

Domestic Assurance Sample Document

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)) requires that institutions have an OLAW-approved Animal Welfare Assurance before carrying out any activities involving live vertebrate animals. U.S. institutions receiving PHS funds through a grant or contract award are to use the Animal Welfare Assurance for Domestic Institutions (Domestic Assurance).

The Domestic Assurance should **not** be used by:

- Foreign institutions
- Institutions that currently do not have their own animal care and use programs
- Institutions that are proposing animal activity to be conducted solely at a collaborating institution

If one of these bullets describes your institution or if you don't know whether your institution is required to submit an Assurance, contact us at olawdoa@mail.nih.gov for guidance.

How to use the sample document

We have provided this sample document to help you develop an acceptable Domestic Assurance. Specific instructions, information, and recommended references are provided in italicized text and should be deleted from the final document. Please strive for clear concise text. It will be easier for you to complete and for us to review the Assurance if you follow the format of this sample.

One or two page attachments can be used to provide the following:

- Organizational structure of the animal care and use program
- IACUC membership roster
- Facility and species inventory
- Most recent semiannual report of program and facilities. This is needed **only** for Category 2 programs, those not accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

All other program elements are to be described in the body of the Assurance. Do not send any other attachments. We do not accept additional documents, appendices, binders, or manuals.

Tip: If you are not familiar with the PHS Policy or are preparing an Assurance for the first time, we encourage you to visit the [PHS Policy Tutorial](#).

How to submit

Fax your completed Assurance to 301-915-9465 or e-mail to olawdoa@mail.nih.gov

Questions?

Contact the Division of Assurances by phone at 301-496-7163 or e-mail olawdoa@mail.nih.gov

Additional references

- Domestic Assurance webpage, <http://grants.nih.gov/grants/olaw/sampledoc/assur.htm>
- Online Seminar "Writing a Good Assurance," http://grants.nih.gov/grants/olaw/educational_resources.htm#online-seminars
- OLAW homepage, <http://grants.nih.gov/grants/olaw/olaw.htm>
- PHS Policy, <http://grants.nih.gov/grants/olaw/references/phspol.htm>

[NAME OF INSTITUTION]

[Insert Assurance number here if this is a renewal, e.g., A3000-01.

For new Assurances, a number will be assigned at approval.]

Animal Welfare Assurance for Domestic Institutions

I, [Insert the name of Institutional Official] as named Institutional Official for animal care and use at [Name of Institution], provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

I. Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS. This Assurance covers only those facilities and components listed below.

- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:

[List every branch and major component covered by the Assurance.]

- B. The following are other institution(s), or branches and components of another institution:

[List the names of other institutions, or branches and components of other institutions. They must be recipients of PHS funding or pending PHS award.]

[Note: only those entities listed in this section will be entitled to use the Assurance number for grant and contract submissions to PHS agencies.]

Recommended References:

- o [Antibody production](#)
- o [Avian embryos](#)
- o [Foreign collaborations and performance sites](#)
- o [Non-PHS funded activities](#)
- o [Non-research activities](#)

II. Institutional Commitment

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.](#)"
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.

Recommended Reference:

- o [Distribution of Assurance within Institution](#)

- D. This Institution has established and will maintain a program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).

Recommended Reference:

- o [Use of the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching](#)

- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are as follows:

[Insert or attach a description or organizational chart for these components:

- *chief executive officer*
- *Institutional Official*
- *IACUC*
- *veterinarian*
- *animal facility management*

Note: the description or chart must demonstrate the direct reporting structure and lines of communication from the IACUC to the Institutional Official and from the Veterinarian to the Institutional Official.]

Recommended References:

- o [Effective administrative organizations](#)
- o [Difference between Chief Executive Officer and Institutional Official](#)

- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Name: *[Enter veterinarian's name]*

Qualifications

- Degrees:

[Enter professional degrees and certifications]

- Training or experience in laboratory animal medicine or in the use of the species at the institution:

[Briefly describe training or experience in laboratory animal medicine or the species being used. Do not include or attach a CV.]

Authority: Dr. *[enter veterinarian's name]* has *[specify direct or delegated]* program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

[If full time, enter "full time employee" and the percentage of time contributed to the animal care and use program.

If part time or if a consulting veterinarian is used, enter the approximate number of hours per week or month and the percentage of those hours contributed to the animal care and use program.]

[Note: if there is more than one veterinarian associated with the program; provide the information below for each.

If only one veterinarian is associated with the program, describe provisions in place for a back-up veterinarian.]

