protecting the nation's food supply. Mission-critical knowledge gaps are addressed through translation research focused on the risks associated with FDA regulated products throughout their life cycles, from production to consumption. Ideally extramural research is sought that complements the Center's intramural research efforts, and which will enhance the Agency's and the

Nation's ability to reduce the incidence of foodborne illness and protect the integrity of the nation's food supply. FDA's mission-critical needs require that the research not simply end with the generation of new knowledge and technologies, but extend to the validation of new approaches by using realistic conditions that accurately reflect the diversity of the food industry and offer potential solutions that can be accept by appropriate sectors of the food industry.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH (CDRH)

CDRH develops FDA policy and solves problems related to public health and safety of medical devices and radiation-emitting electronic products. It evaluates applications for premarket approval of medical devices, approves products development protocols and exemption requests for investigational devices. It classifies devices into regulatory categories, develops safety effectiveness standards and good manufacturing practices regulations, operates post market surveillance and compliance programs, and provides technical, non-financial assistance to small manufacturers. The Center also conducts programs to reduce human exposure to hazardous ionizing and nonionizing radiation, through an electronic product radiation control program and other programs designed to control and limit radiation exposure. The Center develops and conducts research and testing programs in the areas of physical, life, and engineering sciences related to the human health effects of radiation and medical device technologies, provides expertise and analyses for health-risk assessments, and also develops new or improved measurement methods, techniques, instruments and analytical procedures for evaluating product performance and reliability.

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

A. Examine the setup, documentation and optimization of our Sun Grid Engine (SGE). The architecture of this networking application is particularly suited to managing surge capacity in high performance computing. The modeling of many physiologic functions and bioinformatic analyses can take months or even years to run on a standard desktop computer. The SGE takes the overall problem and distributes it to a cloud of computers on a network so that no user knows, or cares, if a computation is performing in the background on their machine. As FDA rolls out laptops with multi-core CPU's and which are equipped with prodigious amounts memory this experiment in "cloud computing" could become a reality on the Whiteoak Campus. The scope of work would be to develop, document, and provide training systems for developers, network architects, and users on working methodologies for the integration of cloud computing with the existing FISMA compliant conventional networking.

B. Develop a high-speed, low light spectral CMOS linear imaging system to measure complete spectra of multiple variables from living tissue. Complete spectra of fluorescence signals (including auto-fluorescence and FRET) could be measured along a line at high speeds (10 kHz) with a rectangular CMOS grid (e.g. 10 x 1,000 pixels -> 10 sites 1000 wavelengths).

C. Develop bioassays/biosensors to identify injurious levels of nerve stimulation utilizing bioluminescence and neurotransmitter detection technologies. Research capabilities needed include voltage clamp, current clamp and extracellular techniques in peripheral nerves and brain slices to explore stimulation protocols that release neuroactive substances released in injury and inflammation which are not normally evoked under normal physiological conditions.

D. Design, build, and validate a phantom that is traceable to a national metrology institute (NMI) such as NIST (or any other NMI) to improve the accuracy and clinical utility of bone mineral density measurements made using dual energy X-ray absorptiometry (DXA). The calibration phantom should be constructed using biosurrogate materials with known/tabulated data for body tissue and tissue substitutes.

CENTER FOR VETERINARY MEDICINE (CVM)

CVM is a public health organization that enables the marketing of effective drugs, food additives, feed ingredients, and animal devices that are safe to animals, humans, and the environment. The Center, in partnership with Federal and state agencies and other customers, ensures animal health and the safety of food derived from animals. The Center makes timely, quality decisions and takes regulatory actions to ensure that these products provide for quality health care of animals, minimize the transmission of zoonotic diseases, and increase the efficiency of production of animal-derived food and fiber. Regulatory decisions are supported by research, the monitoring of product safety, and efficacy, and the continual improvement of processes.

Research and development opportunities within the Center for Veterinary Medicine that lend themselves to performance by small businesses include, but are not limited to, the following areas of interest:

A. Development, for the specific purpose of obtaining approval or conditional approval, of products for the treatment, control or prevention of diseases or conditions occurring in minor species or small numbers of major species.

B. Development and validation of high throughput/screening quantitative and qualitative analytical methods for analyzing drugs, additives, and contaminants in animal tissues and feeds.

C. Development of methods to determine absorption, distribution, metabolism, and excretion of drugs, feed additives and contaminants (microbial and chemical) in food animals, including minor species.

D. Development of new biomarkers and models for determining the safety and effectiveness of veterinary drugs and food additives in domestic animals, including minor species.

E. Development of methods to determine the effects of drugs, food additives, and contaminants (microbial and chemical) on immunological and physiological functions of domestic animals, including minor species.

OFFICE OF CRITICAL PATH PROGRAMS

The Office of Critical Path Programs, in FDA's Office of the Chief Scientist, coordinates the cross-agency Critical Path Initiative (CPI), FDA's strategy for transforming the way medical products are developed, evaluated, and manufactured. CPI activities are under way throughout the Agency, from the product centers to the Office of the Commissioner. For details, see http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative/default.htm. Collaboration is key to the CPI initiative because bringing safe, effective, and innovative therapies to the American public requires FDA to leverage the resources and expertise of all stakeholders, including other Federal agencies, academia, healthcare professionals, patient and consumer groups, regulated industry, and health-related organizations. In 2008, CPI collaborations involved 84 government agencies, universities, industry leaders, and patient groups from 28 states and 5 countries on a raft of groundbreaking research projects.

Research and development opportunities within FDA that lend themselves to performance by grantees include, but are not limited to, the following:

A. Studying the immunological correlates of TB immunity and developing tools to evaluate TB vaccine efficacy.

B. Developing study models for testing combination-antimicrobials as a strategy to prevent the development of drug resistance.

C. Developing new approaches to preclinical safety testing.

D. Identifying biomarkers for safety and efficacy evaluation of medical products.

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT

The Office of Orphan Products Development was established to identify and facilitate the development of orphan products. Orphan products are drugs, biologics, medical devices and foods for medical purposes, which are indicated for a rare disease or condition (i.e., one affecting fewer than 200,000 people in the United States). These products may be useful in a rare disease/disorder but lack commercial sponsorship because they are not considered commercially attractive for marketing. A subcategory of orphan products are those marketed products in which there is evidence suggesting usefulness in a rare disease/disorder but which are not labeled for that disease/disorder because substantial evidence of safety and effectiveness for that use is lacking.

Research and development opportunities within the FDA that lend themselves to performance by small businesses include, but are not limited to, the following:

A. Development of products for the treatment of rare diseases or disorders including but not limited to neurological, metabolic, genetic, ophthalmologic, hematologic, and dermatological diseases or disorders for the specific purpose of obtaining marketing licensure.

B. Development of products for use in diagnosis of rare diseases for which the diagnostic tool would be used in fewer than 200,000 persons annually in the United States.

C. Development of vaccines for the prevention of rare diseases to be used in fewer than 200,000 persons annually in the United States.

Other Research Topic(s) Within the Mission of FDA

For additional information on research topics and administrative and business information, contact:

Ms. Kimberly Pendleton Chew
Chief, Grants Management Officer
240-402-7610 , Fax: 301-827-0505
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Food and Drug Administration
Division of Acquisition Support and Grants
5630 Fishers Lane - HFA 500
Rockville, MD 20857

ADMINISTRATION FOR CHILDREN AND FAMILIES

The Administration for Children and Families (ACF), within the Department of Health and Human Services (HHS) is responsible for federal programs that promote the economic and social well-being of families, children, individuals, and communities. ACF partners with State and local governments, for-profit and non-profit organizations, faith- and community-based organizations, American Indian Tribes and Native American communities to design, administer and promote programs in areas such as child welfare, childcare, Head Start, healthy marriage, Temporary Assistance for Needy Families (TANF), and responsible fatherhood.

The Office of Planning, Research and Evaluation (OPRE) facilitates ACF's SBIR investments. The Office provides guidance, analysis, technical assistance, and oversight to ACF programs on strategic planning aimed at measurable results; research and evaluation methodologies; demonstration testing and model development; statistical, policy and program analysis; synthesis and dissemination of research and demonstration findings.

The focus of the research topics for SBIR should reflect the research and programmatic interests of ACF. Particular areas of interest for ACF include but are not limited to:

- Adoption and Foster Care
- Child Abuse & Neglect
- Child Care
- Child Support
- Developmental Disabilities
- Early Head Start
- Energy Assistance
- Family/Domestic Violence
- Fatherhood and Healthy Marriage
- Head Start
- Native American and Tribal Programs
- Refugee Resettlement
- Human Trafficking
- Temporary Assistance for Needy Families
- Youth Development

For additional information on ACF programs and research, please visit the ACF web site at http://www.acf.hhs.gov and the Office of Planning, Research and Evaluation's web site at http://www.acf.hhs.gov/programs/opre/index.html.

For additional information on research topics, contact:

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For administrative and business management questions, contact:

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APPENDIX A: NATIONAL INSTITUTES OF HEALTH SBA-APPROVED SBIR/STTR TOPICS FOR AWARDS OVER STATUTORY BUDGET LIMITATIONS

National Institutes of Health SBA-Approved SBIR/STTR Topics for Awards over Statutory Budget Limitations

1/1/2015

NIH has received approval from SBA for the topics listed within for budgets greater than $225,000 for Phase I SBIR/STTR awards and greater than $1,500,000 for Phase II SBIR/STTR awards for 2015. Applicants are **strongly encouraged** to contact NIH program officials prior to submitting any award budget in excess of these amounts. Applicants are also required to follow NIH Institute- and Center-specific budget guidance found in all SBIR and STTR funding opportunity announcements.

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NATIONAL CANCER INSTITUTE (NCI)

A. Therapeutics (e.g. Small Molecules, Biologics, Radiomodulators, and Cell-based Therapies)

B. *In Vitro* and *In Vivo* Diagnostics (e.g. Companion Diagnostics and Prognostic Technologies)

C. Imaging Technologies (e.g. Agents, Devices, and Image-Guided Interventions)

D. Devices for Cancer Therapy (e.g. Interventional Devices, Surgical, Radiation and Ablative Therapies)

E. Agents for Cancer Prevention (but not “Technologies for Cancer Prevention”)

F. Development of Low Cost Technologies for Global Health

G. Development of Companion Diagnostics

H. Vaccine Development for Cancer Prevention

I. Novel Technologies to Address “Undruggable” Drug Targets

NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES (NCATS)

A. Innovative platforms for identification and prioritization of targets for therapeutic intervention with clear clinical impact
B. Technologies to determine alternative uses for existing therapeutic interventions
C. Tools and technologies to allow assaying of activities of compounds on currently “non-druggable” targets
D. Phenotypic assay development, including stem cell technology platforms for human “disease in a dish” applications and the evaluation of toxicity
E. Co-crystallization high-throughput screening techniques
F. Small molecule and biologics analytical characterization
G. Tools and technologies that increase the predictivity or efficiency of medicinal chemistry, biologic, or other intervention optimization
H. Accelerate bioengineering approaches to the development and clinical application of biomedical materials, devices, therapeutics, and/or diagnostics
I. Tools and technologies that increase the efficiency of human subjects research, including development of technologies that facilitate rapid diagnosis and/or clinical trial recruitment and subject tracking, IRB evaluation, and/or regulatory processes
J. Novel platforms, technologies and tools to enable clinical and translational research, particularly those with mechanisms for inclusion of patient reported data

K. Searchable access to information about researchers and their expertise, including but not limited to their publications, published data sets, methods, patents, clinical trials, partnerships, collaborators, and clinical specialty/expertise (if applicable)
L. Tools for meaningful sharing of research data with low barrier for provision and user friendly access
M. Searchable access to information about research resources, facilities, methods, cells, genetic tests, molecules, biologic reagents, animals, assays, technologies with links to their use in published research studies

NATIONAL CENTER FOR COMPLEMENTARY AND INTEGRATIVE HEALTH (NCCIH)

A. Biomarkers which correlate with efficacy of complementary health approaches.

B. Standardized, reliable and economical tools and methods that correlate with complementary health approaches.

C. Formulation and development of IND-approved complementary health approaches.

D. Identification and prioritization of associated with biological targets for pain relief from complementary health approaches.

E. Safety and mechanistic aspects of natural product-drug interactions.

F. Non-traditional phenotypic assay development for complex natural product mixtures.

G. Integrated *in silico* tools for exploiting the natural product bioactivity.

NATIONAL EYE INSTITUTE (NEI)

General Research and Development Topics

A. New or improved ophthalmic or surgical instruments for diagnosis and treatment of eye disorders.

B. Drug delivery systems; gene therapy, cell-based therapy or regenerative medicine;

Retinal Diseases

A. New therapeutic approaches for inflammatory and degenerative diseases and for inhibition of abnormal angiogenesis in the retina and choroid

Corneal Diseases

A. Therapeutic agents and drug delivery methods for the treatment of corneal injury, infection, dry eye, ocular pain, and other ocular surface disorders

Lens and Cataract

A. New approaches in the management of cataracts

Glaucoma and Optic Neuropathies

A. New therapeutic agents for treatment of glaucoma

Visual Impairment and Blindness

A. New or improved devices, systems, or programs that meet the rehabilitative and everyday living needs of blind or visually-impaired persons

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE (NHLBI)

A. Biomedical technologies (medical devices, instruments, pharmaceuticals, drugs, therapeutics, vaccines, diagnostics and biologics) for heart, lung, blood, and sleep related diseases and disorders requiring Federal regulatory approval (FDA) or clearance to be commercialized.

B. Small and large animal testing of products of tissue engineering and regenerative medicine, drugs, medical devices, therapeutics, and biologics and studies involving *in vivo* animal experiments for heart, lung, blood, and sleep related diseases and disorders.

C. Clinical trials and other experiments involving human subjects for heart, lung, blood, and sleep related diseases and disorders.

D. Therapeutics (drugs, devices, or biologics) development for heart, lung, blood, and sleep related diseases and disorders.

E. Device development for heart, lung, blood, and sleep related diseases and disorders

F. Diagnostics development for heart, lung, blood, and sleep related diseases and disorders.

G. Investigation of biomarkers and biosignatures of heart, lung, blood, and sleep related diseases and disorders.

H. Technologies to enhance clinical research for heart, lung, blood, and sleep related diseases and disorders.

I. Advanced instrumentation and high throughput tools for biomedical research in heart, lung, blood, and sleep related diseases and disorders.

J. Tools and platforms to improve the dissemination and implementation of evidence-based interventions for heart, lung, blood, and sleep related diseases and disorders.

NATIONAL HUMAN GENOME RESEARCH INSTITUTE (NHGRI)

A. Development of novel or significant improvements on current next generation sequencing technology

B. Bioinformatics software for genomic, genetic and sequence data analysis, functional genomics and genomic data integration

C. Genomics tools ranging from new instruments to sophisticated molecular biology kits

D. Incorporating genomic results into electronic medical records

E. Informatics tools that assist in delivering genomic medicine to patients

F. Single cell genomic analysis

NATIONAL INSTITUTE ON AGING (NIA)

Division of Behavioral and Social Science (DBSR)

A. Development and translation of behavioral economics approaches (incentives or disincentives) to motivate sustainable behavior change to improve health and well-being.

   a. Increasing levels of physical activity or promoting treatment adherence
   b. Addressing biases such as loss aversion, errors in affective forecasting, present bias, ambiguity effect, base-rate neglect, and susceptibility to framing effects in health and financial decision making
   c. Using information, or the mode of data presentation to systematically improve decision making (e.g., through “nudges,” policies, or practices that constrain choices)

B. Development of robotics applications to aid elderly
   a. Socially assistive robots allowing elderly to remain independent in their homes. Technology could support machine cognition, language understanding and production, human-robot interaction (cognition, perception, action control, linguistics, and developmental science), perception, and systems.
   b. Use of robots to promote social interaction and engagement and reduce loneliness among the elderly;
   c. Use of robots to motivate elderly to exercise.

C. Development of cognitive training applications/intervention to improve cognitive function in elderly

   a. Rapidly develop novel, engaging computer-based cognitive training programs that are based on efficacious approaches and which use cognitive training to target a specific neural system/functional domain.
   b. Augment existing computerized cognitive interventions to be personalized, engaging, adaptive, sufficiently challenging, and optimal for maximizing real world functional improvements.

D. Development of blood-spot technology for biological data collection:

   a. Development of multiple and reliable assays for limited blood-spot specimens for large surveys.

Division of Biology of Aging

A. Effects of metabolism on the aging process, e.g., how metabolic regulation influences longevity, and the development of anti-oxidants or other interventions to reduce oxidative or other stresses and aging-related diseases.

B. Development of minimally-perturbing techniques for collecting blood from mice, rats, and other animals several times a day in sufficient quantities for measurement of hormone levels and other circulating factors in young and old non-human animals, or development of non-invasive research and test methods for use in non-human animals.

C. Development of interventions that improve the immune response to foreign molecules or reduce the response to self or suppress age-induced inflammation.

D. Development of novel strategies for treating age-related renal, pulmonary, urology, reproductive disorders, and age-related changes in hormone production and function, including devices, pharmacological targets and their validation, small molecules and other approaches to treat these disorders in the elderly; early-stage pharmacological validation of novel targets and accompanying pre-therapeutic leads for these age-related diseases are encouraged.

E. Development of novel methodology for treating osteoarthritis, including devices, processes and pharmacological agents with the potential to: (1) slow the rate of joint deterioration, (2) promote the remodeling of damaged joints, (3) reduce the likelihood of progression to osteoarthritis, and/or (4) improve outcomes for patients with active osteoarthritis.

F. Development of interventions that reduce the level of damage to nucleic acids, proteins and lipids and the macromolecular complexes formed from these molecules, and improve the damage surveillance and repair potential of cells.

G. Development of tools and resources in genetics and genomics to study molecular mechanisms of normal aging or aging-related diseases.

Division of Geriatrics and Clinical Gerontology

A. Development of clinical decision-support tools able to broadly integrate into the electronic health record to help physicians/providers caring for patients with multiple (3 or more) chronic conditions prioritize, coordinate, and deliver the interventions that are most beneficial and relevant within the context of these patients' lives and the health-care-delivery system.

B. Projects focusing on translation/development of new therapeutic interventions to promote wound healing, improve vaccine response/immune function, and for physical functional problems in old age

C. Development of assistive technologies/robotics to enable and support older persons to live independently and safely at home; socially-assistive robots; robots for caregiver and mobility assistance; robots for exercise and rehabilitation assistance.

D. Development of technologies/robotics to assist in the improvement of physical function and mobility in older persons prior to (prehabilitation) or following (rehabilitation) elective/planned surgery.

E. Development and validation of improved approaches for evaluation, monitoring or treatment of diastolic dysfunction in older adults

F. Development of improved instrumentation/ imaging and sensor technology for measuring ambulation and biomechanics of movement including balance, sway, gait, and postural control to identify stable and unstable patterns of movement during activities of daily living

G. Development of methods and technology to accurately determine the renal glomerular filtration rate (GFR) in older persons and patients with chronic kidney disease; new methods and technology should accommodate the effects of age-related changes in muscle mass, levels of serum creatinine, renal blood flow and renal concentrating ability.

H. Development and validation of non-invasive methods of examining bone quality (density, architecture, and strength of bone).

I. Development and validation of instruments and/or methods to evaluate fatiguability—the level of fatigue related to the intensity, duration, and/or frequency of activity (in contrast to measures of fatigue), particularly in adults with or at-risk of developing age-related conditions or diseases leading to physical disability.

J. Development and validation of innovative approaches to pain control that considers age-related physiologic changes such as gastrointestinal absorption, cutaneous integrity, and musculoskeletal structure and function.

K. Development and validation of new technology such as non-invasive methods to examine blood-flow velocity in arteries, individual coronary arteries, renal arteries, and cerebral arteries

Division of Neuroscience (DN)

A. Development of new and/or validation of existing sensitive, specific and standardized tests for diagnostic screening of MCI and dementia; for example, the development of novel neuropsychological, biochemical, and neuroimaging technology and/or methods or the validation of existing measures/methods/technology for the early detection of cognitive impairment and MCI and the early diagnosis of AD and other dementias, and development of new technology and tests for detection of pre-clinical AD and other dementias of aging.

B. Discovery, development, and/or evaluation of compunds, drugs, biological or natural products, including central-nervous-system delivery systems to remediate age-related cognitive decline, and to treat the cognitive impairment and/or behavioral symptoms associated with MCI, AD, and other dementias of aging as well as to slow and/or reverse the course of the disease or to prevent it entirely.

C. The development of practical applications using innovative technologies (e.g. hand-held, internet, telemedicine GPS, robotics, social networking and communications technologies) to support and improve quality of life, well-being, and the ability of people with with age-related cognitive decline, MCI, AD or other dementias of aging to live independently and safely at home for an extended period of time; examples include systems and devices to: evaluate, monitor and improve or adapt to changes in cognition; improve health service delivery; support independent living and the conduct of everyday tasks at home; provide information to health care providers and family members with which to evaluate the need for intervention; and promote communication and interaction between individuals living in the community or in institutional settings and their health care providers, friends and family members.

D. Testing in clinical trials of drug, nutritional, behavioral, cognitive or other types of interventions to remediate age-related cognitive decline, and to treat cognitive impairment and/or behavioral symptoms associated with MCI, AD, and other dementias of aging as well as to slow and/or reverse the course of disease or to prevent the onset of disease.

E. Biosensors and prosthetic devices, technologies, and related software development to aid in the assessment, diagnosis, and remediation of age-related cognitive decline or sensory dysfunction (including pain, age-related vision loss, and age-related hearing loss), motor dysfunction (including Parkinson's disease and other motor disorders of aging), or age-related changes in balance, postural control, and gait.

F. Development of novel markers of normal age-dependent cognitive decline or sensory and/or motor system changes at the molecular cellular, circuitry, physiological or behavioral level in humans or relevant animal models.

G. Improved technology for the analysis of structural and functional brain connectivity at the cell, neural circuitry and global network levels to define the normal trajectory of brain structure and function over the adult lifespan.

H. Development of technology, including non-invasive methods and novel probes, to monitor and manipulate the plasticity of neural circuits in the adult and aged nervous system.

I. Development of novel markers of neural stem cell function (proliferation, migration, and differentiation) as well as methods to assess the integration and function of stem cells in the nervous system.

J. Novel approaches for analysis of next-generation sequence data.

NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM (NIAAA)

A. Treatment of alcoholism
   - Pharmacological discovery, strategies, and development
   - Innovative therapeutic approaches
   - Prevention strategies
   - Therapies for co-morbid conditions, including organ damage

B. Technology development to support screening, brief intervention, and referral to treatment for alcohol-involved patients in medical settings

C. Development of novel technologies or methods
   - To detect the effects of alcohol on CNS structure and activities
   - To prevent harmful drinking during pregnancy, to identify prenatal alcohol exposure, and to enhance outcomes of individuals with Fetal Alcohol Spectrum Disorder
   - Tools for alcohol-related laboratory studies, such as animal strains, cell lines, stem cells, in vitro techniques, neuroimaging, ligands, in vivo detection of neuromodulators, or computational tools
   - Stem cell generation, dissemination, and model development
   - Voice technology, cell phones, and other

D. Development of Biomolecular Signatures of Alcohol Exposure and Alcohol-induced Tissue Injury

E. Development, Optimization, and Validation of Novel Tools and Technologies for Neuroscience Research

F. Design, Development, and Improvement of Alcohol Biosensors

G. Investigational New Drug (IND)-enabling Development of Medications or Devices to Treat Alcohol Use Disorder and Alcohol-related Disorders

H. Genotyping of DNA samples from subjects with addiction and substance use disorders

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES (NIAID)

Division of Allergy, Immunology, and Transplantation (DAIT)

A. Allergy, Asthma and Airway Biology Branch will consider preclinical and clinical research for conditions of interest: asthma, food allergy, eosinophilic esophagitis and gastroenteritis in relation to food allergy, atopic dermatitis, urticaria, rhinitis, rhinosinusitis, drug allergy, and sepsis. This includes but is not limited to the development of methodologies to manage, and analyze clinical and epidemiologic research in the above conditions and the development of biomarkers as diagnostic markers, markers of disease severity, predictive markers for treatment effectiveness, particularly of immunologic interventions such as allergen immunotherapy for food and respiratory allergy; novel approaches for detecting infants at risk for developing asthma and other allergic diseases; immune targets for asthma and allergic disease interventions; development of immunotherapies to prevent or treat allergic diseases; development of new reagents and non-murine animal models for allergy research.

B. Basic Immunology Branch will consider preclinical and clinical research to develop the origin, maturation, and interactions of immune cells, immune cell receptors, ligands, cytokine biology, molecular basis of activation, antigen recognition, immune tolerance, immune response regulation, hematopoiesis and stem cell biology, enhancement of vaccine effectiveness in neonates and adults, and basic immunology of vaccines and immunotherapeutics as medical countermeasures for biodefense. This includes but is not limited to development of novel vaccine adjuvants; single cell assays to isolate and study allergen-specific lymphocytes; immunotherapeutic antibodies; biomarkers of host immune defense; single cell and other sample-sparing assays for study of human immunology.

C. Autoimmunity and Mucosal Immunology Branch will consider preclinical and clinical research to develop and improve therapies for the treatment of autoimmune diseases, primary immune deficiencies (not HIV), basic research of disease mechanisms, and biomarkers, immunotherapy of disease processes, disorders mediated by lymphocyte products, and mucosal immunity. This includes but is not limited to innovative treatments for autoimmune diseases; standardized validated diagnostic criteria and outcome measures for autoimmune diseases correlated with disease activity; high throughput assay of T-cell activity in autoimmune diseases; biomarkers to measure risk, disease activity, and therapeutic response in autoimmune diseases; innovative treatments for autoimmune diseases; mucosal immunity.

D. Transplantation Branch will consider preclinical and clinical research in organ, vascularized composite tissue and cellular transplantation: acute and chronic graft rejection, allogeneic and xenogeneic transplantation, development of immunomodulatory agents to prevent and treat graft rejection and to promote acute and long term graft acceptance and immunologic tolerance, genomics of the alloimmune response, graft versus host disease and engraftment for hematopoietic stem cell transplantation, minor histocompatibility antigens, complications of immunosuppression in transplantation, and major histocompatibility complex (MHC) region genomics and technologies for MHC typing. This includes but is not limited to methods and analysis tools to facilitate high throughput, high resolution MHC typing in humans and non-human primates.

E. Radiation Countermeasures Program will consider preclinical research on the identification and evaluation of medical countermeasures (MCMs) for public health radiation emergencies through the development of mitigators and therapeutics for acute radiation syndrome or the delayed effects of acute radiation exposure; radionuclide-specific therapies, including chelating agents, blocking agents, and other novel decorporation agents; improved methods of accurate and high-throughput radiation biodosimetry and bioassays for radionuclide contamination; biomarkers of organ-specific radiation injury; therapeutics for radiation combined injury; therapeutics for radiation-induced immunosenescence; and formulations for pediatric administration. This includes but is not limited to the development of medical countermeasures to protect against, mitigate, and treat the short- and long-term effects of radiation exposure due to terrorist attack; development of novel or improved decorporation agents to remove radionuclides from the body following accidental inhalation, ingestion or wound entry; identification of radiation exposure biomarkers and development of new biodosimetry methods and devices for triage of radiation-exposed people.

Division of Microbiology and Infectious Diseases (DMID)

A. Identify and qualify infectious disease-related biomarkers, including:
   1. Biomarkers to predict susceptibility to infection and/or diagnose an infectious disease.
   2. Biomarkers to predict or monitor a subject's response to therapeutics or vaccinations.
   3. Biomarkers from natural history studies that could be used to assess disease progression in acute and chronic diseases.
B. Development of rapid, highly sensitive and specific clinical diagnostics that are easy to use, cost-effective and can diagnose individuals infected with pathogens or individuals that have been exposed to toxins.
C. Development of vaccines for infectious diseases.
D. Development of vaccine enhancement and formulation technologies with the goal of providing protection against infectious disease agents, providing accelerated immune responses (more rapid schedules or reduced number of immunizations), increase ease of administration (i.e., self-administration), and increase product stability to minimize cold chain requirements.
E. Discovery and development of therapeutics for infectious diseases.

Division of AIDS (DAIDS)

A. Development of anti-HIV agents directed at new viral or cellular targets, including development and in vivo evaluation of sustained release formulations for treatment of HIV infection.
B. Development and evaluation of therapeutic vaccines and other immune-based therapies to attenuate HIV disease progression or reduce HIV infectiousness.
C. Development of therapeutic strategies for curing HIV infection or effecting a sustained remission in the absence of daily antiretroviral drug therapy.
D. Development of methods for detecting and quantifying persistent reservoirs of replication competent latent HIV in blood and tissues, including bio-imaging.
E. Development and evaluation of practical and affordable tests to measure viral load, CD4+ cell counts, drug toxicities and drug resistance to monitor populations infected with HIV and associated infectious agents in resource-poor settings. Development of tests to detect early infection in seropositive HIV-infected individuals and to determine HIV incidence (HIV infection before seroconversion).
F. Discovery and development of agents or strategies for Pre-exposure prophylaxis (PrEP). Development of pharmacological tools to examine PK/PD in fluids and tissue, new formulation and delivery systems for coitally-dissociated use, and optimization of animal models for screening of candidate agents.
G. Development of rapid tests for the detection of ARTs in various human matrices (e.g. blood, urine, hair).
H. Formulation, manufacturing, characterization and evaluation of novel vaccine adjuvants.
I. Evaluation of immune responses to HIV vaccines and vaccine vectors.
J. Development of formulation technologies to prevent or treat HIV and HIV-associated co-infections.

NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES (NIAMS)

A. Research and development of new therapies using small molecules or biologics for arthritis, musculoskeletal and skin diseases.

B. Research and development of novel biomedical devices or tissue engineered products for arthritis, musculoskeletal and skin diseases.

C. Research and development of new biomarkers or novel imaging technologies for arthritis, musculoskeletal and skin diseases.

D. Research and development of innovative internet-based technologies to manage arthritis, musculoskeletal and skin diseases.

NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOENGINEERING (NIBIB)

A. ***Image-Guided Interventions.*** Research on use of images for guidance, navigation and orientation in minimally invasive procedures to reach specified targets. Examples include image-guided interventions for minimally invasive therapies such as surgery and radiation treatment, for biopsies, and for the delivery of drugs, genes and therapeutic devices.

B. ***Magnetic Resonance Imaging and Spectroscopy.*** Development of MR imaging and MR spectroscopic imaging, for both animal and human research, and potential clinical applications. Examples include (but are not restricted to) fast imaging, high field imaging, design of novel RF and gradient coils, novel pulse sequences, design of novel contrast mechanisms, imaging informatics, *in vivo* EPR imaging, molecular imaging, etc. The emphasis should be on technological development rather than detailed applications to specific diseases or organs.

C. ***Medical Devices and Implant Science.*** Design, development, evaluation and validation of medical devices and implants. This includes exploratory research on next generation concepts for diagnostic and therapeutic devices; development of tools for assessing host-implant interactions; studies to prevent adverse events; development of predictive models and methods to assess the useful life of devices; explant analysis; improved *in vitro* and animal models for device testing and validation.

D. ***Micro- and Nano-Systems, Platform Technologies.*** Development of BioMEMS, microfluidics and nanoscale technologies, including micro-total analysis systems, arrays, and biochips, for detection and quantitation of clinically relevant analytes in complex matrices. Application areas include biomedical research, clinical laboratory diagnostics, biodefense, high-throughput screening, drug delivery, tissue engineering, and implantable devices, among others.

E. ***Optical Imaging and Spectroscopy.*** Development and application of optical imaging, microscopy, and spectroscopy techniques; and development and application of optical imaging contrasts. Examples of research areas include fluorescence imaging, bioluminescence imaging, OCT, SHG, IR imaging, diffuse optical tomography, optical microscopy and spectroscopy, confocal microscopy, multiphoton microscopy, flow cytometry, development of innovative light sources and fiber optic imaging devices.

F. ***Telehealth.*** Development of software and hardware for telehealth studies that have broad applications as well as early stage development of telehealth technologies that may have specific focus areas. Research that is supported includes methods to address usability and implementation issues in remote settings, and methods to develop technology for standardizing and incorporating state of the art security protocols for verifying user identities and preserving patient confidentiality across remote access.

G. ***Tissue Engineering and Regenerative Medicine.*** Development of enabling technologies including real-time, non-invasive tools for assessing the function of engineered tissues; real-time assays that monitor the interaction of cells and their environment at the molecular and organelle level; predictive computational models for engineering function 3D tissues; high-throughput assays and instruments to reduce the cost, time, and complexity of tissue engineering; novel bioreactor techniques for expanding stem cells and growing tissues and organs on a large scale; and strategies for preserving, sterilizing, packaging, and transporting living-tissue products. The program also supports applications of rational engineering design principles to functional engineered tissues; the development of novel biomaterials for use as tissue scaffolds that mimic the extracellular matrix and support multiple cell types in defined spatial orientation; and engineering approaches to study how biomaterials interact with cells and guide cell growth, differentiation, and migration.

H. ***Ultrasound.*** Improvement of technologies for diagnostic, interventional and therapeutic uses of ultrasound. The diagnostic ultrasound program includes, but is not limited to the design, development and construction of transducers, transducer arrays, and transducer materials,

innovative image acquisition and display methods, innovative signal processing methods and devices, and optoacoustic and thermoacoustic technology. It also includes the development of image-enhancement devices and methods, such as contrast agents, image and data presentation and mapping methods, such as functional imaging and image fusion. The interventional ultrasound program includes the use of ultrasound for therapeutic use, or as an adjunct for enhancement of non-ultrasound therapy applications. Examples include, but are not limited to, high-intensity focused ultrasound (HIFU) as a non-invasive or minimally invasive interventional surgical or therapy tool, and as an adjunct interventional tool. It also includes the use of ultrasound contrast agents for therapy and for targeted drug delivery, and the use of ultrasound for image-guided surgery, biopsy, and other interventions.

EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT (NICHD)

Child Development and Behavior Branch

A. Development and evaluation of serious games for bullying, with a particular interest in games that address cyberbullying are encouraged. Examples include but are not limited to games that address issues such as raising awareness of bullying, preventing engagement in bullying, and helping youth who are being bullied cope, problem solve and identifying support or resources to help address the situation.

Contraceptive Discovery and Development Branch

A. Contraception.

Developmental Biology and Structural Variation Branch

A. Innovative technologies for imaging developmental processes and gene expression; technologies for gene manipulations and perturbations.

Fertility and Infertility Branch

A. Development of novel techniques for assessment of gamete quality.

Gynecologic Health and Disease Branch

A. Development of innovative technologies for the treatment of pelvic floor dysfunction including pelvic organ prolapse, urinary incontinence or fecal incontinence.

Intellectual and Developmental Disabilities Branch

A. Technology development to improve screening, diagnosis and treatment of intellectual and developmental disabilities.

Maternal and Pediatric Infectious Disease Branch

A. New technologies relevant to resource-limited countries for point of care diagnosis of HIV and other infectious diseases, including tuberculosis, viral hepatitis, other congenital infections such as cytomegalovirus, respiratory infections, etc., in infants, children and pregnant/breastfeeding women.

Obstetric and Pediatric Pharmacology and Therapeutics Branch

A. Development of nanosized formulations to optimize efficacy and minimize toxicity of pediatric drugs

Pediatric Growth and Nutrition Branch

A. Isolation, purification and synthesis of human milk oligosaccharides with antimicrobial activity.

Pediatric Trauma and Critical Illness Branch

A. Research and development of devices and innovative therapeutic technologies for management of physical disabilities and related problems stemming from and acute injuries.

Population Dynamics Branch

A. Technological innovations or inventions to improve collection of biomarker data in large population-representative surveys.

Pregnancy and Perinatology Branch

A. Devices, instruments, and tools to minimize bacterial colonization, reduce proclivity for thrombous formation; reduce health-care associated infection risks.

National Center for Medical Rehabilitation Research

A. Development of medical rehabilitation interventions and biomedical technologies to improve rehabilitation treatment for restoration of function.

NATIONAL INSTITUTE ON DEAFNESS AND OTHER COMMUNICATION DISORDERS (NIDCD)

A. Research and development for biomedical technologies (medical devices, diagnostic instruments, pharmaceuticals, drugs, therapeutics, vaccines, and biologics) that require review and approval by the FDA as a regulated product before commercial distribution.

NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH (NIDCR)

Infectious Diseases and Immunity

A. Develop oral topical formulations with combined microbicidal, analgesic, and anti-inflammatory activities to enhance oral mucosal defenses and prevent and/or control oral infections and lesions in HIV-infected and/or immunosuppressed subjects.

Clinical Research

A. Develop improved methods to detect and predict progression of dental caries, periodontal disease, reversible pulpitis and irreversible pulpitis.

B. Improve or develop new methods to enhance oral and craniofacial surgery. This would include both intraoral and extraoral surgery.

C. Develop improved methods to mechanically repair or treat tooth structure damaged by dental caries or periodontal disease.

Oral, Oropharyngeal and Salivary Gland Cancers

A. Develop regimens for the alleviation of the oral complications of cancer therapy.

B. Develop imaging techniques for the early detection, diagnosis and prognosis of pre-malignant lesions.

Temporomandibular Joint Disorder and Orofacial Pain

A. Discovering and developing novel, pharmacological medications for treating chronic orofacial pain disorders, by leveraging results from ongoing genetic studies of chronic pain conditions

Saliva, Salivary Diagnostics, and Salivary Gland Diseases

A. Development of viral, non-viral and gene therapy-based approaches to address compromised salivary gland function. Development of cell and tissue-based strategies and technologies for restoration of damaged or destroyed salivary gland function.

B. Development of novel compounds or materials that protect and preserve salivary glands from head and neck cancer irradiation therapy.

C. Development of non-invasive methods for the determination of efficacy and safety of artificial saliva, sialogogues, and of their delivery vehicles used in addressing the diminution or lack of saliva (xerostomia) due to Sjögren's Syndrome or head and neck cancer irradiation therapy.

D. Development of immunological strategies and immunotherapy-based approaches for addressing xerostomia from Sjögren's Syndrome.

Biotechnology, Biomaterials, and Applications for Regeneration and Restoration of Oral, Dental and Craniofacial Tissues

A. Development of methods, materials, and devices for orthodontic, prosthetic, and craniofacial applications including those that can be used for craniofacial bone distraction, craniofacial reconstruction, healing, and scarless repair.

B. Development of imagining diagnostics to accelerate clinical implementation of reliable, reproducible, highly specific and sensitive diagnostic instruments for dental caries, cracked teeth, pulp vitality, bone quality, and periodontal diseases.

Clinical and Behavioral Research

A. Develop and test for safety, efficacy, and/or effectiveness of measures or materials for diagnosing, preventing, or treating oral, dental, and craniofacial conditions and disorders.

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES (NIDDK)

NIDDK supports the topics below as they pertain to *Diabetes* (Type 1 and Type 2 Diabetes, Metabolic Disorders, Cystic Fibrosis, and Endocrine Disorders), *Digestive Diseases* (Gastrointestinal Diseases, Liver and Pancreatic Diseases, Obesity, Nutrition, and related diseases), and *Kidney Diseases* (Kidney Diseases, Urologic Diseases, and Hematologic Diseases).

A. Development or evaluation of pharmacological agents (i.e., drugs, therapeutics), gene therapies, cell-based or other biological technologies for intervention in or prevention of *Diabetes and Digestive and Kidney Diseases*.
B. Development or evaluation of biomedical devices, tools, or instrumentation for intervention in or prevention of *Diabetes and Digestive and Kidney Diseases*.
C. Development of biomarkers, assays, diagnostic technologies or associated reagents for assessing state or function in normal, developing, or diseased cells or tissues affected by *Diabetes and Digestive and Kidney Diseases*.
D. Development or evaluation of imaging, screening, or evaluation technologies for assessing state or function in normal, developing, or diseased cells or tissues affected by *Diabetes and Digestive and Kidney Diseases.*
E. Development or evaluation of animal or cell models for studying *Diabetes and Digestive and Kidney Diseases*.
F. Development or evaluation of novel materials or material treatments (e.g., sterilization, coating, etc.) for use in devices or other tools or methods used to prevent, diagnose, or treat *Diabetes and Digestive and Kidney Diseases*.
G. Development of cell- or data-banks for the biomedical research community.
H. Development or evaluation of technologies, including software applications, for improving patient adherence in *Diabetes and Digestive and Kidney Diseases*.
I. Development or evaluation of technologies for improving clinical research in *Diabetes and Digestive and Kidney Diseases*, including technologies for improving data collection and reporting of patient outcomes.
J. Development or evaluation of –omics, informatics, or internet-based technologies for biomedical research or clinical applications in diagnosing or managing *Diabetes and Digestive and Kidney Diseases*.
K. Development or evaluation of technologies to prevent or avert cell or tissue injury during other disease states or surgical procedures.

NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

A. Drug discovery and development-enabling activities: Development of innovative technologies, methods or tools, including but not limited to:

   1. Innovative in vitro, in situ, or in vivo tools for the molecular analysis of the central nervous system, normal and/or diseased.

   2. Tools to simplify drug design through the use of advanced computing (simulation) methods.

   3. Novel analytical technologies and methods that enhance the understanding of basic mechanisms of drug action and improve drug testing; technologies designed to overcome the performance limitations of current drug discovery and development tools.

   4. Technologies, including molecular imaging, gene expression profiling, and genotyping and sequencing approaches designed to better inform the diagnosis and treatment of substance use disorders

B. Drug discovery and development activities: Application of emerging and existing technologies and platforms to Substance Use Disorder (SUD) drug development. Medical products with potential to minimize drug seeking, compulsive behavior, and/or addictive processes. Examples might include, but are not limited to:

   1. Chemistry / pharmaceutical drug development

   2. Formulation and/or enhanced delivery of drugs

   3. Preclinical and/or clinical drug development

   4. Identification and development of biomarkers related to SUD treatment outcomes

NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES (NIEHS)

A. Development and validation of alternative test methods to protect human and animal health while reducing, refining, or replacing animal tests.

NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES (NIGMS)

Division of Cell Biology and Biophysics

A. Development of instrumentation, devices, and methods for detecting in real time, analyzing, and separating biologically important compounds, macromolecules, and their interactions.

B. Development of new methods and materials directed toward the solution of biological macromolecule structures, including membrane proteins, assemblies and complexes by, but not limited to, x-ray diffraction, electron diffraction, NMR and mass spectroscopy.

C. Imaging probes and sensors, other reagents and methods, instrumentation, software for microscopy, spectroscopy, and single molecule analysis of molecules, cells, tissues, embryos and small model organisms. Technologies for applications of microscopy, spectroscopy and single molecule analysis in basic biomedical research, including but not limited to light, electron, X-ray and scanning probe microscopy and fluorescence, magnetic and electron paramagnetic spectroscopy. NOT included are small animal and preclinical imaging and high throughput platforms for diagnostic and clinical applications.

D. Development of high-throughput and computational methods and strategies to define/characterize the function and interactions of biological macromolecules and cells.

Division of Genetics and Developmental Biology

A. Development of probes for detection of human genetic polymorphisms, including disease genes.

B. Development of valid animal models for genetic diseases and birth defects.

C. Development of tools and technologies to detect and monitor complex human phenotypes or traits.

D. Development or improvement of methods for high throughput detection of epigenomic changes.

E. Development of improved technology, reagents and tools to derive, grow, isolate, differentiate and characterize cells.

Division of Pharmacology, Physiology, and Biological Chemistry

A. Methods for isolation, characterization, and production of natural and bio-engineered products.

B. Development of methodology to improve the efficiency of discovery, development, and production of bio-medically relevant compounds.

C. Isolation, characterization, and development of factors and strategies, methods, or treatments involved in tissue repair, wound healing, sepsis, and traumatic injury, emergency, peri-operative, or critical care conditions, and associated pain management.

D. Research to improve drug design and delivery.

E. Development of technologies, including instrumentation, software, reagents, and methods for proteomics, including but not limited to robotics, sample preparation and pre-fractionation, analytical separations, mass spectrometry, intelligent automated data acquisition, and improved informatics technologies.

F. Development of technologies, including instrumentation, software, reagents, and methods for glycomics, including but not limited to development of: specific glycan structural databases, methodologies for synthesis of robust glycan libraries, glycan labeling reagents and glyco-enzyme inhibitors, and analytical tools for determining carbohydrate structure and biological function..

Division of Biomedical Technology, Bioinformatics, and Computational Biology

A. Development of instrumentation and devices for detection, analysis and separation of biologically important molecules, and for elucidating their interactions both in vitro and intra-cellularly.

B. Development of information and communication technology from computer and other quantitative sciences in support of biomedical or behavioral research, that apply best practices and proven methods for software design, construction and implementation to promote adoption by a broad biomedical research community.

NATIONAL INSTITUTE OF MENTAL HEALTH (NIMH)

All divisions:

A. Preclinical drug/device development studies, including pharmacology, efficacy and toxicology.

B. Completion of studies as required by the Food and Drug Administration (FDA) for Investigational New Drug (IND) or Radioactive Drug Research Committee (RDRC) application.

C. Studies in normal healthy volunteers to determine a drug's safety profile, metabolism, etc.

D. Clinical studies in patient/disease population to assess the drug's effectiveness.

E. Assessment of devices with regard to performance standards related to the FDA approval process.

F. Safety and effectiveness studies of novel medical devices.

G. Evaluation of novel imaging approaches for diagnostic purposes.

H. Clinical studies in support of Pre-Market Approval for biomarkers/medical devices by the FDA.

I. Rapidly develop novel, engaging computer-based cognitive training programs that are based on efficacious neurotherapeutic approaches and which use cognitive training to target a specific neural system/functional domain.

J. Augment existing computerized cognitive interventions to be personalized, engaging, adaptive, sufficiently challenging, and optimal for maximizing real world functional improvements.

K. Test the feasibility, efficacy and potential adverse effects of these programs utilizing measures of functional outcomes in an identified clinical population, particularly those with neuropsychiatric disorders, ASD, and/or HAND, at a specified developmental stage, including measurement of the duration of treatment effects

L. Rapid development and evaluation of mobile based platforms and applications.

Division of Neuroscience and Basic Behavioral Science (DNBBS)

A. Novel imaging probes to study brain structure and function at all levels, from the molecular to the whole organ, using any imaging modality (PET, fMRI, optical, etc.).

B. Drug discovery/drug development of novel compounds which act on molecular pathways (receptors, enzymes, second messengers, etc.) that are not typically targeted with currently available psychiatric drugs, and that have a strong biological justification as a novel mechanism for treatment of psychiatric disorders.

C. Novel screening assays for high throughput acquisition and analysis of data about behavior and the brain, from the level of genes to the level of behavior.

D. Novel technologies that would enable researchers to study how populations of neural cells work together within and between brain regions, in order to understand how changes in neural activity contributes to mental disorders.

E. Complex instrumentation for neuroscience research

F. Complex brain or cellular imaging or analysis.

G. Tools to facilitate the detailed analysis of complex circuits and provide insights into cellular interactions that underlie brain function.

H. Proof-of-concept testing and development of new technologies and novel approaches for large scale recording and manipulation of neural activity, at or near cellular resolution, at multiple spatial and/or temporal scales, in any region and throughout the entire depth of the brain

I. Iterative refinement of such tools and technologies with the end-user community with an end-goal of scaling manufacture towards reliable, broad, sustainable dissemination and incorporation into regular neuroscience practice.

J. Novel informatics tools to facilitate the sharing of complex data sets between laboratories.

K. Novel tools for investigating brain-derived GPCRs in mental health research.

Division of Developmental Translational Research (DDTR)

A. Develop, test and validate reliable and stable biomarkers that can identify at-risk individuals prior to disease onset, improve diagnosis, predict treatment response, or measure disease progression. Biomarkers are also needed in clinical trials to identify dose ranges, to identify a specific subpopulation of subjects to enroll in a treatment trial, or to measure efficacy or toxicity/side effects.

B. Develop novel and targeted interventions (pharmacological, cognitive, behavioral, computer, or device-based) that affect particular neural circuits and signaling pathways relevant to the developmental trajectory of the disease.

C. Based on expanded knowledge of neurobehavioral trajectories, develop novel objective assessment tools that can identify early signs of risk or onset of recurrence of particular mental disorders or in domains of functioning (see MH's RDoC project: http://www.nimh.nih.gov/research-funding/rdoc/index.shtml) for pediatric populations.

D. Develop computational behavioral assessment tools that can be used across ages, species, and cultures to evaluate dysfunction in domains relevant to mental disorders (e.g., mood dysregulation, deficits in executive function).

E. Develop computational platforms to enable the integration and sharing of data characterizing typical and atypical developmental trajectories in humans and non-human animals.

F. Clinical research tools.

Division of Adult Translational Research and Treatment Development (DATR)

A. Develop valid measures of the various constructs in the Research Domain Criteria (RDoC) matrix (see http://www.nimh.nih.gov/research-funding/rdoc/index.shtml), e.g., neurocognitive tasks, psychometrically sophisticated questionnaires, measures of behavior, and biomarkers, into a commercial product.

B. Conduct early stage, proof of concept clinical trials to advance the development of novel therapeutics. The clinical trials are expected to include biological/behavioral data to assess target engagement and to help determine potential success or failure of the compound before moving on to larger clinical trials (see NOT-MH-11-015 http://grants.nih.gov/grants/guide/notice-files/NOT-MH-11-015.html).

C. Develop, test and validate reliable and stable biomarkers that can identify at-risk individuals prior to disease onset, improve diagnosis, predict treatment response, or to measure disease progression. Biomarkers are also needed in clinical trials to identify dose ranges, to identify a specific subpopulation of subjects to enroll in a treatment trial, or to measure efficacy or toxicity/side effects.

D. Develop clinical risk assessment instruments that encompass multiple domains (e.g., genetic, neurobiological, and environmental), are sensitive to developmental stage, and have high predictive power for the onset or recurrence of mental illness.

E. Develop novel and targeted interventions (pharmacological, behavioral, or devices) that affect particular neural circuits and signaling pathways relevant to the developmental trajectory of the disease.

F. Develop electronic sensors, monitoring devices and systems, and data analysis software for automated detection and diagnosis of mental disorders and key transdiagnostic dimensions of psychopathology.

G. Develop risk assessment measures, methods and paradigms capable of evaluating individualized risk for developing mental disorders, or for developing particular benefits or harms during treatment for mental disorders, and communicating such probabilistic information to patients and their families in a readily understandable manner.

H. Clinical research tools.

Division of AIDS Research (DAR)

A. Develop and test novel, non-invasive diagnostic approaches (instrumentation, imaging, biomarkers, central nervous system [CNS] cell-based *in vitro* models) to detect neurocognitive dysfunction associated with HIV-1 infection and innovative technologies to study the mechanisms involved in HIV-1 associated neuropathogenesis and persistence of HIV-1 in the CNS or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy.

B. Design and test novel therapeutic strategies aimed at amelioration of HIV-1 associated neurocognitive disorders (HAND) and eradication of HIV-1 from CNS reservoirs or strategies to prevent viral resurgence in the CNS upon cessation of anti-retroviral therapy.

C. Discover and develop innovative technologies for targeting therapies to the brain, including antiretroviral drugs, nanotechnology, imaging tools to study HIV-aging interactions or HIV-related neurodegeneration and neuroprotective strategies with improved capability to cross the blood-brain barrier for amelioration of HAND.

D. Design new strategies to reduce adverse effects of anti-retroviral drugs such as neuropsychiatric side effects and drug-drug interactions.

E. Develop or adapt neurological/neuropsychological/neurobehavioral assessments to evaluate HIV-1 associated abnormalities in adults or children in resource poor environments that are adaptable to different cultures and languages.

F. Develop innovative approaches to improve the scientific assessment of HIV sexual risk behavior or medication adherence through wireless technologies, remote sensing devices, biomarkers, or other novel methods..

G. Develop and test tools, curricula, and strategies that seek to reduce documented racial/ethnic, gender, and age-related disparities in HIV infection or in HIV treatment adherence and treatment outcomes.

H. Develop novel tools and approaches to identify, recruit, enroll, and/or retain those most vulnerable to HIV/AIDS (e.g., African-American MSM, adolescents) in HIV prevention research and/or initiatives.

I. Develop and test tools, curricula, or other approaches designed to facilitate the effective implementation of emerging biomedical HIV prevention methods (e.g., pre-exposure prophylaxis, microbicides, circumcision, etc.), including but not limited to approaches that address behavioral aspects of biomedical prevention (e.g., provider knowledge and training; patient uptake, adherence, HIV screening, and risk-reduction counseling; adverse event monitoring, etc.).

J. Develop or adapt and evidence-based HIV sexual risk reduction, psychosocial coping, or treatment adherence interventions for delivery through the internet or mobile devices, with the aim of expanding intervention access, fidelity of delivery, and/or intervention tailoring.

K. Develop novel tools and approaches designed to improve HIV treatment outcomes by rapidly linking individuals diagnosed with HIV to primary medical care, enhancing patient readiness for initiation of antiretroviral medications, improving and sustaining patient adherence to antiretroviral medications, and/or improving patient retention in medical care.

L. Develop innovative approaches designed to improve the quality of HIV testing, (including rapid home based HIV antibody tests), HIV counseling, prevention, and treatment services by strengthening patient-provider communication and/or modifying the decision-making processes and practice behaviors of health care providers.

M. Develop innovative approaches designed to improve the uptake and understanding of rapid home based HIV antibody tests by key populations at higher risk for HIV as well as innovative interventions that can be paired with home test kits to increase linkage and engagement in HIV care for those testing positive.

N. Develop novel information technology tools designed to improve dissemination of evidence-based interventions and assist healthcare providers, community-based organizations, and professional or advocacy organizations in identifying, adopting, and implementing proven HIV prevention and treatment interventions.

Division of Services and Intervention Research (DSIR)

A. Randomized clinical trials evaluating the effectiveness of known efficacious interventions.

B. Analyses of naturalistic databases to evaluate the effectiveness of known efficacious interventions.

C. Identifying moderators and mediators of intervention effects as a step to design and test personalized interventions.

D. Evaluating the combined or sequential use of interventions.

E. Determining the optimal length of intervention, establishing the utility of continuation or maintenance treatment (that is, for prevention of relapse or recurrence).

F. Evaluating the long-term impact of efficacious interventions on symptoms, functioning, and quality of life.

Services research covers all mental health services research issues across the lifespan and disorders, including but not limited to:

A. Services organization, delivery (process and receipt of care), and related health economics at the individual, clinical, program, community and systems levels in specialty mental health, general health, and other delivery settings (such as the workplace).

B. Interventions to improve the quality and outcomes of care.

C. Enhanced capacity for conducting services research.

D. The clinical epidemiology of mental disorders across all clinical and service settings.

E. The dissemination and implementation of evidence-based interventions into service settings.

NATIONAL INSTITUTE ON MINORITY HEALTH AND HEALTH DISPARITIES (NIMHD)

A. Telehealth technologies for remote diagnosis and monitoring.

B. Telemedicine to improve access to specialty care which would normally not be accessible because of high cost and transportation. This would also link up academic tertiary-oriented health centers with community-based primary care homes.

C. Use of currently available technology (e.g. phone lines, televisions with remote controls, cellphones, weight scales, diabetic glucometers, thermometers) within underserved settings to provide self-management and patient education, increase patient-clinician communication and surveillance of chronic disease conditions.

D. Improved early detection (via saliva testing, breath testing, blood testing) of diseases where there are significant health disparities.

NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE (NINDS)

The NINDS accepts a broad range of small business applications that are significant, innovative, and relevant to its mission. Examples of research topics within the mission of NINDS are shown below. This list is not all inclusive and some research areas fall into multiple categories.

1. Therapeutics and Diagnostics Development for Neurological Disorders, including biomarker and diagnostic assays, therapeutics (drugs, biologics, and/or devices) for treatment of neurological disorders, and technologies/methodologies to deliver therapeutics to the nervous system.
2. Clinical and Rehabilitation Tools, including intraoperative technologies for neurosurgeons, rehabilitation devices and programs for neurological disorders, and brain monitoring systems
3. Technology and Tools, including technologies to image the nervous system, neural interfaces technologies, and tools for neuroscience research and drug development.

Within these research topics, the following research may require additional funds above the hard budget caps:

A. *In vivo* animal testing required for therapeutics and diagnostics development.

B. Drug and biologics preclinical discovery and development activities for regulatory submission, such as lead identification/optimization, preclinical efficacy testing, IND-enabling studies, and manufacturing for clinical trials.

C. Device preclinical discovery and development activities for regulatory submission, such as hardware prototyping, device/software verification, biocompatibility/sterilization testing, pre-clinical efficacy testing, large animal GLP safety testing, and preparing material/devices for human testing.

D. Clinical testing of therapeutics (drugs, devices, or biologics), diagnostics, clinical and rehabilitation tools (i.e. intraoperative technologies, rehabilitation devices and programs, and brain monitoring systems), and technologies for clinical research. This would include clinical research studies to test scientific hypothesis that are not feasible or practical to conduct in animal models but would inform a final device design.

E. *In vivo* animal testing of technologies for animal research and development of animal models for drug development and neuroscience research.

F. Research that requires special facilities to contain hazardous or infectious materials.

NATIONAL INSTITUTE OF NURSING RESEARCH (NINR)

Research and Development of Technologies for Health Promotion and Alleviation, Adaptation to, or Management of Symptoms

A. Technologies to be used in the hospital, long-term care, hospice, assisted living facility, or home setting that improve symptom diagnosis, evaluation and management in persons with chronic conditions.

B. Devices that improve the acceptance and use of assistive and monitoring devices.

C. Devices to diagnose and screen for COPD early in the course of the disease, particularly targeting young adults.

D. Technologies to assist in health promotion and prevention activities across the lifespan.

E. Devices to assist in providing palliative care for patients with life threatening illnesses through the disease trajectory whether in active treatment or at the end of life.

F. Technologies to assist individuals in reducing environmental exposures, i.e., chemical, bacterial and viral agents, and indoor/outdoor allergens.

G. Devices to facilitate resource sharing such as: technologies that will enable valid and reliable measurement tools/instruments to be readily available and shared by research scientists focused on similar issues in a variety of populations.

H. Adaptation of existing or development of new technologies that will link under-represented and/or underserved populations with available resources to sustain healthy life styles and eliminate health disparities.

I. Devices to measure and monitor effect of physical activity on symptom improvement.

Research and Development of Technologies to Enhance Self Care and Clinical Care

A. Technologies to assist patients to adhere to chronic regimens such as reminding children to take steroid inhalers during the day for asthma; alerting obese adults when high calorie and fat content foods are about to be eaten; adhering to medication regimens; and prompting sedentary adults to exercise.

B. Devices that improve delivery of care to persons who have restricted or impaired movement due to (1) conditions of neurological disease or injury, peripheral vascular disease, rheumatoid disease, or intractable pain, (2) life sustaining equipment, such as dialysis machines or left ventricular assist devices, or (3) orthopedic fixation devices.

C. Devices to enable providers and or research scientists to monitor successful adherence to complex medication regimens (e.g., Highly Active Anti-Retroviral treatment).

D. Technologies that monitor short and long term self-care behavior changes.

E. Biological and behavioral monitoring devices for patients in at-risk and underserved populations in rural and frontier areas that will enable access to clinical care.

F. Telehealth and mHealth technologies to improve patient outcomes through increasing quality, type, and speed of health information sharing, e.g., assessing traumatic injury severity at remote sites and transmitting this information to acute care settings for assessment and evaluation; communicating signs and symptoms of clients at home to health care providers in

distant locations; tailoring care for diverse patients in a wide variety of settings, and promoting community interventions to eliminate health disparities.

G. Technologies to treat chronic wounds that fail to heal, specifically decubitus ulcers, venous stasis ulcers, and diabetic ulcers.

H. Technologies to be used in the hospital or home care setting to monitor or assess preterm, low-birth weight or other high-risk infants.

I. Technologies to assist informal caregivers in providing care or assistance to family members in the home.

J. Noninvasive devices to assess exposure to chemical, bacterial and viral agents for children and adults and transmit this information to health care personnel for assessment and evaluation.

K. Technologies to disseminate research information (i.e., biobehavioral responses, communication of risk, bioethics) to nurses practicing in emergency settings and in the community.

L. Technologies and informatics-based solutions that promote health, including comprehensive high-throughput technologies.

M. Develop and creatively apply new and existing knowledge to the implementation of health information technology, including electronic health records.

N. Health care technologies to facilitate decision support, self-management, and access to health care.

O. Utilization of genetic and genomic technologies to advance knowledge of the “symptome” including the biological underpinnings of symptoms associated with chronic illness.

Other Research Topic(s) Within the Mission of the Institute

A. ***Micro- and Nano-Systems, Platform Technologies.*** Development of BioMEMS, microfluidics and nanoscale technologies, including micro-total analysis systems, arrays, and biochips, for detection and quantitation of clinically relevant analytes in complex matrices. Application areas include biomedical research, clinical laboratory diagnostics, biodefense, high-throughput screening, drug delivery, tissue engineering, and implantable devices, among others.

B. ***Nanotechnology.*** Research and development of new enabling technologies for the fabrication and use of nanoscale components and systems in diagnostic and therapeutic applications. Examples include: development of new nanoscale patterning and manipulation systems; new approaches to the sensing and quantification of biologically important molecules using nanoscale specific properties; studies relating to the safety and commercialization of nanotechnology-enabled biomedical products.

NATIONAL LIBRARY OF MEDICINE (NLM)

A. Technology development and applications to improve storage, retrieval, access, management and use of biomedical knowledge

B. Computational representation of biomedical knowledge

C. Enhancement of human intellectual capacities through virtual reality, artificial intelligence, and machine learning

D. *In silico* science

E. Natural language understanding

F. Support for health decisions

G. Integration, organization and retrieval in very large databases, disparate forms of knowledge, and multiple datasets

H. Investigations of topics relevant to health information science, computational modeling, and management of information during disasters

DIVISION OF PROGRAM COORDINATION, PLANNING, AND STRATEGIC INITIATIVES (DPCPSI), OFFICE OF RESEARCH INFRASTRUCTURE PROGRAMS (ORIP)

RESEARCH AND DEVELOPMENT IN COMPARATIVE MEDICINE

A. Development of new technologies to rapidly phenotype large number of animals.

B. Development of technologies to identify biomarkers for clinical diagnostics in well validated disease models.

C. Development of vaccines and new therapeutic agents to prevent and/or control selected laboratory animal diseases. One high priority need is to develop methods to control and prevent Herpes virus B in nonhuman primates.

D. Design of specialized equipment and caging for laboratory animals to permit optimal environmental control and operational efficiency, including improvements in caging and remote monitoring in animal facilities.

E. Identification, development, and characterization of spontaneous and engineered vertebrate animal models for studies of various human diseases, excluding most random mutagenesis projects performed on rodents.

F. Development and refinement of high throughput technologies and devices for the effective cryopreservation, long-term maintenance, and monitoring of stem cells and laboratory animal embryos, gametes, and their predecessors.

G. Development of improved reagents, techniques, and equipment to perform, analyze, capture and process data gathered in “omics” studies (genomics, transcriptomics, phenomics, proteomics, glycomics, epigenomics, metabolomics) in normal and disease-condition animal models.

H. Development of biological tools and reagents for reconstruction, remodeling, repair and regeneration of tissues damaged by injury or disease. Development of the technologies and procedures to test efficacy and safety of these experiments in animal models. Approaches to detect and track the implanted cells and tissues *in vivo*.

I. Development of new technologies in animal/cell models to study the function (activation/silencing) of noncoding DNA or RNA regions in the development of diseases.

J. Development of acellular biomaterials, biosensors and reagents to promote, detect and track reconstruction, remodeling, repair and regeneration of tissues damaged by injury or disease.

Other Research Topic(s) within the Mission of the Office of Research Infrastructure Programs

A. Development of methodologies, diagnostics, technologies, equipment, assay systems and portable devices that can be used in community settings, such as health centers, neighborhood clinics, doctor offices, public schools, libraries, and rural and remote locations to facilitate biomedical and behavioral research;

B. Development of culturally appropriate educational materials for student, teacher and community health literacy and disease prevention/intervention such as: software, videos, printed material to facilitate translation and dissemination of evidence-based health information;

C. Innovative applications of health information technology, including telemedicine/telehealth tools and technologies, to facilitate electronic health information exchange, enable clinical research at the point of care, and improve access to quality health care for hard to reach populations; and

D. Development of Serious science, technology, engineering and mathematics (STEM) Games with a biomedical focus that will complement teacher professional development, improve student achievement, career aspirations and expand community health literacy.