2) Name: [Enter veterinarian's name]

Qualifications

- Degrees:
[Enter professional degrees and certifications]
- Training or experience in laboratory animal medicine or in the use of the species at the institution:
[Briefly describe training or experience in laboratory animal medicine or the species being used. Do not include or attach a CV.]

Responsibilities:

[Describe authority and responsibilities]

Time contributed to program:

[If full time, enter "full time employee" and the percentage of time contributed to the animal care and use program.

If part time, enter the approximate number of hours per week or month and the percentage of those hours contributed to the animal care and use program.]

Recommended References:

- o [ACLAM Guidelines on Adequate Veterinary Care. \(PDF\)](#)
- o [Description of the responsibilities and qualifications of the veterinarian.](#)

- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations.

[Complete the IACUC membership table provided (see Part VIII.).

Note: for nonaffiliated members, list specific position titles (e.g., banker, teacher, volunteer fireman; not "community member" or "retired")

Note: names of members, other than the chairperson and veterinarian, may be represented by a number or symbol.]

Recommended References:

- o [ARENA/OLAW IACUC Guidebook \(PDF\)](#)
- o [Consulting veterinarian's affiliation with the Institution](#)
- o [Membership requirements](#)
- o [Multiple IACUC positions filled by the same individual](#)
- o [Reimbursement of nonaffiliated member](#)
- o [Maintenance of properly constituted IACUC](#)

D. The IACUC will:

- 1) Review at least once every 6 months the Institution's program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

[Describe how the IACUC conducts the semiannual program reviews. For example, who performs the reviews, what items are included, where, when, and how those items are reviewed, and if a checklist is used.]

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

[Describe how the IACUC conducts the semiannual facility inspections. For example, who performs the inspections, what areas are inspected, and if a checklist is used.]

Recommended References:

- [Sample Semiannual Program and Facility Review Checklist](#)
- [Inspections of laboratories and other animal sites](#)
- [Inspections of facilities housing animals for 12 hours](#)
- [Sites/study areas where animals are housed only sporadically or for less than 24 hours](#)

- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

[Describe the following procedures:

- *How the IACUC develops, approves, and submits the semiannual reports of the program review and facility inspection to the Institutional Official*
- *How the IACUC identifies and approves departures from the PHS Policy and the Guide*
- *How the IACUC identifies and corrects deficiencies*

Specify what is to be reported such as:

- *The institutions adherence to the PHS Policy and the Guide*
- *IACUC-approved departures from the PHS Policy and the Guide and reason for each departure*
- *Identification of deficiencies and designation as either minor or significant*
- *Schedule and plan for correcting deficiencies*
- *Minority views]*

Recommended References:

- [Sample format for the semiannual report to the Institutional Official](#)
- [Distinguishing minor deficiencies from significant deficiencies and reporting deficiencies to the Institutional Official](#)

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

[Describe the following:

- *Mechanisms that facilitate/enable individuals to report concerns*
- *How the IACUC reviews reported concerns*
- *How the IACUC reports concerns and relates findings and recommendations to the Institutional Official]*

- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

[Describe how the IACUC develops, approves, and submits written recommendations to the Institutional Official regarding any aspect of the Institution's animal care and use program, facilities, or personnel training.]

- 6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

[Describe how the IACUC conducts protocol review, from initial receipt of the protocol through approval of the activity. Include details such as:

- *How protocols are received*
- *The pre-review or initial screening process, if one is used*
- *How members are notified*
- *How materials are distributed to members*
- *How meetings are conducted*
- *The methods of protocol review (full committee and/or designated member), including a description of the process and possible outcomes*
- *How conflicts of interest are handled*
- *The voting process*

- Also, include descriptions of any alternate processes or procedures for special or expedited reviews]

Recommended References:

- o [Guidance on use of telecommunications for IACUC meetings](#)
- o [Methods of IACUC review](#)
- o [Use of designated member review subsequent to full committee review](#)
- o [Correct Conduct of Full Committee and Designated Member Protocol Review](#)
- o [Expedited review](#)
- o [Scientific merit review](#)
- o [Tracking the number of animals used](#)
- o [Use of cold-blooded vertebrates](#)
- o [Quorum and attendance of nonaffiliated member and veterinarian](#)

- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

[Describe how the IACUC reviews proposed significant changes in previously approved activities.

Note: review and approval of proposed significant changes must comply with the same requirements as review and approval of new protocols under PHS Policy IV.C.]

Recommended Reference:

- o [Significant changes to approved protocols](#)

- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

[Describe how the IACUC notifies investigators and the IO of its decisions regarding protocol review.

Describe what happens if the IACUC withholds approval.]

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

[Describe how the IACUC monitors ongoing activities (postapproval monitoring).

Describe how the IACUC conducts a complete review of previously approved protocols at least every 3 years.

Describe the annual review process for USDA covered species, if applicable.]

Recommended References:

- o [Postapproval monitoring](#)
- o [Model for Performing Continuing Review of Research Activities](#)
- o [Frequency of review](#)
- o [Annual review \(USDA\) vs. triennial review \(PHS\)](#)

- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

[Describe how the IACUC suspends an ongoing activity.

Describe how the IO reports an IACUC suspension to OLAW.]

- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

[Describe the Institution's occupational health and safety program for personnel involved in the care and use of animals. Refer to the following relevant topics listed in the Guide:

- Control and prevention strategies
- Hazard identification and risk assessment
- Facilities, equipment, and monitoring
- Personnel training
- Personal hygiene
- Animal experimentation involving hazards
- Personal protection
- Medical evaluation and preventive medicine for personnel (including immunizations, vaccinations, and procedures for reporting and treating bites, scratches, and injuries.)
- Where appropriate, describe special precautions for personnel working with nonhuman primates (e.g., tuberculosis screening, training and procedures for bites and scratches, and education regarding Macacine herpesvirus 1, formerly Cercopithecine herpesvirus 1 (Herpes B)).

Note: do not reference or send attachments.]

Recommended References:

- o [Institute of Laboratory Animal Resources Occupational Health and Safety in the Care and Use of Research Animals, 1997](#) 
- o [Employee health issues](#)
- o ["Occupational Health and Safety Programs"](#)

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

[Complete the Facility and Species Inventory table provided (see Part X.).

Note: list common names for animal species, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog.

Note: animal areas (buildings/rooms) may be represented by a number or symbol in this submission to OLAW.]

- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

[Describe training or instruction provided to people caring for or using laboratory animals in the proper and humane animal care and use.

Describe training or instruction on research or testing methods that minimize the number of animals required to obtain valid results and limit animal pain and distress.

Describe training or orientation provided to the IACUC members, including background materials and resources.

Note: do not reference or send attachments.]

Recommended References:

- o [Training in the Laboratory Animal Science Community: Strategies to Support Adult Learning, 2007](#) 
- o [Employee training programs](#)

IV. Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual

reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

[From the following two paragraphs, retain the one that is applicable and delete the one that is not applicable.]

- (1) This Institution is Category 1 — accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request.

*** OR ***

- (2) This Institution is Category 2 — not accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached.

[For Category 2 only, attach the most recent semiannual program review and facility inspection report.]

Recommended Reference:

- o [Sample semiannual report to the Institutional Official](#)

V. Recordkeeping Requirements

- A. This Institution will maintain for at least 3 years:
 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, *[Insert name or title of the Institutional Official signing the Assurance]*.
 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

VI. Reporting Requirements

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
 2. Any change in the description of the Institution's program for animal care and use as described in this Assurance
 3. Any change in the IACUC membership
 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's program and facilities (including satellite facilities) and submitted the evaluations

to the Institutional Official, [*Insert name or title of the Institutional Official signing the Assurance*].

5. Any minority views filed by members of the IACUC

[*Note: if there are no changes to report, provide written notification that there are no changes.*]

Recommended References:

- o [Reporting of modifications to facilities/programs in annual report to OLAW](#)
- o [Sample annual report to OLAW](#)
- o [Annual reporting requirements](#)

- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
 1. Any serious or continuing noncompliance with the PHS Policy
 2. Any serious deviations from the provisions of the *Guide*
 3. Any suspension of an activity by the IACUC

Recommended References:

- o [Guidance on prompt reporting, NOT-OD-05-034](#)
- o [OLAW and APHIS: Common Areas of Noncompliance, Lab Animal, 2000: 29\(5\)32-37 \(PDF - 65 KB\)](#)
- o [Reporting sanctions to non-PHS funded activities](#)
- o [Guidance on allowable costs, NOT-OD-07-044](#)

- C. Reports filed under VI.A. and VI.B. above should include any minority views filed by members of the IACUC.

VII. Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name:	
Title:	
Name of Institution:	
Address: <i>(street, city, state, country, postal code)</i>	
Phone:	Fax:
E-mail:	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature:	Date:

B. PHS Approving Official <i>(to be completed by OLAW)</i>	
<p>Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465</p>	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

* This information is mandatory.

** Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

*** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

**** [PHS Policy](#) Membership Requirements:

Veterinarian veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.

Scientist practicing scientist experienced in research involving animals.

Nonscientist member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).

Nonaffiliated individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[*Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.*]

IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

Contact #1	
Name:	
Title:	
Phone:	E-mail:
Contact #2	
Name:	
Title:	
Phone:	E-mail:

