



Electronic Research Administration
A program of the National Institutes of Health



National Institutes of Health
Office of Extramural Research

Inclusion Management System (IMS) User Guide for Internal Agency Staff

System Version 1.9.2

Document Version 1.3.0

July 17, 2015



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DOCUMENT HISTORY

Date	System Version	Document Version	Description of Change	Author
Oct. 17, 2014	1.0.0	1.0.0	Initial publication of document	eRA Communications
Jan. 30, 2015	1.7	1.1.0	Updated to include new features as reported in release notes for January 2015 quarterly release .	eRA Communications
April 17, 2015	1.8.2	1.2.0	Updated to include new features as reported in the release notes for April 2015 quarterly release .	eRA Communications
July 17, 2015	1.9.2	1.3.0	Updated to include new features as reported in the release notes for July 2015 quarterly release.	eRA Communications

The most current version of this document will be available on the eRA Federal Intranet site: <http://inside.era.nih.gov>.

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1 Introduction to Inclusion Management System (IMS)

The inclusion of women and minorities in clinical research is mandated by law (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2) and [NIH policy](#). Regardless of source of NIH support (e.g., intramural, extramural, contract, grant, cooperative agreement, etc.), all studies that meet the [NIH definition for clinical research](#) must address plans for the inclusion of women and minorities, provide a planned enrollment report (or cumulative report if working with an existing dataset) breaking down the sample by sex/gender, race, and ethnicity, and report at least annually on inclusion enrollment progress.

POLICY AND RELATED RESOURCES:[NIH Policy on the Inclusion of Women and Minorities in Clinical Research](#).

The Inclusion Management System (IMS) supports monitoring and oversight of inclusion data, taking advantage of the structured inclusion data being collected on competing applications to pre-populate inclusion data records and allow grantees or Agency staff (in certain circumstances) to directly manage their inclusion data in the system throughout the awarded project period.

With the IMS....

- Inclusion enrollment report forms received with competing application submissions will automatically populate the IMS.
- NIH grantees completing their RPPR (Research Progress Performance Report) will be prompted in Item G.4.b to access and update inclusion records directly in IMS.
- Grantees will be able to access their inclusion enrollment data in IMS via the eRA Commons Status page, and can add, review, or update their inclusion data as needed.
- Ongoing enrollment information from the previous Population Tracking data system has migrated to the IMS (as of October 2014). Due to changes in the report format, grantees will be prompted to update Cumulative Inclusion Enrollment data into the IMS format at the time of the RPPR. They are encouraged to update Planned Enrollment data as well, but are not required to do so.
- Inclusion enrollment (planned and actual) can be entered and managed by staff for contracts involving clinical research.

Inclusion Data Records

An Inclusion Data Record (IDR) typically consists of the planned enrollment, cumulative (actual) enrollment, and the mandatory and optional attributes that further describe the study or study population. IDRs can be created several ways:

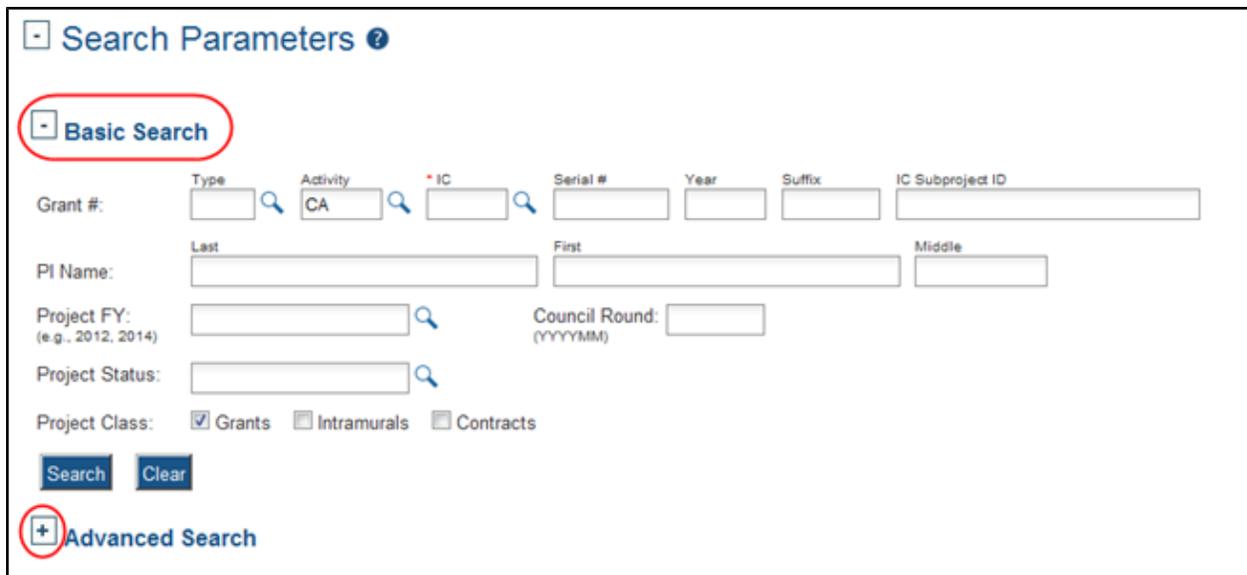
1. An IDR will be created when an enrollment report form is submitted with a competing application through Grants.gov or ASSIST;
2. A grantee may create an IDR directly in IMS through the Commons Status or RPPR screens; and
3. For certain types of funding (e.g., paper grant submissions, contracts, etc.), NIH staff will create an IDR in IMS on behalf of the investigator. Regardless of which avenue for creation of an IDR, NIH staff needs to ensure that the IDR (or IDRs) is set up in the manner appropriate for monitoring inclusion in the context of the science.

2 Search Parameters

The search screen is used to search for and view a set of requested applications or awards and corresponding inclusion data records (IDRs). The screen is divided into two types of searches: Basic and Advanced. In the **Basic Search**, you can query for records using parameters such as grant number, PI name, project status. The **Advanced Search** allows you to enter more detailed search criteria, either specific to the application or award or to the corresponding IDRs. There are three methods of accessing the search screen:

- From within IMS directly
- From Program Module (PGM) via the **Export Hitlist to IMS** button on the search screen
- From QVR by selecting **eRA Modules–Inclusion Management System**

Upon entering the screen from the IMS menu, the **Basic Search** section is expanded. The **Advanced Search** sections can be expanded by selecting the [+] icons displays the parameters in that section.



The screenshot shows the 'Search Parameters' interface. At the top, there is a 'Search Parameters' header with a question mark icon. Below it, the 'Basic Search' section is expanded and highlighted with a red circle. This section contains several input fields: 'Grant #' with a 'Type' dropdown (set to 'CA'), 'Activity' dropdown, 'IC' dropdown, 'Serial #' text box, 'Year' text box, 'Suffix' text box, and 'IC Subproject ID' text box. Below these are 'PI Name' fields for 'Last', 'First', and 'Middle'. There are also 'Project FY' (with examples like 2012, 2014) and 'Council Round' (YYYYMM) text boxes, and a 'Project Status' dropdown. At the bottom of the Basic Search section are 'Project Class' checkboxes for 'Grants' (checked), 'Intramurals', and 'Contracts'. Two buttons, 'Search' and 'Clear', are located below the checkboxes. At the bottom of the screen, the 'Advanced Search' section is collapsed, indicated by a red circle around its '+' icon.

Figure 1: Default View of Search Parameters

To perform a search, enter the appropriate parameters and select the **Search** button. You can reset the search parameters by selecting the **Clear** button. The different search parameters are discussed later in this topic.

PGM When accessing this screen via the Program Module (PGM), the *Search Parameter* fields will be collapsed, and the hitlist automatically displayed to include the project(s) that were requested in the PGM module, including parent project and subprojects. The limit of records

displayed when accessing this screen via PGM is 500. If your PGM search results in more than 500 records, only the first 500 records are displayed.

NOTE: If returning to this page after performing a search and navigating away, hitlist will remain intact from original search.

QVR: IMS and QVR are integrated allowing QVR to send search results to IMS. After performing a search in QVR, you can select the **eRA Modules–Inclusion Management System** option to send the QVR hit list to IMS.

When IMS is accessed via QVR, the search parameter fields are collapsed and the search results pre-populated with the result set from your current QVR search, including all associated components of a project where applicable.

The label **Results include QVR Hit List** appears at the top of the screen to indicate that the results in the hit list correspond to a QVR search. You can use the search parameters to further narrow the results. You can clear the QVR hit list results by selecting the **Clear QVR Hit List** link displayed next to the label.

The QVR label will only display on the search screen if IMS was accessed via QVR. Clearing the QVR hit list removes the label, as well.

The limit of records displayed when accessing via QVR is 500. If your QVR query results contain more than 500 records, only the first 500 display in IMS. IMS will alert you with a warning message when this occurs.

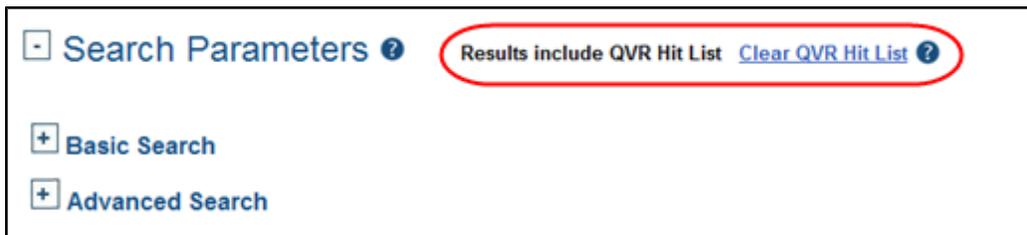


Figure 2: QVR Hit List on IMS Search Parameters

To perform an additional search in IMS (after importing a hitlist from QVR or PGM), enter the appropriate parameters and select the **Search** button. You can reset the search parameters by selecting the **Clear** button. If you are finished with the imported hitlist (from PGM or QVR) and want to perform a search directly in IMS, it is important to press the **Clear** button to ensure that the criteria from the QVR or PGM-imported search are removed.

2.1 Basic Search

Search Parameters ?

Basic Search

Grant #: Type Activity IC Serial # Year Suffix IC Subproject ID

PI Name: Last First Middle

Project FY: Council Round: (e.g., 2012, 2014) (YYYYMM)

Project Status:

Project Class: Grants Intramurals Contracts

Advanced Search

Figure 3: Basic Search Query Parameters

Results include QVR Hit List

Label is displayed on the screen only if you access IMS from QVR. Use the **Clear QVR Hit List** link to remove QVR search results.

Grant

Enter values into the fields or select the lookup icon next to the field to search for a select a value. You may enter/select multiple values.

The **Grant #** field is made up of individual fields representing the components that make up the entire grant number pr intramural project number. When searching by **Grant #**, one or all of the component fields can be used, however, the IC is required when searching by Grant #. The Grant # is comprised of the following:

Type: Represents the type of project, such as new, renewal, etc. To search on this field, enter a value or use the look-up tool to search for and select a value.

Activity: Represents the specific category of support, such as research project, fellowship, etc. To search on this field, enter a value or use the look-up tool to search for and select a value.

IC: Represents the institute/center associated with the project. To search on this field, enter a value or use the look-up tool to search for and select a value. This field is required when searching by **Grant #**.

NOTE: This field is pre-populated with your own IC.

Serial #: A unique number identifying the specific project. To search on this field, enter a value.

Year: Represents the current year of support (e.g., 01 indicates a new project). To search on this field, enter a value.

Suffix: Used for supplements, amendments, or fellowship institutional allowances and not included in all project numbers. To search on this field, enter a value.

IC Subproject ID: The identification number for a subproject. To search on this field, enter a value.

PI Name (Last, First, Middle)

Enter a value into the field(s). If searching by Middle or First Name, Last Name must also be entered.

Project FY

Enter the fiscal year of the project into the field. You may enter multiple years using commas (,) between values.

Council Round

Council Round must be entered in a YYYYMM format.

Project Status

Enter values into the fields or select the lookup icon next to the field to search for a select a value. You may enter/select multiple values.

Project Status values are as follows:

Awarded

Cancelled

Division of Receipt and Referral

NRFC

Pending

Pending Award

Pending Council

Pending IRG

Selected for Resources, no funding involved

Terminated

To be Paid

Unknown

Withdrawn

Project Class

Select the **Grants**, **Intramurals**, and/or **Contracts** checkbox(es) to limit the project class included in your search. This field defaults to Grants only if QVR hit list label is not displayed (to avoid accidental filtering on secondary search) and is not required.

2.2 Advanced Search

The **Advanced Search** area contains a section of parameters specific to projects and one specific to IDRs. A search may be performed using criteria from either or both sections.

The screenshot displays a web interface for search parameters. At the top is a 'Search Parameters' header with a collapse icon and a help icon. Below it is the 'Basic Search' section, which includes several input fields: 'Grant #' with sub-fields for 'Type', 'Activity', 'IC' (containing 'CA'), 'Serial #', 'Year', 'Suffix', and 'IC Subproject ID'; 'PI Name' with sub-fields for 'Last', 'First', and 'Middle'; 'Project FY: (e.g., 2012, 2014)'; 'Council Round: (YYYYMM)'; and 'Project Status'. A 'Project Class' section has three checkboxes: 'Grants' (checked), 'Intramurals', and 'Contracts'. Below these are 'Search' and 'Clear' buttons. At the bottom, a red rounded rectangle highlights three expandable sections: 'Advanced Search', 'Project Fields', and 'IDR Fields', each with a plus icon.

Figure 4: Advanced Search Contains Grant Fields and IDR Fields Sections

2.2.1 Project Fields

The screenshot shows a web interface for search parameters. At the top, there is a 'Search Parameters' header with a help icon. Below it are three expandable sections: 'Basic Search', 'Advanced Search', and 'Project Fields'. The 'Project Fields' section is highlighted with a red rounded rectangle. It contains the following fields: 'Appl ID' (text input), 'Display Paper Applications only' (checkbox), 'Clinical Trial Code' (dropdown), 'Phase III Clinical Trial Code' (dropdown), 'PCC' (text input), 'Inclusion Monitoring Required?' (dropdown), 'FOA' (text input), 'PO Name' (split into 'Last', 'First', and 'Middle' text inputs), and 'Contract Document#' (text input with a small example below it). At the bottom of the form are 'Search' and 'Clear' buttons.

Figure 5: Grant Fields Query Parameters under Advanced Search

Appl ID

The unique, system identifier number assigned to a project. Enter a value into the field.

Display Paper Applications only checkbox

Select this checkbox to return only paper application submissions in your search results. When unchecked, both paper and electronic application submissions are returned.

Clinical Trial Code

Select an option from the drop-down box, **Yes** or **No**.

Phase III Clinical Trial Code

Select an option from the drop-down box to search for that value.

Phase III Clinical Trials Codes are as follows:

X – Not Clinical Research, or unscored; Gender/Minority Codes not assigned

Y – NIH-defined Phase III Clinical Trial

N – Clinical Research – not an NIH-defined Phase III clinical trial

PCC

The Program Class Code on a project. Enter a value into the field. The system returns all similar values without the use of a wildcard (e.g., entering 1A will return 1A123, 1A345, etc.).

Inclusion Monitoring Required

Select an option from the drop-down box, **Yes** or **No**.

Refer to the topic titled [Inclusion Monitoring Required on Page 23](#) for more information on these other Inclusion Monitoring Required values.

Although the search values are limited to *Yes* and *No*, search results will include all matching records beginning with either *Yes* and *No*. Choosing to search on *Yes* could return records with a value of *Yes* or *Yes-POL*, which is for projects that were originally *No* and changed to *Yes* per a policy decision. Searching on *No* could return records with the value of *No*, *No-POL*, *No-DCC*, *No-ISS*, or *No-CTP*. *No-POL* is for projects that were originally *Yes*, but changed to *No* per policy. *No-DCC* (Data Coordinating Center) and *No-ISS* (Individual Site Study) are values used when multiple, separate awards involve the same clinical study(s) and where monitoring will be specified to occur on a specific award(s). *No-CTP* (Contract Tracked on Project) is set automatically for contract parent awards. For contract projects (created in CIMS 1688 module), the values will be *Yes* or *No* based on whether human subjects are involved.

FOA

Enter a valid Funding Opportunity Announcement number into this field.

PO Name (Last, First, Middle)

Contract Document #

Enter a contract document number into this field to search for contracts with this contract document number. The contract document number is part of the contract number. It ties together contracts in different FYs and parent and project contracts. The search will bring contract **parent(s)** and contract **project(s)** for a selected FY (or all FY(s) if FY is not specified). You may enter multiple contract document numbers by using commas (,) between values.

For more information on contracts, refer to the topic titled [Contracts on Page 99](#).

2.2.2 IDR Fields

The screenshot shows a search interface with the following fields:

- Search Parameters (toggle)
- Basic Search (toggle)
- Advanced Search (toggle)
- Project Fields (toggle)
- IDR Fields (toggle, highlighted with a red box)**
 - Foreign Enrollment Flag: dropdown menu
 - Source Unique Value (SUV): text input field
 - IDR #: text input field
 - IDR IC ID: text input field
 - Clinical Trial Code: dropdown menu
 - Phase III Clinical Trial Code: dropdown menu
 - IDR Status: dropdown menu
 - Recruitment Status: dropdown menu
 - Existing Dataset or Resource: dropdown menu
 - No Planned Enrollment Reason: dropdown menu
 - IDR FY: (e.g., 2012, 2014) text input field with search icon
 - Follow Up Flag: dropdown menu
 - Data Quality Control: dropdown menu
- Search and Clear buttons

Figure 6: IDR Fields Query Parameters under Advanced Search

Foreign Enrollment Flag

Foreign/Domestic indicates whether the IDR involves participants from a non-US site (i.e., foreign) or a US site (i.e., domestic). It is a required attribute.

Foreign/Domestic Indicator values are as follows:

Foreign

Domestic

Source Unique Value (SUV)

The Source Unique Value (SUV) is a unique identifier for an IDR, assigned to intramural or contract project, when the IDR is inserted via the contract and intramural web service. The indicator stays consistent from year to year, regardless of IC changes. This information is not editable in IMS. To search for an IDR by its SUV, enter the identifier into the free-text field.

IDR

The **IDR#** is the unique Inclusion Management System-generated identifier for the inclusion data record (IDR). This number remains unchanged throughout the lifetime of the grant. Enter a value in the field to search for that specific IDR.

IDR IC ID

The **IDR IC ID** is an identification number entered by Agency staff as one of the optional IDR attributes. This value is not the same as the system-generated IDR #. This field could be blank if an IDR IC ID number was not assigned.

Clinical Trial Code

Select an option from the drop-down box, **Yes** or **No**. This field indicates whether the specific IDR involves a clinical trial. It is an optional attribute. This field could be blank if the clinical trial code was not assigned by staff.

Phase III Clinical Trial Code

This field indicates whether the specific IDR involves an NIH-defined Phase III clinical trial.

Select an option from the drop-down box.

Phase III Clinical Trials Codes are as follows:

X – Not Clinical Research, or unscored; Gender/Minority Codes not assigned

Y – NIH-defined Phase III Clinical Trial

N – Clinical Research – not an NIH-defined Phase III clinical trial

IDR Status

Select a value from the drop-down box to search for projects with a corresponding Inclusion Data Record with a particular status.

IDR Status values are as follows:

Blank: Default value, returns all

Accepted – Not Rolled Forward: The IDR is either marked as Not Funded or as Type 2 Progress Report. The project is awarded, but the IDR is not rolled forward into an out year record.

Accepted (Original Submission): The IDR has been accepted at award issuance based on what was originally submitted. (Data migrated from the previous data system may also have this status when awarded.)

Accepted (PI Revisions): Grantee has modified the IDR after original submission, but before release of the award

Accepted by Agency: OER has frozen ability to modify inclusion data for IDRs on contracts or intramural projects for the selected FY.

Grantee Updates in Progress: Grantee user has created the IDR; Grantee user has initiated updates on an IDR (Edit Planned or Edit Cumulative); and/or SO has routed an IDR back to the PI

Inclusion Updated: Grantee has updated cumulative (actual) enrollment counts via the RPPR module in Commons

Previous FY Data: Data from previous fiscal year has been rolled forward into the next project record

Pending SO: IDR has been routed to the SO

Received by Agency: IDR form (Planned or Cumulative) has been received as part of the electronic application submission (i.e., Grants.gov/eSub or ASSIST); Grantee user (SO) has routed the IDR via IMS in the Commons Status module to the Agency; Agency user has created a new IDR in IMS; IDR is inserted or updated via web service. This applies to intramural projects and certain contracts.

Received by Agency – RPPR: Grantee user submitted IDR to Agency as part of the Research Performance Progress Report (RPPR)

Requires Updates: Grantee user accessed the inclusion data via the RPPR module in Commons; Grantee user has created a new Planned Inclusion Form via the RPPR module in Commons

Recruitment Status

Select a value from the drop-down box to search for projects and corresponding Inclusion Data Records with a specific study recruitment status. Note that this is an optional attribute that may not be populated. Search values are as follows:

Blank: Default value, returns all

Not yet recruiting: Participants are not yet being recruited

Recruiting: Participants are currently being recruited

Enrolling by invitation: Participants are being (or will be) selected from a predetermined population

Active, not recruiting: Study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled

Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred)

Suspended: Recruiting or enrolling participants has halted prematurely but potentially will resume

Terminated: Recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated

Withdrawn: Study halted prematurely, prior to enrollment of first participant

Existing Data Set

If there are questions regarding the definition of an existing dataset or resource, please refer to the following FAQ: http://grants.nih.gov/grants/funding/women_min/datasets_faq.htm

Existing Dataset values include:

Yes

No

No Planned Enrollment Reason

The **No Planned Enrollment Reason** indicates why there is no planned enrollment data for the Inclusion Data Record (i.e., planned enrollment counts are equal to zero).

Valid values are as follows:

Blank

TS Phase I Toxicity Study

Delayed On-Set

IDR FY

Fiscal year of the IDR.

Enter values into the fields or select the lookup icon next to the field to search for a select a value. You may enter/select multiple values.

Follow Up Flag

Select an option from the drop-down box, **Yes** or **No**.

Yes: Returns only projects marked for follow-up by Agency staff. Parent grants marked for

follow-up will result in all subprojects displayed in results even if not all subprojects are marked for follow-up.

No: Returns only projects not marked for follow-up by Agency staff. Parent grants not marked for follow-up will result in all subprojects displayed in results regardless of whether those subprojects are marked for follow-up or not.

Blank: No selection will return all matching records regardless of follow-up indication.

Data Quality Control Query

When performing a search using a **Data Quality Control Query** parameter, the **Project FY** is also required, and you must enter a value into the **Project FY** field.

Select an option from the drop-down list.

Blank: Default value, returns all records.

Delayed On-set: Query for all IDRs flagged as delayed on-set

Foreign countries exist for domestic IDR: Query for all grants including all their subprojects where IDR(s) exist with Foreign/Domestic indicator set to Domestic, but foreign countries are entered in the system on the country list

Inclusion monitoring is NOT required, but IDR(s) exist: Query for all projects including all their subprojects where the Inclusion Required flag for the parent is *No* or *No-POL*, but IDR(s) are present in the system, excluding Delayed On-set IDRs

Inclusion monitoring is required, but IDR(s) don't exist: Query for all projects (including all their subprojects) where the Inclusion Required flag for the parent is *Yes* or *Yes-POL*, but IDR(s) are not present in the system, excluding Delayed On-set IDRs

Inconsistent Phase III Clinical Trial Codes at Project and IDR Levels: Phase III Clinical Trial Code on project level is set to *N* or *X*, but this code on IDR level is set to *Y*

Manually updated Inclusion Required field: Query for all grants including all their subprojects where Inclusion Required field has been manually updated by OER

Not Funded: Query for grants having an IDR(s) that will not be funded. Not Funded IDRs are not rolled forward into the out year record. At the time of award, the status of the *not funded* IDR is updated to *Accepted – Not rolled forward*.

Zero Enrollment: Query for all IDRs with zero cumulative (actual) inclusion enrollment

Zero Planned: Query for all IDRs with zero planned enrollment

Zero Planned and Enrollment: Query for all IDRs with zero planned and actual enrollment

Zero Planned, Not Delayed On-set: Query for all IDRs with zero planned enrollment and not flagged as a delayed on-set study

2.3 Search Results

Projects and their corresponding IDRs that match the entered search parameters –or were selected from PGM, GM, or QVR – will display in the hitlist at the bottom of the screen. The number of matching records is capped at 500, with 50 records displayed per page. Pagination links appear at the top and bottom of the results hitlist for navigating to additional records.

Flag	Project#	Any IDR in Received by Agency Status?	FY	PI Name	HS	Inclusion Monitoring Required?	PCC	PO Name
<input type="checkbox"/>	1R01CA123456-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	Austen, Jane	20	Yes	2PIM	Bennet, Elizabeth
Project Title: Pride & Prejudice and the Human Psyche								
<input type="checkbox"/>	1R01CA654321-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	CRANE, STEPHAN	E2	Yes	3XCM	Fleming, Henry
Project Title: The Red Badge of Courage and Other Skin Anomalies								
<input type="checkbox"/>	1R01CA222222-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	DOYLE, ARTHUR CONAN	20	Yes	5PDI	HOLMES, SHERLOCK
Project Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from the disease								
<input type="checkbox"/>	1R01CA333333-01 IDRs Exist: N Manage IDRs GUM SMS	No	2015	Joyce, James	20	Yes		
Project Title: A Study on The Portrait of the Artist as a Young Man through Adulthood								
<input type="checkbox"/>	1R01CA765432-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	Lee, Harper	20	Yes	F0TD	Finch, Atticus
Project Title: Improving and managing the development of methods used to Kill a Mockingbird disease an More								
<input type="checkbox"/>	1R01CA234567-01 IDRs Exist: N Manage IDRs GUM SMS	No	2015	POE, EDGAR ALLAN	20	Yes		CLEMM, VIRGINIA
Project Title: Study of The Tell-tale Heart Disease and its various treatments								
<input type="checkbox"/>	1P01CA345678-01 IDRs Exist: Y Manage IDRs GUM SMS	No	2015	SHAKESPEARE, WILLIAM	20	Yes	0KBP	Goodfellow, Robin
Project Title: A Midsummer Night's Dream and sleeping disorders								

Figure 7: Sample Results Displayed in the Hitlist

The hitlist table displays each project in a row. Associated IDRs are collapsed beneath each project row and can be displayed individually by selecting the plus sign (+) or all at once using the **Expand All** link at the top of the list. The IDR section of this hitlist is discussed in greater detail below. Refer to the sub-section of this topic called [IDR Hit List on Page 21](#) for more information.

Search Parameters ?

Expand All | Show Subprojects | Show Only Queried IDRs 500 items found, displaying 51 to 100 [First/Prev] 1, 2, 3, 4, 5, 6, 7, 8 [Next/Last]

Flag	Project#	Any IDR in Received by Agency Status?	FY	PI Name	HS	Inclusion Monitoring Required?	PCC	PO Name
<input type="checkbox"/>	1R01CA123456-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	Austen_Jane	20	Yes	2PIM	Bennet_Elizabeth
Project Title: Pride & Prejudice and the Human Psyche								
<input type="checkbox"/>	1R01CA654321-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	CRANE_STEPHAN	E2	Yes	3XCM	Fleming_Henry
Project Title: The Red Badge of Courage and Other Skin Anomalies								
<input checked="" type="checkbox"/>	1R01CA222222-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	DOYLE_ARTHUR CONAN	20	Yes	5PDI	HOLMES_SHERLOCK
Project Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from the disease								
	Flag	IDR#	IDR IC ID	IDR Status	Planned Data Last Upd Date/ID	Actual Data Last Upd Date/ID		
	<input type="checkbox"/>	1021513		Received by Agency	09/12/2014 / DOYLE_ARTHUR CONAN			
	Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More							
	<input type="checkbox"/>	1021512		Received by Agency	09/12/2014 / DOYLE_ARTHUR CONAN			
	Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More							
<input type="checkbox"/>	1R01CA333333-01 IDRs Exist: N Manage IDRs GUM SMS	No	2015	Joyce_James	20	Yes		
Project Title: A Study on The Portrait of the Artist as a Young Man through Adulthood								
No Inclusion Data Records								
<input type="checkbox"/>	1R01CA765432-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	Lee_Harper	20	Yes	F0TD	Finch_Atticus
Project Title: Improving and managing the development of methods used to Kill a Mockingbird disease an ...More								
<input type="checkbox"/>	1R01CA234567-01 IDRs Exist: N Manage IDRs GUM SMS	No	2015	POE_EDGAR ALLAN	20	Yes		CLEMM_VIRGINIA
Project Title: Study of The Tell-tale Heart Disease and its various treatments								
<input type="checkbox"/>	1P01CA345678-01 IDRs Exist: Y Manage IDRs GUM SMS	No	2015	SHAKESPEARE_WILLIAM	20	Yes	0KBP	Goodfellow_Robin
Project Title: A Midsummer Night's Dream and sleeping disorders								

Figure 8: Expanding Records in the Hitlist

If subprojects exist, they are displayed in their own rows below the parent application. The **Hide Subprojects** link at the top of the list is used to remove the subprojects from the view.

NOTE: If only a specific subproject matches the entered search criteria, that subproject will display along with its parent application. In this case, other subprojects belonging to the parent will not display (e.g., searching by Appl ID of a subproject will return only the matching subproject and its parent, not the other subprojects).

Search Parameters ?

Expand All | **Hide Subprojects** | Show Only Queried IDRs

Flag	Project#	Any IDR in Received by Agency Status?	FY	PI Name	HS	Inclusion Monitoring Required?	PCC	PO Name
<input type="checkbox"/>	2P01MH123456-16 IDRs Exist: Y Manage IDRs GUM SMS	No	2015	AUSTEN_JANE	20	Yes	W6CL	WOODHOUSE_EMMMA
Project Title: Pride & Prejudice and the Human Psyche								
<input type="checkbox"/>	2P01MH123456-16/Core-001 IDRs Exist: N Manage IDRs SMS	No	2015	AUSTEN_JANE	N		W6CL	
Subproject Title: Core A: Administrative and Clinical Support								
<input type="checkbox"/>	2P01MH123456-16/Core-002 IDRs Exist: N Manage IDRs SMS	No	2015	BENNET_ELIZABETH	N		W6CL	
Subproject Title: Core B: Biostatistics and Bioinformatics								
<input type="checkbox"/>	2P01MH123456-16/Core-003 IDRs Exist: N Manage IDRs SMS	No	2015	DARCY_FITZWILLIAM	N		W6CL	
Subproject Title: Core C: Cell Processing and Immune Assessment								
<input type="checkbox"/>	2P01MH123456-16/Program-Integration-00 IDRs Exist: N Manage IDRs SMS	No	2015	AUSTEN_JANE	N		W6CL	
Subproject Title: Program Integration								
<input type="checkbox"/>	2P01MH123456-16/Project-001 IDRs Exist: Y Manage IDRs SMS	Yes	2015	AUSTEN_JANE	Y		W6CL	
Subproject Title: Project 1								
<input type="checkbox"/>	2P01MH123456-16/Project-002 IDRs Exist: Y Manage IDRs SMS	Yes	2015	DEBURGH_CATHERINE	Y		W6CL	
Subproject Title: Project 2								
<input type="checkbox"/>	2P01MH123456-16/Project-003 IDRs Exist: Y Manage IDRs SMS	Yes	2015	BINGLEY_CHARLES	Y		W6CL	
Subproject Title: Project 3								

Figure 9: IMS Search Results for Parent and Subprojects

2.3.1 Hit List Links

The following links appear at the top of the search results and are used to control the display of the results.

Pagination Links: Select the specific page number link, [First/Prev], or [Next/Last] link to navigate through all resulting records in the hit list.

Expand All: Select this link to display the collapsed list of associated IDR records under each grant record. This link exists only when those records are hidden. Expand the list of IDRs for an individual project by selection the plus sign icon (+) in the **Flag** column for the project.

Collapse All: Select this link to hide all IDR records associated with each grant. This link exists only when those records are displayed. Collapse the list of IDRs for an individual project by selection the minus sign icon (-) in the **Flag** column for the project.

Hide Subprojects: Select this link to remove subprojects from the view

Show Subprojects: Select this link to display subprojects (if applicable). Only subprojects that match the search will be displayed.

Show Only Queried IDRs: Select this link to display only IDRs that meet the specific search criteria. Other IDRs associated with a given project or subproject that do not meet the criteria will be filtered out and not displayed.

Flag	Project#	Any IDR in Received by Agency Status?	FY	PI Name	HS	Inclusion Monitoring Required?	PCC	PO Name
+	1R01CA123456-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	Austen, Jane	20	Yes	2PIM	Bennet, Elizabeth
Project Title: Pride & Prejudice and the Human Psyche								
+	1R01CA654321-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	CRANE, STEPHAN	E2	Yes	3XCM	Fleming, Henry
Project Title: The Red Badge of Courage and Other Skin Anomalies								
-	1R01CA222222-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	DOYLE, ARTHUR CONAN	20	Yes	5PDI	HOLMES, SHERLOCK
Project Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from the disease								

Figure 10: Hit List Links for Viewing Records

2.3.2 Hit List Columns

Records matching the entered search criteria display in a table. If no matching records are found, IMS will display *No records found* instead of the hitlist. In this event, review your search criteria and try again.

Flag	Project#	Any IDR in Received by Agency Status?	FY	PI Name	HS	Inclusion Monitoring Required?	PCC	PO Name																														
+	1R01CA123456-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	Austen, Jane	20	Yes	2PIM	Bennet, Elizabeth																														
Project Title: Pride & Prejudice and the Human Psyche																																						
+	1R01CA654321-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	CRANE, STEPHAN	E2	Yes	3XCM	Fleming, Henry																														
Project Title: The Red Badge of Courage and Other Skin Anomalies																																						
-	1R01CA222222-01 IDRs Exist: Y Manage IDRs GUM SMS	Yes	2015	DOYLE, ARTHUR CONAN	20	Yes	5PDI	HOLMES, SHERLOCK																														
Project Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from the disease																																						
<table border="1"> <thead> <tr> <th>Flag</th> <th>IDR#</th> <th>IDR IC ID</th> <th>IDR Status</th> <th>Planned Data Last Upd Date/ID</th> <th>Actual Data Last Upd Date/ID</th> </tr> </thead> <tbody> <tr> <td>+</td> <td>1021513</td> <td></td> <td>Received by Agency</td> <td>09/12/2014 / DOYLE, ARTHUR CONAN</td> <td></td> </tr> <tr> <td colspan="6">Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More</td> </tr> <tr> <td>-</td> <td>1021512</td> <td></td> <td>Received by Agency</td> <td>09/12/2014 / DOYLE, ARTHUR CONAN</td> <td></td> </tr> <tr> <td colspan="6">Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More</td> </tr> </tbody> </table>									Flag	IDR#	IDR IC ID	IDR Status	Planned Data Last Upd Date/ID	Actual Data Last Upd Date/ID	+	1021513		Received by Agency	09/12/2014 / DOYLE, ARTHUR CONAN		Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More						-	1021512		Received by Agency	09/12/2014 / DOYLE, ARTHUR CONAN		Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More					
Flag	IDR#	IDR IC ID	IDR Status	Planned Data Last Upd Date/ID	Actual Data Last Upd Date/ID																																	
+	1021513		Received by Agency	09/12/2014 / DOYLE, ARTHUR CONAN																																		
Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More																																						
-	1021512		Received by Agency	09/12/2014 / DOYLE, ARTHUR CONAN																																		
Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More																																						
-	1R01CA333333-01 IDRs Exist: N Manage IDRs GUM SMS	No	2015	Joyce, James	20	Yes																																
Project Title: A Study on The Portrait of the Artist as a Young Man through Adulthood																																						

Figure 11: Search Results Hitlist Columns

The following data is included in the results table:

Flag

This column displays a red flag if at least one IDR under the grant record has been marked for follow-up. When the hitlist is expanded, the flags can be found displayed next to the individual IDRs. Click on the flag to mark or unmark it as needed.

This column also holds the link for expanding or collapsing the list of IDRs for an individual project. Select the plus sign (+) to expand the list or the minus sign (-) to collapse it as applicable.

Project #

This column displays the project number as a hyperlink; the icon for opening Grant Folder (for grants); indication of paper application; Y/N to indicate that IDRs exist; and links for opening the Manage IDRs screen, Grants Update Module (GUM), and Subproject Management System (SMS) where applicable. Click here for an explanation of each field in this column.

Grant number hyperlink: Displayed only for grants. Select the grant number to open the Grant Snapshot Report. This link is only available for parent grants of subprojects or for single grants. Subproject grants do not have access to this report and the grant number does not display as a link for subprojects.

Contract Number: Displayed only for contracts. Select the contract number to open the *Contracts Information* pop-up. Refer to the topic titled *Contracts on Page 99* for details about this screen.

For the same contract document number within the same FY, the hitlist will display contract **parent** (contract numbers ending in 0) and contract **projects** (contract numbers ending in

anything other than 0). For more information on contracts, parent vs project contracts, contract document numbers, etc., please refer to the topic titled [Contracts on Page 99](#).

Grant Folder: Select the folder icon next to the grant number to open the Grant Folder. Grant Folder is only available for parent grants and single grants.

Paper application indicator: The word (paper) appears next to a grant number to indicate submission as a paper application.

IDRs Exist: Indicates whether IDRs exist for the project by displaying a Y or N value. For some projects (see below), the indicator displays as a link to the *IDR Counts* pop-up screen. [Refer to the section of this document titled IDR Counts on Page 27](#) for info on this screen.

- *Single project grants:* Indicates the existence of IDRs for that grant. The number is not displayed as a link.
- *Parent grant with subprojects:* Indicates that IDRs exist on either the parent project or on at least one subproject. The number is displayed as a link, which opens the *IDR Counts* pop-up window for the parent grant.
- *Subprojects:* Indicates that IDRs exist for this particular subproject. The number is displayed as a link, which opens the *IDR Counts* pop-up window for the parent grant.
- *Multi-year funded awards:* Not displayed for these award types.
- *Contracts:* Indicates that IDRs exist for that specific contract (regardless of where it is a parent or project contract).

Manage IDRs link: Select this link to open the *Manage Inclusion Data Records* screen. The information on the screen varies depending on the **Manage IDRs** link selected.

- *Single project grants:* Manage Inclusion Data Records screen displays all IDRs for the grant.
- *Parent grant with subprojects:* Manage Inclusion Data Records screen displays IDRs for the parent grant and all subprojects.
- *Subprojects:* Manage Inclusion Data Records screen displays only IDRs for that subproject record.
- *Contracts:* Manage Inclusion Data Records screen displays for that contract record only.

[Refer to the section of this document titled Manage Inclusion Data Records on Page 29](#) for more information on this screen.

GUM: Select this link to open the Grants Update Module (GUM) for the project. The link to GUM is available for parent grants, single grants, and contracts. Note that GUM does not provide much information for contracts and may have limited utility.

SMS: Select this link to open the Subproject Management System (SMS) for the parent grant. This link is not available for multi-year funded awards, contracts, or intramural projects. For more information on SMS, refer to the Subproject Management System (SMS) User Guide located online at http://inside.era.nih.gov/files/SMS_userguide.pdf.

Any IDR in Received by Agency Status

Yes or No value to indicate whether or not the at least one of the IDRs under the grant is in *Received by Agency* status. For parent grants, this indication applies to the parent and subprojects.

For contracts, the value reflects only the specific contract project.

FY

Represents the fiscal year of the grant record.

PI Name

The name of the contact PI on the project record. For subprojects, this is the Subproject Lead Name entered on the record. The name is displayed as a link, which opens the *PI Details* pop-up displaying the person's contact information.

HS

Displays the Human Subject Code of the single/parent grant, contract parent record, and intramural projects. For subprojects and contract projects, it displays a *Y* (yes) or *N* (no) value.

The value for parent and subproject grant applications is displayed as a link, which opens the *Human Subjects* pop-up, displaying grant application information. [Refer to the section of this document titled *Grant Application Information on Page 24*](#) for more information on this pop-up screen.

Inclusion Monitoring Required?

Displays a *Yes* or *No* value (or those set manually, e.g., *Yes-Pol*, *No-CTP*, etc.) depending on whether inclusion monitoring is required. This value is not displayed for subprojects grants.

PCC

Displays the Program Class Code for the grant or contract record. This field is always blank for intramural projects. This field is always blank for intramural projects.

PO Name

Displays the name of the project's primary Program Official (PO). The name is displayed as a link, which opens the *PO Details* pop-up displaying the PO's contact information.

Project Title/Subproject Title

Displays the project title for the record. In the case of subprojects, this field is labeled **Subproject Title**.

2.3.3 IDR Hit List

Every record in the search results includes the expand icon [+] to expand all associated IDRs for that project. A project's IDRs are displayed in this list sorted by IDR IC ID, followed by IDR #, number in descending order. Initially, up to 10 IDRs display in the hitlist, however, if more than 10 IDRs exist, the remaining records can be displayed by selecting the **see all IDRs...** link at the end of the list of 10.

Search Parameters									
Expand All Show Subprojects Show Only Queried IDRs									
Flag	Project#	Any IDR in Received by Agency Status?	FY	PI Name	HS	Inclusion Monitoring Required?	PCC	PO Name	
	5P01CA456789-16 IDRs Exist: Y Manage IDRs GUM SMS	No	2004	Shakespeare, William	30	Yes	40CL	Marlowe, Christopher	
Project Title: THE TAMING OF THE FLU									
Flag	IDR#	IDR IC ID	IDR Status	Planned Data Last Upd Date/ID	Actual Data Last Upd Date/ID				
P	62847	DM00-274	Accepted (Original Submission) Study Title: Study for the Taming of the Flu	03/23/2004 / Shakespeare, William	02/13/2004 / Shakespeare, William				
P	50572	DM96-122	Accepted (Original Submission) Study Title: Measure for Measure and Other Scientific Methodologies for the Treatment of Sym...More	02/13/2004 / Shakespeare, William	02/13/2004 / Shakespeare, William				
P	50574	DM97-210	Accepted (Original Submission) Study Title: All's Well That Ends Well with advancements in medicine and medical research for ...More	02/13/2004 / Shakespeare, William	02/13/2004 / Shakespeare, William				
P	50573	DM97-206	Accepted (Original Submission) Study Title: A Winter's Tale: A comprehensive study of the common cold and the differences in ...More	02/13/2004 / Shakespeare, William	02/13/2004 / Shakespeare, William				
P	62849	DM98-249	Accepted (Original Submission) Study Title: The Two Noble Kinsmen: A study on genetics and the effects of the flu for members of ...More	03/23/2004 / Shakespeare, William	03/23/2004 / Shakespeare, William				
P	62850	DM99-081	Accepted (Original Submission) Study Title: The Life and Death of King John: Determining the risk factors associated with treatme...More	03/23/2004 / Shakespeare, William	03/23/2004 / Shakespeare, William				
P	50575	DM99-251	Accepted (Original Submission) Study Title: Much Ado About the flu	02/13/2004 / Shakespeare, William	02/13/2004 / Shakespeare, William				
P	62853	ID02-901	Accepted (Original Submission) Study Title: The Merry Hives of Windsor	02/26/2004 / Shakespeare, William	02/26/2004 / Shakespeare, William				
P	62852	ID02-672	Accepted (Original Submission) Study Title: Phase 2 study of A Winter's Tale	02/26/2004 / Shakespeare, William	02/26/2004 / Shakespeare, William				
P	62851	ID02-034	Accepted (Original Submission) Study Title: The Two Noble Kinsmen: A study of therapy and treatments based on DNA	03/23/2004 / Shakespeare, William	03/23/2004 / Shakespeare, William				
see all IDRs...									

Figure 12: See All IDRs Link for Project Containing More than 10 IDRs

In the case of multi-year funded awards, IDRs will display grouped by fiscal year.

+ Search Parameters ⓘ									
Expand All Hide Subprojects Show Only Queried IDRs									
Flag	Project#	Any IDR in Received by Agency Status?		FY	PI Name	HS	Inclusion Monitoring Required?	PCC	PO Name
<input type="checkbox"/>	1R01HL123456-01 Manage IDRs GUM	Yes		2014	POE, EDGAR ALLAN	30	Yes	2PIM	Usher, Roderick
Project Title: The Tell-tale Heart Disease									
Flag	IDR#	IDR IC ID	IDR Status	Planned Data Last Upd Date/ID		Actual Data Last Upd Date/ID			
IDR FY: 2015									
P	1026222		Received by Agency	09/23/2014 / POE, EDGAR ALLAN					
Study Title: Tell-tale Heart Disease: Study Number Three									
P	1010477		Previous FY Data	09/12/2014 / System					
Study Title: Tell-tale Heart Disease: Study Number Two									
P	1010414		Previous FY Data	09/12/2014 / System		09/12/2014 / System			
Study Title: Tell-tale Heart Disease: Study Number One									
IDR FY: 2014									
P	1010477		Accepted (Original Submission)	09/12/2014 / POE, EDGAR ALLAN					
Study Title: Tell-tale Heart Disease: Study Number Two									
P	1010414		Accepted (Original Submission)	09/12/2014 / POE, EDGAR ALLAN		09/12/2014 / POE, EDGAR ALLAN			
Study Tell-tale Heart Disease: Study Number One									

Figure 13: IMS Search Results for Multi-year Project

NOTE: When no inclusion data records exist for the project, the following message appears when the record is expanded: *No Inclusion Data Records.*

The information displayed in the IDR hitlist is as follows:

IDR FY

This value is viewable only for multi-year awards and is displayed once per group of IDRs in the same fiscal year.

Flag

The flag in the IDR hitlist is editable and can be set to mark an IDR for follow-up. When marked for follow-up, the flag displays as bolder and red. Unselecting a marked flag returns the icon to a grey and white lighter color.

Any IMS system user from the Agency can set or unset the follow-up flag. Marking an IDR for follow-up will update the project level search result field with the follow-up flag.

Flag	IDR#	IDR IC ID	IDR Status	Planned Data Last Upd Date/ID		Actual Data Last Upd Date/ID			
P	1021513		Received by Agency	09/12/2014 / DOYLE, ARTHUR CONAN					
Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More									
P	1021512		Received by Agency	09/12/2014 / DOYLE, ARTHUR CONAN					
Study Title: A Study in Scarlet Fever and the effects of treatment on patients suffering from ...More									

Figure 14: Follow-up Flag

IDR #

The **IDR#** is the unique Inclusion Management System-generated identifier for the inclusion data record (IDR). This number remains unchanged throughout the lifetime of the grant.

The words (*Last Budget Period*) appear after the IDR number to indicate that the IDR is a [Last Budget Period](#) type IDR.

The word (*Final*) appears after the IDR number to indicate that the IDR is a final type IDR. Currently, this concept only exists for intramural projects.

The IDR number is displayed as a link which opens the *Inclusion Data Record (IDR) Details* screen for the selected record. Refer to the topic [Inclusion Data Record \(IDR\) Details on Page 66](#) for more information on this screen.

IDR IC ID

Represents the IC-assigned identification number of the inclusion data record. If an IDR IC ID was not assigned to the record as an attribute by Agency staff, this field will be blank.

IDR Status

Indicates the current status of the IDR.

Planned Data Last Upd Date/ID

Indicates the last date on which the IDR Planned Enrollment form was updated as well as the name of the user who performed the update. The name is displayed as a link, which opens the *Person Details* pop-up displaying contact information.

Actual Data Last Upd Date/ID

Indicates the last date on which the IDR Cumulative Enrollment form was updated as well as the name of the user who performed the update. The name is displayed as a link, which opens the *Person Details* pop-up displaying contact information.

Study Title

Displays the study title name for the particular IDR.

2.4 Inclusion Monitoring Required

Typically, the Inclusion Monitoring Required code is set in the eRA system when the activity code is established for the project record. The standard settings for this flag are either *Yes* or *No*. Any changes to an activity code or Human Subject code could result in a change to this code. Also, it is possible that a code change may be necessary because the application does not meet the NIH definition for clinical research or to direct the inclusion workflow in IMS to the appropriate award and to avoid duplicate reporting on networked studies/awards. When a change to the Inclusion Monitoring (Yes/No) code is needed for these reasons, a request may be submitted through the [IC](#)

[Inclusion Operating Procedures Workgroup \(IOPW\)](#) representative to the Office of Extramural Research (OER). This must be done before award.

Inclusion Monitoring Required is set to *Yes* when the following is true:

- Application is an NIH application
- Human Subject code indicates that humans are involved (parent/single grants)
- Activity Code indicates that inclusion should be monitored

The flag is set on the parent project level (for multi-component applications), and there is no ability to set a subproject's code separately from the parent. Parent contracts will default to *No* and contract projects (created in CIMS 1688) that involve human subjects will default to *Yes*.

The setting of this flag is instrumental in governing the rules allowing Agency staff (as well as Grantee users) to determine what is required under inclusion policy and to initiate the inclusion data forms. Inclusion forms cannot be completed for applications with a *No* setting.

IMPORTANT: Only users in OER with specific roles are able to update the **Inclusion Monitoring Required** code. Policy values for this flag are *Yes-Pol* (Yes-Policy Override), *No-Pol* (No-Policy Override), *No-DCC* (Reported on Data Coordinating Center), *No-ISS* (Reported on Individual Site), and *No-CTP* (Contract Tracked on Project).

IC staff will not have this role. Requests to consider a change to the default code setting may be submitted to the NIH Inclusion Policy Officer via the IC Inclusion Operating Procedures Workgroup member. The roster of members can be found [here](#).

2.5 Grant Application Information

The *Human Subjects* pop-up screen is accessed by selecting the value (displayed as a link) in the [HS column of the Search results](#). The pop-up displays **Grant Application Information** for the selected record and varies depending on whether a parent or subproject application was selected.

Flag	Project#	Any IDR in Received by Agency Status?	FY	PI Name	HS	Inclusion Monitoring Required?	PCC	PO Name
+	2P01MH123456-16 Number of IDRs: 5 Manage IDRs GUM SMS	No	2015	AUSTEN, JANE	20	Yes	W6CL	WOODHOUSE, EMMA
Project Title: Pride & Prejudice and the Human Psyche								
+	2P01MH123456-16/Core-001 Number of IDRs: 0 Manage IDRs SMS	No	2015	AUSTEN, JANE	N		W6CL	
Subproject Title: Core A: Administrative and Clinical Support								
	2P01MH123456-16/Core-002 Number of IDRs: 0	No	2015	BENNET, ELIZABETH	N		W6CL	

Figure 15: Human Subjects (HS) Links on IMS Search Results

2.5.1 Grant Application Information for Parent Application Records

For parent applications, the screen displays information specific to the parent application.

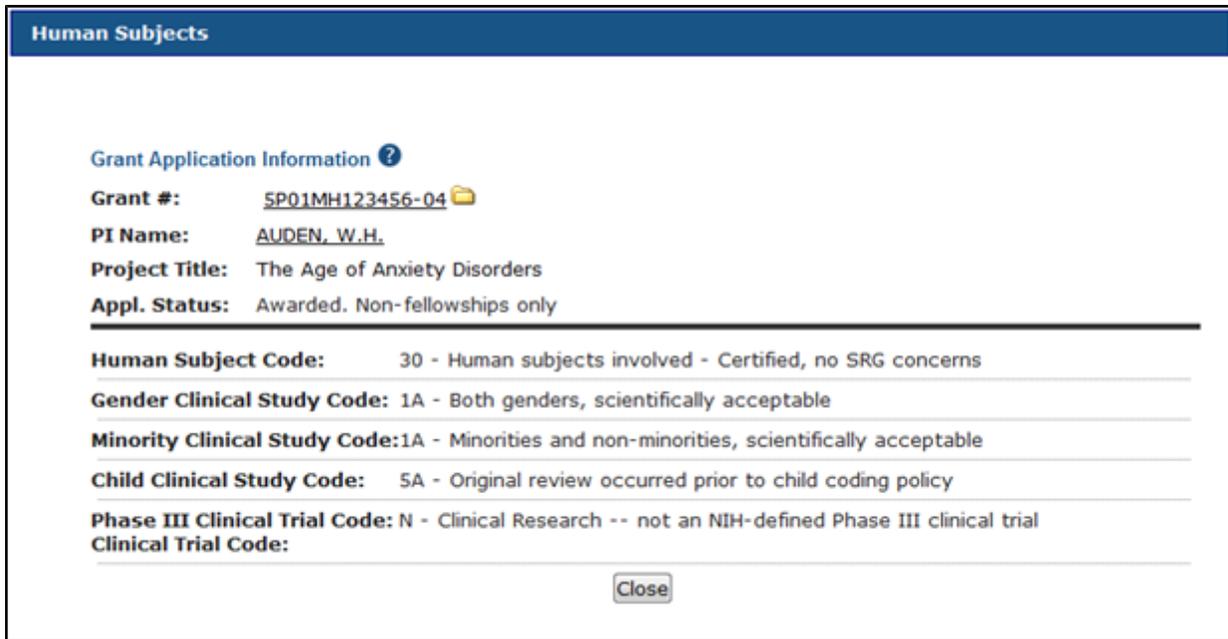


Figure 16: Human Subjects Pop-up for Parent Project

The following information displays on the screen:

Grant #

The grant number of the selected record. For parent grants, it is displayed with links to the *Grant Snapshot* report and the *Grant Folder*. Included next to the grant number is the word (paper) to indicate a paper application.

PI Name

The name of the contact PI on the project record. For subprojects, this is the Subproject Lead Name entered on the record. The name is displayed as a link, which opens the *PI Details* pop-up displaying the person's contact information.

Project Title

The name of the project for the parent application or multi-year funded award.

Appl. Status

The current status of the application.

The screen also displays the code number (where applicable) and description of the following for the parent application:

- **Human Subject Code**
- **Gender Clinical Study Code**
- **Minority Clinical Subject Code**

- **Child Clinical Study Code**
- **Phase III Clinical Trial Code**
- **Clinical Trial Code**

2.5.2 Grant Application Information for Subproject Records

For subproject application records, the screen displays information specific to the selected subproject.

Human Subjects

Grant Application Information ?

Grant #: [2P01MH123456-16/Project-002](#)

PI Name: [BARRIE, J.M.](#)

Project Title: [Project 2: Peter Pan Syndrome](#)

Appl. Status: Pending

Human Subject Code: Y - Human subjects involved

Phase III Clinical Trial Code: N - Clinical Research -- not an NIH-defined Phase III clinical trial

Figure 17: Human Subjects Pop-up for Subproject

The following information displays on the screen:

Grant #

The grant number of the selected subproject record.

PI Name

The name of the Subproject Lead Name as entered on the subproject record. The name is linked to the *PI Details* pop-up.

SubprojectTitle

The name of the project for the subproject application.

Appl. Status

The current status of the subproject application.

The screen also displays the code number and description of the following for the subproject record:

- Human Subject Code
- Phase III Clinical Trial Code

2.6 IDR Counts

The *IDR Counts* pop-up window is accessed by selecting the value (displayed as a link) in the [IDRs Exist field of the Search results](#) for multi-projects. *IDR Counts* provides a read-only summary for the selected application or for the selected subproject's parent application.

IC Subproject ID	PI Name	Subproject Title	# of IDRs
Core-001	AUSTEN, JANE	Core A: Administrative and Clinical Support	1
Core-002	Bennet, Elizabeth	Core B: Biostatistics and Bioinformatics	0
Core-003	DARCY, FITZWILLIAM	Core C: Cell Processing and Immune Assessment	1
Program-Integration-001	AUSTEN, JANE	Program Integration	0
Project-001	AUSTEN, JANE	Project 1	2
Project-002	DEBURGH, CATHERINE	Project 2	2
Project-003	BINGLEY, CHARLES	Project 3	2

Figure 18: IDR Counts Screen

The screen includes the following information:

Grant

For grants, this is the grant number of the selected record. Parent and single-project grants display with links to the *Grant Snapshot* report and the *Grant Folder*. Included next to the grant number is the word (paper) to indicate a paper application.

IDR Counts is not available for contracts.

PI Name

The name of the contact PI on the project record. For subprojects, this is the Subproject Lead Name entered on the record. The name is displayed as a link, which opens the *PI Details* pop-up displaying the person's contact information.

Project Title

The name of the project for the parent application or multi-year funded award.

Appl. Status

The current status of the application.

of IDRs

For parent and subproject applications, this number represents the total number of IDRs on the parent application.

For multi-year funded awards, this number represents the total number of IDRs for all fiscal years combined.

NOTE: The number of IDRs excludes [Last Budget Period Type IDRs](#).

For parent applications and subprojects, a summary table of subproject IDR information is displayed beneath the general header information. This table includes the following information:

- **IC Subproject ID**
- **PI Name** (hyperlinked to the PI Details pop-up)
- **Subproject Title**
- **# of IDRs** (for that specific subproject)

3 Manage Inclusion Data Records

Agency staff uses the *Manage Inclusion Data Records (IDRs)* screen to view a list of all Inclusion Data Records (IDR) for a given application and to manage those individual records as applicable.

Access the screen by performing a search for IDRs on the IMS search screen and selecting the **Manage IDRs** link for a particular application; by selecting the IMS link in Program (PGM) for a particular application; or by selecting the **Access IMS** button in Grants Management (GM) for a particular application.

IMPORTANT: The Program and Grants Management systems have their own online help. For more information on accessing IMS from these systems, please refer to the PGM IMS help topic or GM IMS help topic as needed.

For PGM: [http://inside.era.nih.gov/erahelp/pgm/#Standard Processes/Admin Hit List Hyperlinks/IMS Hyperlink.htm](http://inside.era.nih.gov/erahelp/pgm/#Standard_Processes/Admin_Hit_List_Hyperlinks/IMS_Hyperlink.htm)

For GM: [http://inside.era.nih.gov/erahelp/gm/#Research Subjects/Inclusion Monitoring System.htm](http://inside.era.nih.gov/erahelp/gm/#Research_Subjects/Inclusion_Monitoring_System.htm)

The information on the screen's hit list may vary depending on whether the viewed records are for a single grant, subproject, multi-project grant, multi-year funded grant, contract or intramural project.

- Single-project awards: The hit list displays all IDRs for the single application.
- Individual subproject record: The hit list displays only the IDRs for the single subproject selected from the search results.
- Multi-project awards: The hit list displays all IDRs for the parent and subproject applications, with the parent application at the top of the list.
- Multi-year funded awards: The hit list displays all IDRs for the award, grouped by fiscal year. The current fiscal year displays at the top of the list.
- Contracts: The hit list displays all IDRs for the specific contract.
- Intramural grant: The hit list displays all IDRs for the specific Intramural project.

Manage Inclusion Data Records (IDRs)

Project #: [1P20MH345678-01](#) (paper)
 Fiscal Year: 2015
 PI Name: [SHAKESPEARE, WILLIAM](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: A Midsummer Night's Dream and sleeping disorders
 Appl. Status: Pending Council Review
 Number of Subprojects: 0

[Back to Search and Hit List](#)

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#) * - Required IDR Attributes are needed

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
1P20MH345678-01 PI Name: SHAKESPEARE, WILLIAM Project Title: A Midsummer Night's Dream and sleeping disorders Create New IDR	F	1025761		Received by Agency	09/16/2014 SHAKESPEARE, WILLIAM		View * Edit Attributes
StudyTitle: Sample Project Number 1							

Figure 19: Manage IDRs Screen for Single Project

Manage Inclusion Data Records (IDRs)

Project #: [1P20MH123456-01](#)
 Fiscal Year: 2015
 PI Name: [AUDEN, W.H.](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: The Age of Anxiety Disorders
 Appl. Status: Pending Council Review
 Number of Subprojects: 3

[Back to Search and Hit List](#)

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#) [Transfer IDRs](#)
* - Required IDR Attributes are needed

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
1P20MH123456-01 PI Name: AUDEN, W.H. Project Title: Sample Project Num (...more) Create New IDR	F	1025759		Received by Agency	09/16/2014 AUDEN, W.H.	09/16/2014 AUDEN, W.H.	View * Edit Attributes Edit Planned Edit Actual Delete IDR
StudyTitle: The Age of Anxiety Disorders							
1P20MH123456-01/Core-001 PI Name: Austen, Jane Subproject Project Title: Sample Pr (...more) Create New IDR	F	1025760		Received by Agency	09/16/2014 AUSTEN, JANE		View * Edit Attributes
StudyTitle: Pride & Prejudice and the Human Psyche							
1P20MH123456-01/Admin-Core-001 PI Name: BARRIE, J.M. Subproject Project Title: Administrative Core Create New IDR	F	1025761		Received by Agency	09/16/2014 AUDEN, W.H.		View * Edit Attributes
StudyTitle: A Study of Peter Pan Syndrome							
1P20MH123456-01/Pilot-Projects-Core-001 PI Name: SHAKESPEARE, WILLIAM Subproject Project Title: Pilot Projects Core Create New IDR	F	1025758		Received by Agency	09/16/2014 SHAKESPEARE, WILLIAM		View * Edit Attributes Edit Planned Edit Actual Delete IDR
StudyTitle: A Midsummer Night's Dream: A study on sleep disorders							

Figure 20: Manage IDRs Screen for Parent and Subprojects

Manage Inclusion Data Records (IDRs)

Project #: [1R01HL123456-01](#)
 Fiscal Year: 2015
 PI Name: [Poe, Edgar Allan](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: The Tell-tale Heart Disease
 Appl. Status: Pending Council Review
 Number of Subprojects: 3

[Back to Search and Hit List](#)

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions	
IDR FY: 2015								
1R01HL123456-01 PI Name: Poe, Edgar Allan Project Title: The Tell-tale Heart dis(...more)	F	1026222		Received by Agency	09/23/2014 POE, EDGAR ALLAN		View	
	StudyTitle: Tell-Tale Heart Disease: Study Number Three							
	F	1010477		Previous FY Data	09/12/2014 System		View	
	StudyTitle: Tell-Tale Heart Disease: Study Number Two							
	F	1010414		Previous FY Data	09/12/2014 System	09/12/2014 System	View	
	StudyTitle: Tell-Tale Heart Disease: Study Number One							
	IDR FY: 2014							
	F	1010477		Accepted (Original Submission)	09/12/2014 POE, EDGAR ALLAN		View	
	StudyTitle: Tell-Tale Heart Disease: Study Number Two							
F	1010414		Accepted (Original Submission)	09/12/2014 POE, EDGAR ALLAN	09/12/2014 POE, EDGAR ALLAN	View		
StudyTitle: Tell-Tale Heart Disease: Study Number One								

Figure 21: Manage IDRs Screen for Multi-year Funded Award

Manage Inclusion Data Records (IDRs)

Project #: [1234012000071-0-12300005-1](#) Contract Document Number: 1234012000071
 Fiscal Year: 2014
 PI Name: [VALJEAN, JEAN](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: This Project Title Represents an Example of a Contract PROJECT Title Displayed in IMS System
 Appl. Status: Not Applicable

[Back to Search and Hit List](#)

[Transfer IDRs](#)
 * - Required IDR Attributes are needed

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions	
1234012000071-0-12300005-1 PI Name: VALJEAN, JEAN Project Title: This Project Title Repres(...more) Create New IDR	F	1045392		Accepted by Agency	03/26/2015 GRINGOIRE, PIERRE		View Edit Attributes	
	StudyTitle: Sample Study Title 1							
	F	1045391		Accepted by Agency	03/26/2015 VALJEAN, JEAN	03/26/2015 VALJEAN, JEAN	View * Edit Attributes	
	StudyTitle: Sample Study Title 2							
	F	1045393	Foreign IDR	Accepted by Agency	03/26/2015		View Edit Attributes	
StudyTitle: Sample Study Title 3								

Figure 22: Manage IDRs Screen for Contract Project

The top portion of the screen displays some or all of the information below. Some items are specific to grants or to contracts and may not be applicable to the project you are viewing.

- **Project #**

For grants: Displays the grant number with a link to the *Grant Snapshot* report and the *Grant Folder* for parent and single-projects only

The word *paper* next to a grant number indicates a paper application.

For contracts: Displays the contract number with a link to the *Contract Details* pop-up.

For intramurals: The project number is not hyperlinked.

- **Contract Document Number** (displayed for contracts only)

The contract document number is part of the contract number. It ties together contracts in different FYs and parent and project contracts. The search will bring contract **parent(s)** and contract **project(s)** for a selected FY (or all FY(s) if FY is not specified).

For more information on contracts, refer to the topic titled [Contracts on Page 99](#).

- **Fiscal Year**

- **PI Name**

Linked to the *PI Details* pop-up.

For intramurals, the PI Name is not hyperlinked.

- **Org Name**

- **Project Title**

- **Appl Status**

- **Number of Subprojects** (displayed for parent grants only)

The bottom portion of the screen serves as a hitlist of IDRs for the selected projects with details and links for viewing or editing as appropriate. The information is displayed by project number in a table. The table columns can be sorted using the up/down arrows in each column heading.

Note that the hitlist could include IDRs for studies using an existing dataset or resource or records from previous funding period progress reports; data provided during eSubmission on a Cumulative Inclusion Enrollment Report form; data submitted from intramural data systems; and/or inclusion data migrated from the Population Tracking system to IMS through an IC-specific data system API. For these IDRs, you will only see the **View** action link.

Refer to the sections below titled [Links and Viewing Options on Page 33](#), [Manage IDRs Hitlist on Page 35](#), and [Manage IDRs Action Links on Page 39](#) for information on the links for viewing or editing prospectively enrolling studies.

IMPORTANT: The ability to modify an inclusion data record may be locked for Agency users if the Grantee has accessed the record via the **Inclusion** link found in Commons or within **Section G. Special Reporting Requirements** of the *Research Performance Progress Report* (RPPR). These records will remain locked until the Grantee routes the new/updated IDR(s) through Commons or submits the RPPR. For multi-year funded awards, the records are locked until the RPPR is submitted for the current year or until the time of rollover for the current year, whichever occurs first.

When records are locked, the following message displays on the screen: *At this time, the data is edited by the Grantee in RPPR.*

Select the **Back to Search and Hit List** link to return to the search screen. When the screen is returned, the originally entered parameters and matching results will be displayed.

3.1 Links and Viewing Options

Transfer IDRs link

Select the **Transfer IDRs** link to access the *Transfer Inclusion Data Record(s) (IDRs)* screen.

For grants, IDRs can be transferred from parent to subproject; subproject to parent; or subproject to subproject within the same support year of the same award. For contracts, IDRs can be transferred between a contract parent and contract projects with the same contract document number for the same fiscal year when inclusion monitoring code is set to *Yes* or *Yes-POL*. You cannot transfer IDRs when contracts data are frozen. The **Transfer IDRs** link is not available for intramural projects.

The **Transfer IDRs** link appears for multi-project grant applications when the given project year is unawarded and inclusion monitoring is set to *Yes*. The link is available for IMS users holding the IDR Editor role. This option is not available to multi-year funded awards.

Last Budget Period type IDRs can only be transferred if they are a new study with no *regular* IDR that they are associated with. This type of Last Budget Period IDR is created when the Grantee selects the option to **Create New Planned** after award of the last non-competing year in the funding period. These particular Last Budget Period type IDRs do not have associated regular IDRs. Note: This concept is not applicable for contracts.

Refer to the topic titled [Transfer Inclusion Data Record\(s\) on Page 44](#) for more information on transferring IDRs.

Manage Inclusion Data Records (IDRs)

Project #: [1P20MH123456-01](#)
 Fiscal Year: 2015
 PI Name: [AUDEN, W.H.](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: The Age of Anxiety Disorders
 Appl. Status: Pending Council Review
 Number of Subprojects: 3

[Back to Search and Hit List](#)

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#) [Transfer IDRs](#) * - Required IDR Attributes are needed

Project Details	Flag	IDR#	IDR.IC.ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
1P20MH123456-01 PI Name: AUDEN, W.H. Project Title: Sample Project Num (...more) Create New IDR	☑	1025759		Received by Agency	09/16/2014 AUDEN, W.H.	09/16/2014 AUDEN, W.H.	View * Edit Attributes Edit Planned Edit Actual Delete IDR
StudyTitle: The Age of Anxiety Disorders							
1P20MH123456-01/Core-001 PI Name: Austen, Jane <small>Subsequent Project Title: Sample ID # (...more)</small>	☑	1025760		Received by Agency	09/16/2014 AUSTEN, JANE		View * Edit Attributes

Figure 23: Transfer IDRs Link on Manage IDRs

View Options

The view options display for grant applications with subprojects. The options will not display if the *Manage Inclusion Data Records* screen is currently displayed for an individual subproject. The view options are not applicable for multi-year funded awards and contracts.

Select the **Hide All Subproject** links to display only the parent application.

Select the **Show All Subprojects** to display hidden subprojects associated with the parent award. The link only displays when subprojects have been hidden. Displayed subprojects do not include those of Type R or Type L.

Select the **Show Subprojects with IDRs Only** link to include in the view only those subprojects with IDRs (along with the parent application).

Manage Inclusion Data Records (IDRs)

Project #: [1P20MH123456-01](#)

Fiscal Year: 2015

PI Name: [AUDEN_W.H.](#)

Org Name: UNIVERSITY OF LITERARY REFERENCES

Project Title: The Age of Anxiety Disorders

Appl. Status: Pending Council Review

Number of Subprojects: 3

[← Back to Search and Hit List](#)

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#)

[Transfer IDRs](#) ?
* - Required IDR Attributes are needed ?

Prospective Studies:

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
1P20MH123456-01 PI Name: AUDEN_W.H. Project Title: Sample Project Num (...more) Create New IDR	P	1025759		Received by Agency	09/16/2014 AUDEN_W.H.	09/16/2014 AUDEN_W.H.	View * Edit Attributes Edit Planned Edit Actual Delete IDR

Figure 24: View Option Links on Manage IDRs

3.2 Manage IDRs Hitlist

Project Details

Includes the grant number (for grants) hyperlinked to the *Grant Snapshot* report with an additional link to the *Grant Folder* (links are for single-project or parent applications only; contract number (for contracts) hyperlinked to the *Contracts Information* pop-up; project number for intramurals (not hyperlinked); **PI Name** displayed as a link opening the *PI Details* pop-up (not hyperlinked for intramurals); **Project Title** (or Subproject Title) displaying the name of the particular project. Included next to the grant number is the word (paper) to indicate a paper application.

Use the (**...more**) link to display the entire project title if hidden. Use the (**less**) link to show less of the title.

NOTE: For subprojects, the **PI Name** displays the subproject lead name as entered on the subproject record.

Create New IDR

Select the **Create New IDR** link –located within the **Project Details** column– to access the *Edit Planned Inclusion Data* screen for creating a new IDR. Refer to the topic titled [Edit Planned Inclusion Data on Page 58](#) for more information.

The **Create New IDR** link appears for single- and multi-project applications when the project is unawarded and inclusion monitoring setting is at *Yes*. For competing grants in a status other than Pending Award (PA), Pending Council (PC), To Be Paid (TP), and NRFC (N), summary statements must exist. It will appear for agency staff if they have permission to create new IDRs for that application type.

For single-project applications, the link is displayed for paper applications to those with the IDR Editor role.

This link is not available to agency staff for [Last Budget Period](#) type IDRs.

In the case of multi-year funded applications (for example, R15s), the link is available for the current fiscal year only, if inclusion monitoring is set to *Yes* and after the summary statement exists (competing applications only). The link is displayed for multi-year funded paper applications to those with the IDR Editor role.

For contracts, the **Create New IDR** link is available when inclusion monitoring is set to *Yes* or *Yes-Pol*, until the inclusion data are administratively frozen for a given fiscal year.

This link is not available to agency staff for intramurals.

Manage Inclusion Data Records (IDRs)

Project #: [1P20MH123456-01](#)
 Fiscal Year: 2015
 PI Name: [AUDEN, W.H.](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: The Age of Anxiety Disorders
 Appl. Status: Pending Council Review
 Number of Subprojects: 3

[« Back to Search and Hit List](#)

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#) [Transfer IDRs](#) ?

* - Required IDR Attributes are needed ?

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
1P20MH123456-01 PI Name: AUDEN, W.H. Project Title: Sample Project Num (...more) Create New IDR	P	1025759		Received by Agency	09/16/2014 AUDEN, W.H.	09/16/2014 AUDEN, W.H.	View * Edit Attributes Edit Planned Edit Actual Delete IDR
StudyTitle: The Age of Anxiety Disorders							
1P20MH123456-01/Core-001 PI Name: Austen, Jane Subproject Project Title: Sample Pr (...more) Create New IDR	P	1025760		Received by Agency	09/16/2014 AUSTEN, JANE		View * Edit Attributes
StudyTitle: Pride & Prejudice and the Human Psyche							
1P20MH123456-01/Admin-Core-001 PI Name: BARRIE, J.M. Subproject Project Title: Administrative Core Create New IDR	P	1025761		Received by Agency	09/16/2014 AUDEN, W.H.		View * Edit Attributes
StudyTitle: A Study of Peter Pan Syndrome							
1P20MH123456-01/Pilot-Projects-Core-001 PI Name: SHAWESDEANE, WILLIAM							View * Edit Attributes

Figure 25: Project Details on Manage IDRs

IDR FY

IDRs for multi-year funded awards are grouped and separated within the list by fiscal year, with the current year's IDRs at the top of the list. The **IDR FY** field is only displayed for these multi-year funded awards and shows the fiscal year of each group of IDRs.

Flag

Select the flag icon in this column to mark the IDR as needing follow-up. When marked for follow-up, the flag icon is displayed in red and an additional flag appears on the **Project Details** portion of the screen. Select the flag again to unmark the IDR. This flag setting can be used as a search parameter when querying for IDRs.

IDR#

The **IDR#** is the unique Inclusion Management System-generated identifier for the inclusion data record (IDR). This number remains unchanged throughout the lifetime of the grant.

The words (*Last Budget Period*) appear after the IDR number to indicate that the IDR is a [Last Budget Period](#) type IDR.

The word (*Final*) appears after the IDR number to indicate that the IDR is a final type IDR. Currently, this concept only exists for intramural projects.

The IDR number is displayed as a link which opens the *Inclusion Data Record (IDR) Details* screen for the selected record. Refer to the topic [Inclusion Data Record \(IDR\) Details on Page 66](#) for more information on this screen.

IDR IC ID

The **IDR IC ID** is an identification number entered by Agency staff as one of the optional IDR attributes. This value is not the same as the system-generated IDR #. This field could be blank if an IDR IC ID number was not assigned.

The inclusion data records per project are sorted by IDR IC ID by default, alphabetically followed by numerically. If the IDR IC ID does not exist, the record will display in secondary sort order, which is by IDR#.

IDR Status

The status of the inclusion data record is displayed in this field.

IDR Status values are as follows:

Accepted – Not Rolled Forward: The IDR is either marked as Not Funded or as Type 2 Progress Report. The project is awarded, but the IDR is not rolled forward into an out year record.

Accepted (Original Submission): The IDR has been accepted at award issuance based on what was originally submitted. (Data migrated from the previous data system may also have this status when awarded.)

Accepted (PI Revisions): Grantee has modified the IDR after original submission, but before release of the award

Accepted by Agency: OER has frozen ability to modify inclusion data for IDRs on contracts or intramural projects for the selected FY.

Grantee Updates in Progress: Grantee user has created the IDR; Grantee user has initiated updates on an IDR (Edit Planned or Edit Cumulative); and/or SO has routed an IDR back to the PI

Inclusion Updated: Grantee has updated cumulative (actual) enrollment counts via the RPPR module in Commons

Previous FY Data: Data from previous fiscal year has been rolled forward into the next project record

Pending SO: IDR has been routed to the SO

Received by Agency: IDR form (Planned or Cumulative) has been received as part of the electronic application submission (i.e., Grants.gov/eSub or ASSIST); Grantee user (SO) has routed the IDR via IMS in the Commons Status module to the Agency; Agency user has created a new IDR in IMS; IDR is inserted or updated via web service. This applies to intramural projects and certain contracts.

Received by Agency – RPPR: Grantee user submitted IDR to Agency as part of the Research Performance Progress Report (RPPR)

Requires Updates: Grantee user accessed the inclusion data via the RPPR module in Commons; Grantee user has created a new Planned Inclusion Form via the RPPR module in Commons

Planned Last Update Date/ID

This column shows the date on which the IDR planned enrollment form was last updated, as well as the name of the IMS user who updated the form. The name is displayed as a hyperlink, which opens the *Person Details* pop-up screen showing organization and contact information for the person.

Actuals Last Update Date/ID

This column shows the date on which the IDR cumulative enrollment form was last updated, as well as the name of the IMS user who updated the form. The name is displayed as a hyperlink, which opens the *Person Details* pop-up screen showing organization and contact information for the person.

Study Title

Displays the study title for the specific inclusion data record.

Actions

The **Actions** column displays links for performing actions against the IDR. The links available in this column vary depending on the award status, IDR status, and the system user viewing the record. Refer to the [Manage Inclusion Data Records Action Links](#) section below for details on the possible links found in this column.

NOTE: The information above is true only for projects with IDRs. For projects without inclusion data, the following message displays instead: *No Inclusion Data Records.*

If the Grantee has provided an explanation for the lack of IDRs, that explanation displays under the message as follows: **Grantee Explanation:** <explanation as entered by Grantee>

3.3 Manage IDRs Action Links

Depending on the award type, IDR status, and/or IMS system user's role, the following action links may be available from the *Manage Inclusion Data Records Action* column. Not all links are available to all users or for all inclusion data records.

Manage Inclusion Data Records (IDRs) ⓘ

Project #: [1P20MH123456-01](#) ⓘ
 Fiscal Year: 2015
 PI Name: [AUDEN, W.H.](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: The Age of Anxiety Disorders
 Appl. Status: Pending Council Review
 Number of Subprojects: 3

« Back to Search and Hit List

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#) Transfer IDRs ⓘ
* - Required IDR Attributes are needed ⓘ

Project Details ▾	Flag ▾	IDR# ▾	IDR IC ID ▾	IDR Status ▾	Planned Last Update Date/ID ▾	Actuals Last Update Date/ID ▾	Actions
1P20MH123456-01 ⓘ PI Name: AUDEN, W.H. Project Title: Sample Project Num (...more) Create New IDR	Ⓟ	1025759		Received by Agency	09/16/2014 AUDEN, W.H.	09/16/2014 AUDEN, W.H.	View * Edit Attributes Edit Planned Edit Actual Delete IDR
StudyTitle: The Age of Anxiety Disorders							
1P20MH123456-01/Core-001 PI Name: Austen, Jane Subproject Project Title: Sample Pr (...more) Create New IDR	Ⓟ	1025760		Received by Agency	09/16/2014 AUSTEN, JANE		View * Edit Attributes
StudyTitle: Pride & Prejudice and the Human Psyche							
1P20MH123456-01/Admin-Core-001 PI Name: BARRIE, J.M. Subproject Project Title: Administrative Core Create New IDR	Ⓟ	1025761		Received by Agency	09/16/2014 AUDEN, W.H.		View * Edit Attributes
StudyTitle: A Study of Data Data Syndrome							

Figure 26: Sample of Possible Action Links on Manage IDRs

View

Select the **View** link to open a read-only view of the *Inclusion Data Record (IDR) Details* screen.

Refer to the topic titled [Inclusion Data Record \(IDR\) Details on Page 66](#) for more information.

The **View** link is available at all times for all IMS system users.

NOTE: For IDRs involving Existing Studies and IDRs migrated from the Population Tracking system, **View** is the only action option. View is also the only option for applications with inclusion monitoring set to *No*.

Edit Attributes

Select the **Edit Attributes** link to access the *Edit Inclusion Data Record (IDR)* screen for editing or viewing attributes. Refer to the topic titled [Edit Inclusion Data Record \(IDR\) on Page 49](#) for more information.

The **Edit Attributes** link appears for single- and multi-project awards when the project year is unawarded and inclusion monitoring is set to *Yes*. For competing grants in a status other than Pending Award (PA), Pending Council (PC), To Be Paid (TP), and NRFC (N), summary statements must exist. The link is also available for Last Budget Period IDRs. Users must have the IDR Editor role.

In the case of multi-year awards, the link is available at any time for the current fiscal year only to system users holding the IDR Editor role.

For contracts created in IMS, the **Edit Attributes** link is available when inclusion monitoring is set to *Yes* or *Yes-Pol*, until the inclusion data are administratively frozen for a given fiscal year. For contracts where IDR is created/updated via web service, this link is not available. For intramural projects this link is not available.

If required attributes have not been set for a given IDR NOT marked as *Delayed-Onset*, *Not Funded*, and/or *Type 2 Progress Report*, that IDR is marked with a red asterisk (*) next to the **Edit Attributes** link. Additionally, a notation at the top of the screen indicates ** - Required IDR Attributes are needed*. The indication only applies to the records included on the screen, and for multi-year funded awards, only to the current fiscal year.

Manage Inclusion Data Records (IDRs)

Project #: 1P20MH123456-01
 Fiscal Year: 2015
 PI Name: AUDEN, W.H.
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: The Age of Anxiety Disorders
 Appl. Status: Pending Council Review
 Number of Subprojects: 3

[Back to Search and Hit List](#)

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#)

Transfer IDRs ?
 * - Required IDR Attributes are needed ?

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
1P20MH123456-01 PI Name: AUDEN, W.H. Project Title: Sample Project Num (...more) Create New IDR	P	1025759		Received by Agency	09/16/2014 AUDEN, W.H.	09/16/2014 AUDEN, W.H.	View * Edit Attributes Edit Planned Edit Actual Delete IDR
StudyTitle: The Age of Anxiety Disorders							
1P20MH123456-01/Core-001 PI Name: Austen, Jane Subproject Project Title: Sample Pr (...more) Create New IDR	P	1025760		Received by Agency	09/16/2014 AUSTEN, JANE		View * Edit Attributes
StudyTitle: Pride & Prejudice and the Human Psyche							

Figure 27: Required IDR Attributes Are Needed

Edit Planned

Select the **Edit Planned** link to access the *Edit Planned Inclusion Data* screen for editing existing enrollment data. Refer to the topic titled [Edit Planned Inclusion Data on Page 58](#) for more information.

The **Edit Planned** link appears for single- and multi-project applications when the project year is unawarded and inclusion monitoring is set to *Yes*. For competing grants in a status other than Pending Award (PA), Pending Council (PC), To Be Paid (TP), and NRFC (N), summary statements must exist. Additionally, the link is only available for agency staff if IMS determines that the Grantee has not ever updated the data.

For single-project applications, the link is displayed for paper applications to those NIH staff members with the IDR Editor role when the IDR is in *Received by Agency* or *Previous FY Data* status.

In the case of multi-year funded applications, the link is available for the current fiscal year only, if inclusion monitoring is set to *Yes*. For competing grants in a status other than Pending Award (PA), Pending Council (PC), To Be Paid (TP), and NRFC (N), summary statements must exist. Additionally, the link is only available to agency staff if IMS determines that the Grantee has not ever updated the data.

For multi-year funded paper applications, the link will display to those with the IDR Editor role.

For contracts created in IMS, the **Edit Planned** link is available when inclusion monitoring is set to *Yes* or *Yes-Pol*, until the inclusion data are administratively frozen for a given fiscal year. For contracts where IDR is created/updated via web service, this link is not available. For intramural projects this link is not available.

This link is not available to agency staff for [Last Budget Period](#) type IDRs.

Edit Actuals

Select the **Edit Actuals** link to access the *Edit Actuals Inclusion Data* screen for editing actual enrollment data. Refer to the topic titled [Edit Actuals Inclusion Data on Page 62](#) for more information.

The **Edit Actuals** link appears for single- and multi-project applications when the project year is unawarded and inclusion monitoring is set to *Yes*. For competing grants in a status other than Pending Award (PA), Pending Council (PC), To Be Paid (TP), and NRFC (N), summary statements must exist. Additionally, the link is only available to agency staff if IMS determines that the Grantee has not ever updated the data.

For single-project awards, the link is displayed for paper applications to those with the IDR Editor role when the IDR is in *Received by Agency* or *Previous FY Data* status.

In the case of multi-year funded projects, the link is available for the current fiscal year only, if inclusion monitoring is set to *Yes*. For competing grants in a status other than Pending Award (PA), Pending Council (PC), To Be Paid (TP), and NRFC (N), summary statements must exist. Additionally, the link is only available to agency staff if IMS determines that the Grantee has not ever updated the data.

For multi-year funded paper applications, the link will display to those with the IDR Editor role.

For contracts created in IMS, the **Edit Actuals** link is available when inclusion monitoring is set to *Yes* or *Yes-Pol*, until the inclusion data are administratively frozen for a given fiscal year. For contracts where IDR is created/updated via web service, this link is not available. For intramural projects this link is not available.

This link is not available to agency staff for [Last Budget Period](#) type IDRs.

Delete

Use the **Delete** link to delete the inclusion data record. When the link is selected, a confirmation message displays: *Are you sure you want to delete this Inclusion Data Record? You will lose all related enrollment data. Do you want to continue?*

From this confirmation, select the **Continue** button to complete the process or the **Cancel** button to abort the deletion. Deleting an inclusion data record also deletes all related IDR information,

including the IDR attributes, Planned Inclusion Data, and Actual Inclusion Data. Once confirmed, this action cannot be undone.

The **Delete** link appears for single- and multi-project applications when the project year is unawarded, the IDR is in a status of *Received by Agency*, and IMS determines that the Grantee never updated the data. Additionally, the IDR must not have been submitted with the grant application via ASSIST or grants.gov or via the RPPR.

For contracts created in IMS, the **Delete** link is available when inclusion monitoring is set to *Yes* or *Yes-Pol*, until the inclusion data are administratively frozen for a given fiscal year. For contracts where IDR is created/updated via web service, this link is not available. For intramural projects this link is not available.

You must hold the IDR Editor role to delete IDR(s), and generally, only IDRs for paper applications or contracts can be deleted. If it is necessary to delete an IDR and the link is not available, you should contact the [IC IOPW](#) member to assist. It should be a rare circumstance where IDR(s) need to be deleted.

This link is not available to agency staff for [Last Budget Period](#) type IDRs.

3.4 Required IDR Attributes Are Needed

Inclusion Data Records (IDRs) consist of three parts:

- Planned Inclusion Data
- Cumulative(Actual) Inclusion Data
- IDR Attributes

IDR attributes can be entered using the *Edit Inclusion Data Record (IDR)* screen. Some attributes cannot be updated by Agency staff. These include attributes that exist on the form (e.g., Study Title, Foreign/Domestic Indicator, and comments) and attributes set automatically by IMS (IDR FY, IDR #, IDR Status). These attributes display on the screen as read-only fields.

Other IDR attributes are entered by Agency staff, with two of these attributes being required:

- **Existing Dataset or Resource**
- **Phase III Clinical Trials Code**

NOTE: These attributes are not required for IDRs marked as *Delayed Onset*, *Not Funded* and/or *Type 2 Progress Report*.

Refer to the topic titled [Edit Inclusion Data Record \(IDR\) on Page 49](#) for more information.

When the required attributes of an IDR are missing, a red asterisk (*) displays next to the **Edit Attributes** link on the *Manage Inclusion Data Records (IDRs)* screen.

NOTE: For intramural projects and contracts where the IDR is created/updated via web service, this is not applicable.

Select the **Edit Attributes** link to access the *Edit Inclusion Data Record (IDR)* screen to add the required attributes.

Manage Inclusion Data Records (IDRs)

Project #: [1P20MH123456-01](#)
 Fiscal Year: 2015
 PI Name: [AUDEN, W.H.](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: The Age of Anxiety Disorders
 Appl. Status: Pending Council Review
 Number of Subprojects: 3

[« Back to Search and Hit List](#)

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#)

[Transfer IDRs](#) ?
 * - Required IDR Attributes are needed ?

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
1P20MH123456-01 PI Name: AUDEN, W.H. Project Title: Sample Project Num (...more) Create New IDR	P	1025759		Received by Agency	09/16/2014 AUDEN, W.H.	09/16/2014 AUDEN, W.H.	View * Edit Attributes Edit Planned Edit Actual Delete IDR
StudyTitle: The Age of Anxiety Disorders							
1P20MH123456-01/Core-001 PI Name: Austen, Jane Subproject Project Title: Sample Pr (...more) Create New IDR	P	1025760		Received by Agency	09/16/2014 AUSTEN, JANE		View * Edit Attributes
StudyTitle: Pride & Prejudice and the Human Psyche							

3.5 Transfer Inclusion Data Record(s)

Use the *Transfer Inclusion Data Record(s) (IDRs)* screen to transfer IDRs from one component of a multi-component application, within the same support year. You can also transfer IDRs between a parent contract and projects. Select the **Transfer IDRs** link on *Manage Inclusion Data Records (IDRs)* to access the screen.

IMPORTANT: When the *Transfer Inclusion Data Record(s)* screen is accessed after award of the last support year of the grant, the screen provides the ability to transfer only Last Budget Period type IDRs which do NOT have associated regular IDRs. All other IDRs are excluded from the hitlist and are not eligible to be transferred.

Manage Inclusion Data Records (IDRs)

Project #: [1P20MH123456-01](#)
 Fiscal Year: 2015
 PI Name: [AUDEN, W.H.](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: The Age of Anxiety Disorders
 Appl. Status: Pending Council Review
 Number of Subprojects: 3

[Back to Search and Hit List](#)

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#) [Transfer IDRs](#) * - Required IDR Attributes are needed

Project Details	Flag	IDR#	IDR.IC.ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
1P20MH123456-01 PI Name: AUDEN, W.H. Project Title: Sample Project Num (...) Create New IDR	☑	1025759		Received by Agency	09/16/2014 AUDEN, W.H.	09/16/2014 AUDEN, W.H.	View * Edit Attributes Edit Planned Edit Actual Delete IDR
StudyTitle: The Age of Anxiety Disorders							
1P20MH123456-01/Core-001 PI Name: AUSTEN, JANE <small>Subsequent Project Title: Sample IDR</small>	☑	1025750		Received by Agency	09/16/2014 AUSTEN, JANE		View * Edit Attributes

Figure 28: Link for Accessing the Transfer Inclusion Data Records (IDRs) Screen

For grants, IDRs can be transferred from parent to subproject; subproject to parent; or subproject to subproject within the same support year of the same award. For contracts, IDRs can be transferred between a contract parent and contract projects with the same contract document number for the same fiscal year when inclusion monitoring code is set to *Yes* or *Yes-POL*. You cannot transfer IDRs when contracts data are frozen. The **Transfer IDRs** link is not available for intramural projects.

The **Transfer IDRs** link appears for multi-project grant applications when the given project year is unawarded and inclusion monitoring is set to *Yes*. The link is available for IMS users holding the IDR Editor role. This option is not available to multi-year funded awards.

Last Budget Period type IDRs can only be transferred if they are a new study with no *regular* IDR that they are associated with. This type of Last Budget Period IDR is created when the Grantee selects the option to **Create New Planned** after award of the last non-competing year in the funding period. These particular Last Budget Period type IDRs do not have associated regular IDRs. Note: This concept is not applicable for contracts.

When the link is selected, the *Transfer Inclusion Data Record(s) IDR* screen opens. The top portion of the screen displays the basic project information, including the project number, PI name linked to the contact information pop up, application status, and number of subprojects. This information varies depending on the type of project.

Below this is the portion of the screen representing the source of the transfer. The source IDRs are presented in separate tables, one for view-only IDRs and the other for editable IDRs, when applicable. Both tables include the same information, when inclusion data records exist:

Project #

This column displays the grant number or contract number, PI name, and project title (or

subproject title) associated with the IDR. The grant number is displayed as a link to the *Grant Snapshot* report for parent applications with a corresponding link to the *Grant Folder*. The contract number is linked to the *Contracts Information* screen.

The **PI Name** is also displayed as a link leading to the *PI Details* pop-up window. The displayed name is the Contact PI for parent applications and the Subproject Lead Name for subprojects.

Longer project titles might be truncated. Select the **More...** link to display the entire title.

Select for Transfer

The checkbox in this column provides a means for selecting which IDRs to transfer. These steps are described below. An IDR is available for transfer - and the checkbox displays - only if the IDR is in *Received by Agency*, *Received by Agency – RPPR*, or *Previous FY Data* status.

IDR #

The Inclusion Data Record number is displayed as a link to the *Inclusion Data Record (IDR) Details* screen.

IDR IC ID

The **IDR IC ID** is an identification number entered by Agency staff as one of the optional IDR attributes. This value is not the same as the system-generated IDR #. This field could be blank if an IDR IC ID number was not assigned.

IDR Status

This shows the current status of the IDR.

Study Title

Longer study titles might be truncated. Select the **More...** link to display the entire title.

At the bottom of the screen, a drop-down list titled **Target** houses all components of the multi-component project or contract records (can be parent and/or project(s), if the record has inclusion monitoring code *Yes* or *Yes-POL*) to which you can transfer the IDR(s). This does not include Review-only type subprojects (type R) or subprojects created in the RPPR module of Commons (type L).

To transfer the IDRs:

1. Find the appropriate project/subproject record(s) and mark the corresponding **Select for Transfer** checkbox(es).
2. From the **Transfer to:** drop-down list, select the project/subproject to which you are

transferring the IDR(s).

3. Select the **Transfer** button.

Transfer Inclusion Data Record(s) (IDRs)

Project #: [1P20MH123456-01](#)

Fiscal Year: 2015

PI Name: [AUDEN, W.H.](#)

Org Name: UNIVERSITY OF LITERARY REFERENCES

Project Title: The Age of Anxiety Disorders

Appl. Status: Pending Council Review

Number of Subprojects: 3

[Back to Manage IDR\(s\)](#)

IDR(s) can only be transferred when in certain IDR statuses. If there is no "select to transfer" check box, it is in a status where transfer cannot be completed.

Project Details	Select for Transfer	IDR#	IDR IC ID	IDR Status	Study Title
1P20MH123456-01 PI Name: AUDEN, W.H. Project Title: Sample Project Number One	<input type="checkbox"/>	1025759		Received by Agency	The Age of Anxiety Disorders
1P20MH123456-01/Core-001 PI Name: Austen, Jane Subproject Project Title: Sample Project Number Two	<input type="checkbox"/>	1025760		Pending SO	Pride & Prejudice and the Human Psyche
1P20MH123456-01/Admin-Core-001 PI Name: BARRIE, J.M. Subproject Project Title: Administrative Core	<input type="checkbox"/>	1025761		Received by Agency- RPPR	A Study of Peter Pan Syndrome
1P20MH123456-01/Pilot-Projects-Core-001 PI Name: SHAKESPEARE, WILLIAM Subproject Project Title: Pilot Projects Core	<input checked="" type="checkbox"/>	1025758		Received by Agency	A Midsummer Night's Dream: A study on sleep disorders

Transfer to:

Figure 29: Transfer Inclusion Data Records(s) (IDRs) Screen

NOTE: To leave the screen without completing a transfer, select the **Back to Manage (IDRs)** link or the **Cancel and Go Back** button. These options will return you to the *Manage Inclusion Data Records (IDRs)* screen.

When the **Transfer** link is selected, you will be returned to the *Manage Inclusion Data Records (IDRs)* screen, which will be updated to reflect the transfer. The transfer happens immediately with no confirmation, however, IMS will ignore any action in which the source and target are the same.

3.6 IDRs in the Last Budget Period

On award, the status of a regular IDR is changed to *Accepted*, thus freezing the data. However, grantees might need to report changes in enrollment data for the research performed during the period of time between award of the last support year and the end of the project period. Grantees can do this by creating a *Last Budget Period IDR*, which is assigned to the last support year of the grant, along with the regular IDR. They may also create a new IDR in the last budget period should a new study commence during that timeframe.

Last Budget Period type IDRs can be identified by the label (*Last Budget Period*) under the IDR number wherever it is displayed. Last Budget Period type IDRs have the same IDR #s as their

associated regular IDRs and display under those regular IDRs in hitlists within IMS. Newly created IDRs during the last budget period will not have a regular IDR they are associated with.

As with regular IDRs, Last Budget Period IDRs must be routed and submitted to the agency after being created via Commons Status. A Last Budget Period IDR is not visible for agency users before the Grantee submits it to Agency.

NOTE: Grantees can edit both Planned and Actual data for the last budget period.

Last Budget Period IDRs are created manually by the Grantee, meaning no automatic rollover of data will populate or create a Last Budget Period type IDR. Last Budget Period type IDR(s) are NOT part of the progress report for the last support year of the grant since they are created after that.

Manage Inclusion Data Records (IDRs) ?

Project #: [5R01NR123456-05](#) 📧
 Fiscal Year: 2015
 PI Name: [DOYLE, ARTHUR CONAN](#)
 Org Name: UNIVERSITY OF LITERARY REFERENCES
 Project Title: A Study in Scarlet Fever
 Appl. Status: Awarded. Non-fellowships only
 Number of Subprojects: 3

[⏪ Back to Search and Hit List](#) * - Required IDR Attributes are needed ?

Project Details ⌵	Flag ⌵	IDR# ⌵	IDR IC ID ⌵	IDR Status ⌵	Planned Last Update Date/ID ⌵	Actuals Last Update Date/ID ⌵	Actions	
5R01NR123456-05 📧 PI Name: DOYLE, ARTHUR CONAN Project Title: A Study in Scarlet Fev (...more)	F	1030325		Previous FY Data	01/28/2015 Holmes_Sherlock	01/28/2015 Holmes_Sherlock	View	
	StudyTitle: A Study in Scarlet Fever							
	F	1030325 (Last Budget Period)		Grantee Updates in Progress	01/28/2015 Holmes_Sherlock	01/28/2015 Holmes_Sherlock	View * Edit Attributes	
	StudyTitle: A Study in Scarlet Fever							
	F	143756		Previous FY Data	01/28/2015 Holmes_Sherlock	01/28/2015 Holmes_Sherlock	View	
	StudyTitle: A Study in Scarlet Fever							
F	143756 (Last Budget Period)		Received by Agency	01/28/2015 Holmes_Sherlock	01/28/2015 Holmes_Sherlock	View * Edit Attributes		
StudyTitle: A Study in Scarlet Fever								

Figure 30: Last Budget Period Type IDRs on Manage IDRs Screen

4 Edit Inclusion Data Record (IDR)

The *Edit Inclusion Data Record (IDR)* screen allows Agency staff to update attributes of an existing IDR or add attributes to a newly created IDR. The screen is accessed via the **Edit Attributes** link on the *Manage Inclusion Data Records* screen.

Manage Inclusion Data Records (IDRs)

Project #: [1P20MH345678-01](#) (paper)

Fiscal Year: 2015

PI Name: [SHAKESPEARE, WILLIAM](#)

Org Name: UNIVERSITY OF LITERARY REFERENCES

Project Title: A Midsummer Night's Dream and sleeping disorders

Appl. Status: Pending Council Review

Number of Subprojects: 0

[« Back to Search and Hit List](#)

View Options: [Hide All Subprojects](#) | [Show Subprojects with IDRs Only](#) * - Required IDR Attributes are needed

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
1P20MH345678-01 PI Name: SHAKESPEARE, WILLIAM Project Title: A Midsummer Night' (...more) Create New IDR	P	1025761		Received by Agency	09/16/2014 SHAKESPEARE, WILLIAM		View * Edit Attributes

StudyTitle: Sample Project Number 1

Figure 31: Select Edit Attributes Link to Access Edit Inclusion Data Record (IDR)

Some attributes cannot be updated by Agency staff. These include attributes that exist on the form (e.g., Study Title, Foreign/Domestic Indicator, and comments) and attributes set automatically by IMS (IDR FY, IDR #, IDR Status). These attributes display on the screen as read-only fields.

Other IDR attributes are entered by Agency staff, with some required and some optional (see below). These attribute fields are editable on an unawarded record. To edit the attributes, update all of the required fields and any of the optional fields as applicable. Click the **Save** button to save the changes.

Edit Inclusion Data Record (IDR) ?

Project #: [1P20MH345678-01](#) 🗑️

PI Name: [SHAKESPEARE, WILLIAM](#)

Project Title: A Midsummer Night's Dream and Other Sleep Disorders

Appl. Status: Pending Council Review

IDR #: 1025761

Study Title: ? Sample Project Number 1

Foreign/Domestic: ? Domestic

IDR Status: ? Received by Agency

IDR FY: 2015

Planned Enrollment Report Comments: These are sample comments for demonstration purposes...

Cumulative Inclusion Enrollment Report Comments: These are also sample comments...

Required IDR Attributes

*Required Field

* Existing Dataset or Resource: ? Yes No

* Phase III Clinical Trials Code:

Optional IDR Attributes

Not Funded: ?

Type 2 Progress Report: ?

IDR IC ID: ?

No Planned Enrollment Reason: ?

Enrollment Dates: ? Start End
(MM/DD/YYYY)

Recruitment Status: ?
[Look Up Recruitment Status](#)

Subpopulation: ?

Subpopulation Description: ?

Country(ies): Selected Countries:
UNITED STATES ✖

Clinical Trials Code:

Agency Staff Comments:
(Max 1,000 characters)

Figure 32: Edit Inclusion Data Record (IDR) Screen with Missing Attributes

If required fields are missing those fields will be listed in an error message at the top of the screen.

The *Edit Inclusion Data Record (IDR)* screen includes the following information and editable attributes:

Project Information (read-only)

Edit Inclusion Data Record (IDR)

Project #: 1P20MH345678-01
PI Name: SHAKESPEARE, WILLIAM
Project Title: A Midsummer Night's Dream and Other Sleep Disorders
Appl. Status: Pending Council Review

IDR #: 1025761
Study Title: Sample Project Number 1
Foreign/Domestic: Domestic
IDR Status: Received by Agency
IDR FY: 2015

Planned Enrollment Report Comments: These are sample comments for demonstration purposes...
Cumulative Inclusion Enrollment Report Comments: These are also sample comments...

Required IDR Attributes

Figure 33: Grant and Project Information Portion of Edit IDRs Screen

- **Project #**

For grants, this is the grant number of the selected record. Parent and single-project grants display with links to the *Grant Snapshot* report and the *Grant Folder*. Included next to the grant number is the word (paper) to indicate a paper application.

For contracts, this is the contract number of the selected record. It is linked to the [Contracts Information](#) pop-up screen.

- **PI Name**

The name of the contact PI on the project record. For subprojects, this is the Subproject Lead Name entered on the record. The name is displayed as a link, which opens the *PI Details* pop-up displaying the person's contact information.

- **Project Title**

The name of the project for the parent, multi-year funded award, or contract.

- **Application Status**

The current status of the project.

IDR Information (read-only)

Figure 34: IDR Information Portion of Edit IDRs Screen

- **IDR #**

If the IDR is a [Last Budget Period](#) type IDR, the words (*Last Budget Period*) display next to the IDR #.

- **Study Title**
- **Foreign/Domestic indicator**
- **IDR Status**
- **IDR FY**
- **Planned Enrollment Report Comments**

These are the comments submitted by the Grantee user on the Planned Enrollment Report or by the Agency user (i.e., IDR Editor) on the form data for Planned Enrollment.

- **Cumulative Enrollment Report Comments**

These are the comments submitted by the Grantee user on the Cumulative Inclusion Enrollment Report or by the Agency user (i.e., IDR Editor) on the form data for Actual Enrollment.

Required IDR Attributes

The following fields are required attributes. These fields must be populated with a value.

IDR FY: 2015
Planned Enrollment Report Comments: These are sample comments for demonstration purposes...
Cumulative Inclusion Enrollment Report Comments: These are also sample comments...

Required IDR Attributes
*Required Field

* Existing Dataset or Resource: Yes No

* Phase III Clinical Trials Code:

Save Cancel

Optional IDR Attributes

Not Funded:

Type 2 Progress Report:

IDR IC ID:

Figure 35: Required IDR Attributes on Edit IDRs Screen

- **Existing Dataset or Resource**

If there are questions regarding the definition of an existing dataset or resource, please refer to the following FAQ: http://grants.nih.gov/grants/funding/women_min/datasets_faq.htm

Select the appropriate radio button:

Yes

No

When updating a value previously entered, a warning message will display. Respond to the warning with **Continue** or **Cancel** as appropriate.

Warning: You are about to change whether this study involves an existing dataset or resource. This is an important attribute of this inclusion data record, and this change has implications for reporting. Are you certain you wish to take this action?

- **Phase III Clinical Trials Code**

This field indicates whether the specific IDR involves an NIH-defined Phase III clinical trial. It is a required attribute.

Phase III Clinical Trials Codes are as follows:

Y – NIH-defined Phase III Clinical Trial

N – Clinical Research – not an NIH-defined Phase III clinical trial

NOTE: If the Phase III Clinical Trials Code on the *grant* level is set to *X* or *N*, the value of the cannot be set to *Y* for the IDR.

When updating a value previously entered, a warning message will display. Respond to the warning with **Continue** or **Cancel** as appropriate.

Warning: You are about to change whether this study involves NIH-defined Phase III clinical trial. This is an important attribute of this inclusion data record, and this change has implications for reporting. Are you certain you wish to take this action?

When editing an existing IDR migrated from the POP Tracking system, it is possible that a value of *X – Not Clinical Research; Gender/Minority Codes not assigned* exists in this field. This value is read-only and can only be changed by Data Quality. Contact the eRA Help Desk for assistance.

Optional IDR Attributes

The screenshot shows the 'Optional IDR Attributes' section of the 'Edit IDRs' screen. The section is highlighted with a red border. It includes the following fields and controls:

- Required IDR Attributes:**
 - Existing Dataset or Resource: Yes No
 - Phase III Clinical Trials Code: [Dropdown menu]
 - Buttons: Save, Cancel
- Optional IDR Attributes:**
 - Not Funded:
 - Type 2 Progress Report:
 - IDR IC ID: [Text input]
 - No Planned Enrollment Reason:
 - Enrollment Dates: [Start date picker] [End date picker]
 - Recruitment Status: [Text input] [Look Up Recruitment Status](#)
 - Subpopulation:
 - Subpopulation Description: [Text input]
 - Country(ies): Selected Countries: UNITED STATES
 - Clinical Trials Code: [Dropdown menu]
 - Agency Staff Comments: [Text area, Max 1,000 characters]
 - Buttons: Save, Cancel

Figure 36: Optional IDR Attributes Portion of Edit IDRs Screen

The following attributes are optional.

- Not Funded

Check the **Not Funded** box to indicate that the IDR will not be funded. This generally applies when there are budget/scope reductions to a project. Not Funded IDRs are not rolled forward to the out year record. On award, status of this IDR is updated to *Accepted – Not rolled forward*.

NOTE: The attributes in the **Required Attributes** section are no longer required when the **Not Funded** attribute is selected.

- Type 2 Progress Report (grants only)

Check the **Type 2 Progress Report** box to indicate that the IDR is a part of the competing submission progress report and does not reflect a study that will be active during the new funding period. Type 2 Progress Report IDRs are not rolled forward to the out year record (if this box is checked). On award, the status of this IDR is updated to *Accepted – Not rolled forward*.

NOTE: This box is greyed out for contracts and is not relevant to the contracts process.

Selecting this attribute box and saving the IDR results in the following warning message:

Warning: You are about to set this IDR as being part of the competing submission progress report. This means that the IDR will no longer roll forward in this project period. Do you wish to proceed?

If you do not wish to proceed, select the **Cancel** button, un-select the **Type 2 Progress Report** box, and save again.

NOTE: The attributes in the **Required Attributes** section are no longer required when the **Type 2 Progress Report** attribute is selected.

- IDR IC ID

The **IDR IC ID** is an identification number entered by Agency staff as one of the optional IDR attributes. This value is not the same as the system-generated IDR #. This field could be blank if an IDR IC ID number was not assigned.

- **No Planned Enrollment Reason**

The **No Planned Enrollment Reason** indicates why there is no planned enrollment data for the Inclusion Data Record (i.e., planned inclusion counts are equal to zero). Other than leaving blank, the only value available for selection is **Delayed On-Set**. Delayed on-set refers to studies that could not originally be described with the competing application. This field should not be used to indicate a study that has delayed enrollment start. [Here](#) is more guidance on delayed on-set studies.

When editing an existing IDR migrated from the POP Tracking system, it is possible that a value of *TS Phase I Toxicity Study* exists in this field. This value is read-only and can only be changed by Data Quality. Contact the eRA Help Desk for assistance.

- **Enrollment Dates**

Enter a **Start** and **End** date for enrollment into the study in MM/DD/YYYY format or select dates from the calendar tool.

- **Recruitment Status**

Click the **Look Up Recruitment Status** link to open the list of options. Select the radio button of the appropriate status and select the **Save** button.

To remove a selected status, click the red **X** displayed next to the status term.

Valid Recruitment Status values are as follows:

Not yet recruiting: Participants are not yet being recruited

Recruiting: Participants are currently being recruited

Enrolling by invitation: Participants are being (or will be) selected from a predetermined population

Active, not recruiting: Study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled

Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred)

Suspended: Recruiting or enrolling participants has halted prematurely but potentially will resume

Terminated: Recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated

Withdrawn: Study halted prematurely, prior to enrollment of first participant

- **Subpopulation**

Check the **Subpopulation** box to indicate that enrollment counts involve a subpopulation that the IC elects to provide additional information about.

- **Subpopulation Description**

Use the **Subpopulation Description** free-text field to enter a description of subpopulation(s) involved in the study, if applicable. The text must not exceed 255 characters.

- **Country(ies): Selected Countries**

List the country or countries associated with the IDR. For IDRs with a **Foreign/Domestic** indicator set to *Domestic*, only the United States displays in the field as a read-only value.

For IDRs with an indicator value of *Foreign*, the associated countries display with a red **X** next to them. To remove a country, select the red **X**. To add a country, select the **Look Up Country** link, enter the name of the country in the *Select Countries* pop-up window, and click the **Save** button.

Tip: You can search for and select multiple countries as necessary before hitting the **Save** button and closing the window.

- **Clinical Trials Code**

Select a value of *Yes* or *No* to indicate the Clinical Trials Code at the IDR level.

- **Agency Staff Comments**

Enter comments into the free-text field as necessary. The text must not exceed 1,000 characters.

NOTE: The **Cancel** button can be used at any time to close the *Edit Inclusion Data Record (IDR)* screen without make changes.

5 Edit Planned Inclusion Data

The *Edit Planned Inclusion Data* screen is used to update planned inclusion enrollment data for an existing IDR or to enter data when creating a new IDR. The screen is accessed from the *Manage Inclusion Data Records* screen by selecting either the **Edit Planned** link for editing an existing IDR or the **Create New IDR** link for creating an IDR.

Refer to the topic titled [Manage Inclusion Data Records on Page 29](#) for more information.

Edit Planned Inclusion Data ?

Project #: [SP01CA456789-01](#) Project FY: 2015
 PI Name: [SHAKESPEARE, WILLIAM](#) IDR FY: 2015
 Project Title: The Taming of the Flu
 Project Status: Pending Award, Non-fellowships

Planned Enrollment Report *Required field(s)

(If IDR number is blank, it will be generated on Save) IDR #: ?

*Study Title: ?

*Foreign/Domestic: ?

Comments:

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Asian	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Native Hawaiian or Other Pacific Islander	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Black or African American	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
White	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
More Than One Race	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	0
Total	0	0	0	0	0

Figure 37: Edit Planned Inclusion Data Form

The *Edit Planned Inclusion Data* screen contains the following information:

Header Fields

- **Project #**

For grants, the project number displays the grant number and includes links to the *Grant Snapshot* report and the *Grant Folder* for parent and single-projects only. Included next to the grant number is the word (paper) to indicate a paper application.

For contracts, the project number displays the contract number and links to the *Contract Information* pop-up.

- **Project FY**

Represents the fiscal year of the project.

- **PI Name**

The name of the contact PI on the project record. For subprojects, this is the Subproject Lead Name entered on the record. The name is displayed as a link, which opens the *PI Details* pop-up displaying the person's contact information.

- **IDR FY**

Displays the fiscal year of the application to which the IDR is attached. For multi-year funded awards, this field is defaulted to the current fiscal year.

- **Project Title**

The project title of the project record.

- **Project Status**

Displays the status of the project. For subproject records, this is the subproject status.

Planned Inclusion Enrollment Report Fields

- **IDR #**

Displays the system-generated identification number of the inclusion data record. When creating a new IDR, this field is blank, and the IDR number will generate upon saving.

- **Study Title**

The study title of the IDR, pre-populated with the existing title and editable when editing an IDR.

For a new IDR, this field displays blank. Enter the new IDR's study title into the field. This is required.

- **Foreign/Domestic**

This field indicates whether the IDR involves participants from a non-US (i.e., foreign) site or a US (i.e., domestic) site. This field is pre-populated when editing an existing IDR.

When creating a new IDR, select the value from the drop-down list that is appropriate for the participants involved in the study. If the study involves participants at US and non-US sites, separate IDRs will need to be created. This is a required field.

- **Comments**

An optional text field for entering comments. This field is pre-populated when editing an existing IDR and blank when creating a new IDR.

The planned enrollment form includes racial categories along the left side the of the table and ethnic categories, divided by sex/gender, along the top of the table. The individual enrollment count cells are editable and set to zero by default, when populating a new IDR. When editing an existing form, these values are pre-populated with any other value previously entered. The total fields are calculated by IMS and sum up as rows and columns accordingly. The total values are not editable fields.

Update the values in the individual enrollment count cells as necessary, and select the **Save** button. To leave the form without saving any changes, select the **Cancel** button instead. Saving and cancelling both return you to the *Manage Inclusion Data Records* screen.

IMS will perform validations to make sure the data can be saved. Warnings or errors may appear on the screen preventing you from saving your information.

- If you enter and save 0s on the form when enrollment data previously was migrated from the previous NIH inclusion data system, you will receive a warning message before the data can be saved:

Warning: You are about to submit zeroes for your planned enrollment when data in the previous OMB-approved format exists. Would you like to proceed?

Select **Proceed** to continue or **Cancel** to abort the action.

- If a grantee user has locked the data by accessing it via the their RPPR, your changes cannot be saved, and you will receive an error message.

At this time the data is edited by Grantee in RPPR.

Upon a successful save of a new IDR, attributes (Study Title, Foreign/domestic indicator/planned comments), Planned Inclusion Data (as entered), and Cumulative Inclusion Data (as zeroes) are also created; the new IDR is assigned a unique IDR #; and the IDR status is set to *Received by Agency*.

6 Edit Actuals Inclusion Data

The *Edit Actuals Inclusion Data* screen is used to update actual inclusion data for an IDR. The screen is accessed by selecting the **Edit Actual** link on the *Manage Inclusion Data Records* screen.

Refer to the topic titled *Manage Inclusion Data Records on Page 29* for more information.

Edit Actuals Inclusion Data ?

Project #: 5P01CA456789-01	Project FY: 2015
PI Name: SHAKESPEARE, WILLIAM	IDR FY: 2015
Project Title: The Taming of the Flu	
Project Status: Pending Award. Non-fellowships	

Cumulative Inclusion Enrollment Report *Required field(s)

(If IDR number is blank, it will be generated on Save) IDR #:

Foreign/Domestic: Domestic

Planned Enrollment Report Comments:

*Study Title:

Comments:

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/ Alaska Native	<input type="text" value="32"/>	<input type="text" value="20"/>	<input type="text" value="0"/>	<input type="text" value="16"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="12"/>	<input type="text" value="0"/>	80
Asian	<input type="text" value="20"/>	<input type="text" value="20"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	40
Native Hawaiian or Other Pacific Islander	<input type="text" value="24"/>	<input type="text" value="30"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	54
Black or African American	<input type="text" value="36"/>	<input type="text" value="41"/>	<input type="text" value="0"/>	<input type="text" value="5"/>	<input type="text" value="12"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	94
White	<input type="text" value="39"/>	<input type="text" value="51"/>	<input type="text" value="0"/>	<input type="text" value="3"/>	<input type="text" value="2"/>	<input type="text" value="0"/>	<input type="text" value="1"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	96
More Than One Race	<input type="text" value="10"/>	<input type="text" value="6"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	16
Unknown or Not Reported	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="3"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	3
Total	161	168	3	24	14	0	1	12	0	383

Figure 38: Edit Actuals Inclusion Data Screen

The *Edit Actuals Inclusion Data* screen contains the following information:

Header Fields

- **Project #**

For grants, the project number displays the grant number and includes links to the *Grant Snapshot* report and the *Grant Folder* for parent and single-projects only. Included next to the grant number is the word (paper) to indicate a paper application.

For contracts, the project number displays the contract number and links to the *Contract Information* pop-up.

- **Project FY**

Represents the fiscal year of the project.

- **PI Name**

The name of the contact PI on the project record. For subprojects, this is the Subproject Lead Name entered on the record. The name is displayed as a link, which opens the *PI Details* pop-up displaying the person's contact information.

- **IDR FY**

Displays the fiscal year of the project to which the IDR is attached. For multi-year funded awards, this field is defaulted to the current fiscal year.

- **Project Title**

The project title of the project record.

- **Project Status**

Displays the status of the project. For subproject records, this is the subproject status.

Cumulative Inclusion Enrollment Report Fields

- **IDR #**

Displays the system-generated identification number of the inclusion data record

- **Foreign/Domestic**

Foreign/Domestic indicates whether the IDR involves participants from a non-US site (i.e., foreign) or a US site (i.e., domestic). It is a required attribute.

Foreign/Domestic Indicator values are as follows:

Foreign

Domestic

- **Planned Enrollment Report Comments**

Displays the comments entered on the Planned Enrollment Form.

- **Study Title**

Displays the study title for the IDR, pre-populated from the Planned Enrollment Form. This is an editable, required field.

- **Comments**

An optional text field for entering actual enrollment comments. This field is pre-populated when editing an existing IDR. If any comments were entered before, this field is pre-populated when editing an existing IDR.

The actual enrollment form includes racial categories along the left side the of the table and ethnic categories, divided by sex/gender, along the top of the table. The individual enrollment count cells are editable and set to zero by default, when populating a new IDR. When editing an existing form, these values are pre-populated with any other values previously entered. The total fields are calculated by IMS and sum up as rows and columns accordingly. The total values are not editable fields.

NOTE: The cumulative inclusion form includes fields for entering Unknown/Not Reported race, ethnicity, and sex/gender data.

Update the values in the individual enrollment count cells as necessary, and select the **Save** button. To leave the form without saving any changes, select the **Cancel** button instead. Saving and canceling both return you to the *Manage Inclusion Data Records* screen.

IMS will perform validations to make sure the data can be saved. Warnings or errors may appear on the screen preventing you from saving your information.

- If you enter and save 0s on the form when enrollment data previously was migrated from the previous NIH inclusion data system, you will receive a warning message before the data can be saved:

Warning: You are about to submit zeroes for your cumulative inclusion enrollment data when data in the previous OMB-approved format exists. Would you like to proceed?

Select **Proceed** to continue or **Cancel** to abort the action.

- If a grantee user has locked the data by accessing it via the their RPPR, your changes cannot be saved, and you will receive an error message.

At this time the data is edited by Grantee in RPPR.

When data is saved, the Last Updated Date and Last Updated ID are updated.

7 Inclusion Data Record (IDR) Details

Access the *Inclusion Data Record (IDR) Details* screen by selecting the **IDR#** link or **View** action option from the *Manage Inclusion Data Records* screen or by selecting the **View** option from the **Inclusion** section of the *Grant Folder*. You can also access the screen by selecting the IDR# (displayed as a link) on the *Transfer Inclusion Data Record(s) (IDRs)* screen.

NOTE: Access via Grant Folder is not applicable to contracts.

The screen shows details of a selected IDR, including overall project information, IDR attributes, enrollment distribution, the detailed enrollment report, a summary of enrollment, and history of actions performed against the IDR.

For a single-year funded or multi-project award, the screen displays the latest version of the IDR if accessed via another IMS screen or the selected version of the IDR when accessed via *Grant Folder*. For multi-year funded awards, the screen displays the latest version of the IDR for the requested fiscal year if accessed via another IMS screen or the selected version of the IDR for the requested fiscal year when accessed via *Grant Folder*.

Close

Inclusion Data Record (IDR) Details ?

View Reported FY: 2015

Project #: [1P20MH345678-01](#) (paper)
 PI Name: [SHAKESPEARE, WILLIAM](#)
 Current Inclusion Data | Prior Versions: [09/22/2014](#) [09/19/2014](#)
 Project Title: A Midsummer Night's Dream and Other Sleep Disorders
 Appl. Status: Pending Award. Non-fellowships

Additional Project Information

Inclusion Data Record (IDR)
Enrollment Distribution
Detailed Enrollment Report
Enrollment Summary
Action History

Inclusion Data Record (IDR)

Study Title:	Documentation Team - for Flare screen shots		
IDR Status: ?	Received by Agency	Existing Dataset or Resource: ?	No
Source Unique Value: ?		Site Code:	
IDR #: ?	1026033	IDR IC ID: ?	
No Planned Enrollment Reason: ?			
Enrollment Dates: ?		Recruitment Status: ?	Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently been recruited or enrolled
Subpopulation: ?	No	Subpopulation Description:	
Foreign/Domestic:	Domestic	Country(ies):	UNITED STATES
Phase III Clinical Trials Code:	N-Clinical Research -- not an NIH-defined Phase III clinical trial	Clinical Trials Code:	No
Not Funded: ?		Type 2 Progress Report: ?	
Agency Staff Comments:			

Enrollment Report - Simple View

Planned Enrollment Report

Comments: These are my comments

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	35	58	25	5	123
Asian	30	30	0	0	60

Figure 39: Default View of Inclusion Data Record (IDR) Details Screen

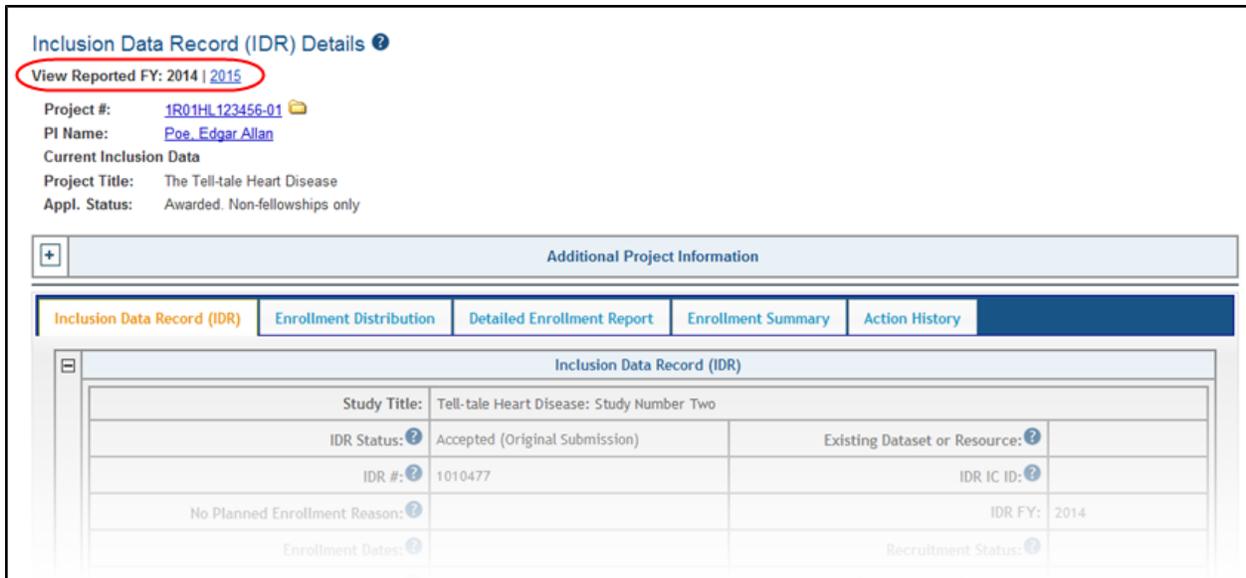


Figure 40: Top Portion of Inclusion Data Record Details for Multi-Year Funded Award

The screen is divided into 3 sections:

- Header
- Additional Project Information
- Tabbed sections of additional data

Header Section

The header section of *Inclusion Data Record (IDR) Details* displays general project information related to the selected IDR. The following information is included in the header section of the screen:

- **View Reported FY**

IMS allows switching between fiscal years by selecting the appropriate year's link. The screen's default view depends on which record was chosen to view when you accessed the screen. When a fiscal year's IDR is in the current view, the link becomes disabled and is displayed as bold text instead.



Figure 41: View Report FY Links on IDR Details

- **Project #**

The project number, displayed with links to the Grant Snapshot report and the Grant Folder for parent and single-projects only (grants) or to the *Contract Details* pop-up screen (contracts).

Please note the difference between grants, intramural, and contracts project numbers. This field displays the grant number (e.g., 1R01AI123456-01) for grants and a similar number starting with Z for intramural projects. The contract number (e.g., N01DE32636-0-0-1) is displayed for contracts. Refer to the topic titled [Contracts on Page 99](#) for information on distinguishing contract parent records from contract project records

- **PI Name**

The name of the contact PI on the project record. For subprojects, this is the Subproject Lead Name entered on the record. The name is displayed as a link, which opens the *PI Details* pop-up displaying the person's contact information.

For intramurals, this is not a hyperlink.

- **Current Inclusion Data|Prior Versions**

When the *Inclusion Data Record (IDR) Details* screen is accessed from any other IMS screen, the screen displays the latest (i.e., current) version of the IDR. To view prior versions of the IDR, select the date link of the prior version you wish to view. To return to the current version, select the **Current Inclusion Data** link. The corresponding link –either the current version or a selected prior version – displays in bold font as a visual indication of the view.

When viewing *Inclusion Data Record (IDR) Details* for a [Last Budget Period type IDR](#), the words (*Last Budget Period*) display next to the **Current Inclusion Data** link. On the same line, links to the prior version of the Last Budget Period type IDR (if applicable) display next to the title **Prior Versions of Last Budget Period**. Links to the prior version(s) of the corresponding regular IDR display beneath this information, next to the label **Prior Versions**; these links do not exist for Last Budget Period IDRs not associated with a regular IDR (i.e., new study).

NOTE: Last Budget Period type IDRs are not applicable to contracts.



Figure 42: Sample Header Section for Last Budget Type IDR

NOTE: When the *Inclusion Data Record (IDR) Details* screen is accessed via the Grant Folder, the screen displays the selected version as default.

- **Project Title**

The name of the project for the parent grant, multi-year funded award, or contract.

- **Appl. Status**

The current status of the project.

Additional Project Information

The **Additional Project Information** section of the screen is collapsed by default and can be expanded by clicking the [+] icon next to the section title. This expandable section displays on all views (tabs) of the screen.

Inclusion Data Record (IDR) Details ?

View Reported FY: 2015

Project #: [1P20MH345678-01](#) (paper)
 PI Name: [SHAKESPEARE, WILLIAM](#)
 Current Inclusion Data | Prior Versions: [09/22/2014](#) [09/19/2014](#)
 Project Title: A Midsummer Nights' Dream and Other Sleep Disorders
 Appl. Status: Pending Award. Non-fellowships

Additional Project Information			
AppI ID:	1234567	FY:	2015
Org Name:	UNIVERSITY OF LITERARY REFERENCES	FOA:	CA12-123
Project Dates:	08/01/2014 - 07/31/2019	Inclusion Monitoring Req'd:	Yes
PCC:	G1AC	PO Name:	Goodfellow, Robin
NCT No. (CT.GOV):			
Phase III Clinical Trial Code:	N - Clinical Research -- not an NIH-defined Phase III clinical trial		
Clinical Trial Code:	No		
Human Subject Code:	30 - Human subjects involved - Certified, no SRG concerns		
Gender Clinical Study Code:	1A - Both genders, scientifically acceptable		
Minority Clinical Study Code:	1A - Minorities and non-minorities, scientifically acceptable		
Child Clinical Study Code:	3A - No children included, scientifically acceptable		

Inclusion Data Record (IDR) | Enrollment Distribution | Detailed Enrollment Report | Enrollment Summary | Action History

Inclusion Data Record (IDR)			
Study Title:	Sample Study Title Number Five		
IDR Status:	Received by Agency	Existing Dataset or Resource:	No
IDR #:	1026033	IDR IC ID:	

Figure 43: Additional Project Information Section of IDR Details

The information in this section includes:

- Appl ID
- Contract Document Number (contracts only)
- Contracting Officer Name (contracts only)
- Org Name
- FOA
- FY
- Project Dates
- Inclusion Monitoring Req'd
- PCC
- PO Name
- NCT No. (CT.GOV)
- Phase III Clinical Trial Code
- Clinical Trial Code

- Human Subject Code
- Gender Clinical Study Code
- Minority Clinical Study Code
- Child Clinical Study Code

Tabbed Sections of Additional Data

Additional IDR data is displayed on tabs within the screen.

The screenshot displays the 'Inclusion Data Record (IDR) Details' page. At the top, it shows project information: Project # 1P20MH345678-01 (paper), PI Name SHAKESPEARE, WILLIAM, Current Inclusion Data | Prior Versions: 09/22/2014 09/19/2014, Project Title: A Midsummer Nights' Dream and Other Sleep Disorders, and Appl. Status: Pending Award. Non-fellowships.

Additional Project Information			
AppI ID:	1234567	FY:	2015
Org Name:	UNIVERSITY OF LITERARY REFERENCES	FOA:	CA12-123
Project Dates:	08/01/2014 - 07/31/2019	Inclusion Monitoring Req'd:	Yes
PCC:	G1AC	PO Name:	Goodfellow, Robin
NCT No. (CT.GOV):			
Phase III Clinical Trial Code:	N - Clinical Research -- not an NIH-defined Phase III clinical trial		
Clinical Trial Code:	No		
Human Subject Code:	30 - Human subjects involved - Certified, no SRG concerns		
Gender Clinical Study Code:	1A - Both genders, scientifically acceptable		
Minority Clinical Study Code:	1A - Minorities and non-minorities, scientifically acceptable		
Child Clinical Study Code:	3A - No children included, scientifically acceptable		

Below the table is a tabbed interface with five tabs: 'Inclusion Data Record (IDR)', 'Enrollment Distribution', 'Detailed Enrollment Report', 'Enrollment Summary', and 'Action History'. The 'Inclusion Data Record (IDR)' tab is highlighted with a red circle.

The 'Inclusion Data Record (IDR)' tab content shows:

Inclusion Data Record (IDR)			
Study Title:	Sample Study Title Number Five		
IDR Status:	Received by Agency	Existing Dataset or Resource:	No

Figure 44: Tabbed Sections of IDR Details

Refer to the appropriate related topic for information on the following tabs:

- **Inclusion Data Record (IDR) tab**
- **Enrollment Distribution tab**
- **Detailed Enrollment Report tab**
- **Enrollment Summary tab**
- **Action History tab**

7.1 Inclusion Data Record (IDR) Tab

The **Inclusion Data Record (IDR)** tab of the *Inclusion Data Record (IDR) Details* screen displays the *Inclusion Data Record* and the *Enrollment Report – Simple View*.

7.1.1 Inclusion Data Record

The **Inclusion Data Record** portion shows the attributes of the IDR as managed by Agency staff. The attributes, which are maintained on the *Edit Inclusion Data Record* screen, are displayed on this screen are read-only.

Inclusion Data Record (IDR) Details ?

View Reported FY: 2015

Project #: [1P20MH345678-01](#) (paper)
 PI Name: [SHAKESPEARE, WILLIAM](#)
 Current Inclusion Data | Prior Versions: [09/22/2014](#) [09/19/2014](#)
 Project Title: A Midsummer Night's Dream and Other Sleep Disorders
 Appl. Status: Pending Award. Non-fellowships

Additional Project Information

Inclusion Data Record (IDR)
Enrollment Distribution
Detailed Enrollment Report
Enrollment Summary
Action History

Inclusion Data Record (IDR)

Study Title: Documentation Team - for Flare screen shots			
IDR Status: ?	Received by Agency	Existing Dataset or Resource: ?	No
Source Unique Value: ?		Site Code:	
IDR #: ?	1026033	IDR IC ID: ?	
No Planned Enrollment Reason: ?			
Enrollment Dates: ?		Recruitment Status: ?	Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently been recruited or enrolled
Subpopulation: ?	No	Subpopulation Description:	
Foreign/Domestic:	Domestic	Country(ies):	UNITED STATES
Phase III Clinical Trials Code:	N-Clinical Research -- not an NIH-defined Phase III clinical trial	Clinical Trials Code:	No
Not Funded: ?		Type 2 Progress Report: ?	
Agency Staff Comments:			

Enrollment Report - Simple View

Planned Enrollment Report

Comments: These are my comments

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	

Figure 45: Inclusion Data Record (IDR) on IDR Details

Study Title

IDR Status

Existing Dataset or Resource

Source Unique Value

Site Code

IDR

IDR IC ID

No Planned Enrollment Reason

IDR FY

Enrollment Dates

Recruitment Status

Indicates the recruitment status of the project. Valid status values include:

Blank: No recruitment status has been entered.

Not yet recruiting: Participants are not yet being recruited

Recruiting: Participants are currently being recruited

Enrolling by invitation: Participants are being (or will be) selected from a predetermined population

Active, not recruiting: Study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled

Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred)

Suspended: Recruiting or enrolling participants has halted prematurely but potentially will resume

Terminated: Recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated

Withdrawn: Study halted prematurely, prior to enrollment of first participant

Subpopulation

The *Yes* or *No* value in this field indicates whether enrollment counts involve a subpopulation that the IC elects to provide additional information about.

Subpopulation Description

Where applicable, displays the entered description for the subpopulation involved in the

study.

Foreign/Domestic

Indicates whether the IDR is foreign or domestic.

Country(ies)

Displays the list of countries associated with the IDR. For IDRs with a Foreign/Domestic indicator set to Domestic, only the United States displays in the field.

Phase III Clinical Trial Code

Displays the Phase III Clinical Trial code for the IDR.

Phase III Clinical Trials Codes are as follows:

Y – NIH-defined Phase III Clinical Trial

N – Clinical Research – not an NIH-defined Phase III clinical trial

Clinical Trial Code

The *Yes* or *No* value in this field indicates whether the specific IDR involves a clinical trial. This value does not exist at the subproject level.

Not Funded

A *Yes* value indicates that the IDR will not be funded. This generally applies when there are budget/scope reductions to a project. Not Funded IDRs are not rolled forward to the out year record. On award, status of this IDR is updated to *Accepted – Not rolled forward*.

Type 2 Progress Report

A *Yes* value indicates that the IDR is a part of the competing submission progress report and does not reflect a study that will be active during the new funding period. Type 2 Progress Report IDRs are not rolled forward to the out year record . On award, the status of this IDR is updated to *Accepted – Not rolled forward*. This is not relevant to the contracts process.

Agency Staff Comments

Displays any comments for this IDR entered by Agency staff.

You can find definitions of these terms in the [Glossary of Related Terms on Page 103](#).

7.1.2 Enrollment Report – Simple View

The **Enrollment Report – Simple View** section of the *Inclusion Data Record (IDR) Details* screen shows simple tables of enrollment information for planned enrollment and cumulative enrollment for the selected version. For more detailed enrollment information, access the **Detailed**

Enrollment Report tab on the screen. Refer to the topic titled [Detailed Enrollment Report on Page 81](#) for more information.

Inclusion Data Record (IDR)	Enrollment Distribution	Detailed Enrollment Report	Enrollment Summary	Action History
-----------------------------	-------------------------	----------------------------	--------------------	----------------

Inclusion Data Record (IDR)

Study Title:	Documentation Team - for Flare screen shots		
IDR Status:	Received by Agency	Existing Dataset or Resource:	No
Source Unique Value:		Site Code:	
IDR #:	1026033	IDR IC ID:	
No Planned Enrollment Reason:			
Enrollment Dates:		Recruitment Status:	Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently been recruited or enrolled
Subpopulation:	No	Subpopulation Description:	
Foreign/Domestic:	Domestic	Country(ies):	UNITED STATES
Phase III Clinical Trials Code:	N-Clinical Research -- not an NIH-defined Phase III clinical trial	Clinical Trials Code:	No
Not Funded:		Type 2 Progress Report:	
Agency Staff Comments:			

Enrollment Report - Simple View

Planned Enrollment Report

Comments: These are my comments

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	35	58	25	5	123
Asian	20	20	0	0	40
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	10	18	0	0	28
White	30	38	4	6	78
More Than One Race	2	4	10	10	26
Total	97	138	39	21	295

Cumulative Enrollment (Actual) Report

Comments: These are my sample comments...

Racial Categories	Ethnic Categories									Total
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/ Alaska Native	33	60	0	25	5	0	2	1	0	126
Asian	21	20	0	0	0	2	0	0	0	43
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	12	15	1	2	1	0	0	0	0	31
White	27	40	2	5	10	0	1	2	0	87
More Than One Race	3	4	0	10	10	0	0	0	0	27
Unknown or Not Reported	1	0	0	0	2	0	1	15	0	19
Total	97	139	3	42	28	2	4	18	0	333

Previous Year Total Enrollment: 0

Figure 46: Enrollment Report–Simple View

Data last saved in the previous NIH inclusion data system and migrated to IMS will display in the previous OMB-approved format. In this case, the following notes will appear on the screen:

- Planned Enrollment Report: *NOTE: Planned enrollment comments (if any) will be viewed in the previous OMB-approved layout until a competing submission is received in FY15 or beyond.*
- Cumulative Enrollment Report: *NOTE: Cumulative enrollment and comments (if any) will be viewed in the previous OMB-approved layout for data reported in FY14 and prior years.*

7.2 Enrollment Distribution

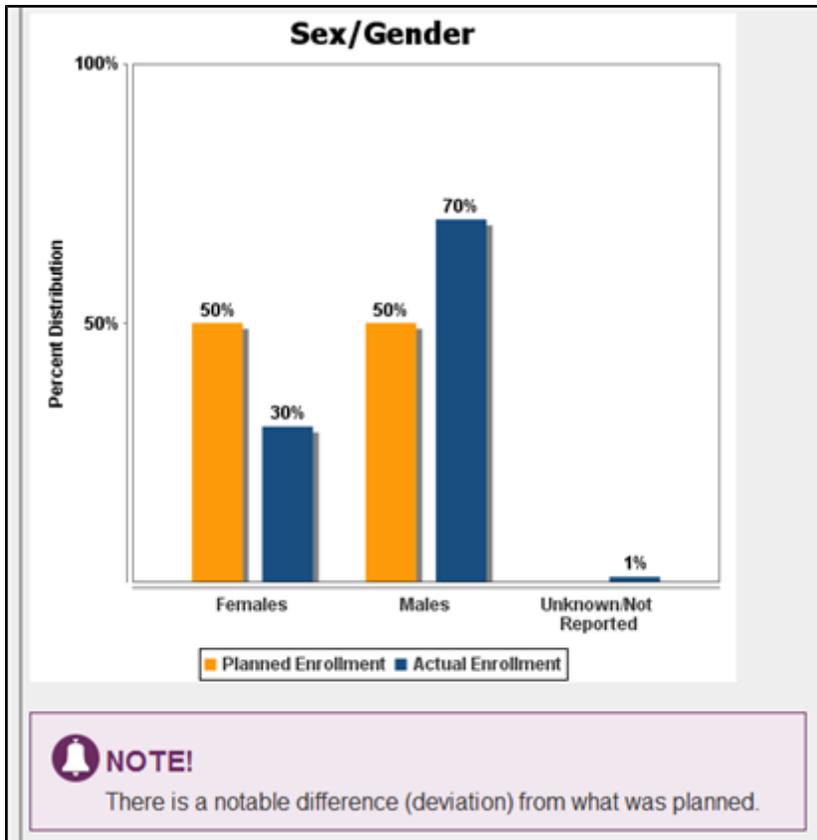
The **Enrollment Distribution** tab of the *Inclusion Data Record (IDR) Details* screen presents a visual representation of the inclusion data – for the selected version of the IDR – by comparing planned enrollment to actual enrollment on the following categories:

- Sex/Gender
- Ethnicity
- Race

Each graph is marked along the Y axis at the 50% mark with 100% as the upper limit. This represents the Percent Distribution. The exact percentage is also indicated above each graph element. The x Axis displays the different sub-categories (e.g., female, male) split between Planned Enrollment (orange bar) and Actual Enrollment (blue bar).

The graphs displayed utilize the Chi-Square Goodness of Fit Test to indicate whether the actual inclusion enrollment data distributions are consistent with the planned enrollment data distributions. This calculation is run for sex/gender, ethnicity, and race separately and is used only for studies with a plan for 75 or more participants that have already enrolled a certain number in each category (excluding unknowns). If the test results suggest that a difference between the observed value (i.e., actual enrollment) and the expected value (i.e., planned enrollment) exists, a message displays for the category in question.

NOTE: There is a notable difference (deviation) from what was planned.



The purpose of this calculation and message is to serve as a tool to alert NIH program staff of the difference between planned and actual distributions. Any subsequent actions would be determined according to IC-specific procedures and/or the Program Officer.

Enrollment Distribution by Sex/Gender

The graph shows the percent of total enrollment for each sex/gender category for both planned and actual enrollment for the IDR, as well as the Unknown/Not Reported category, which is reported for actuals only.

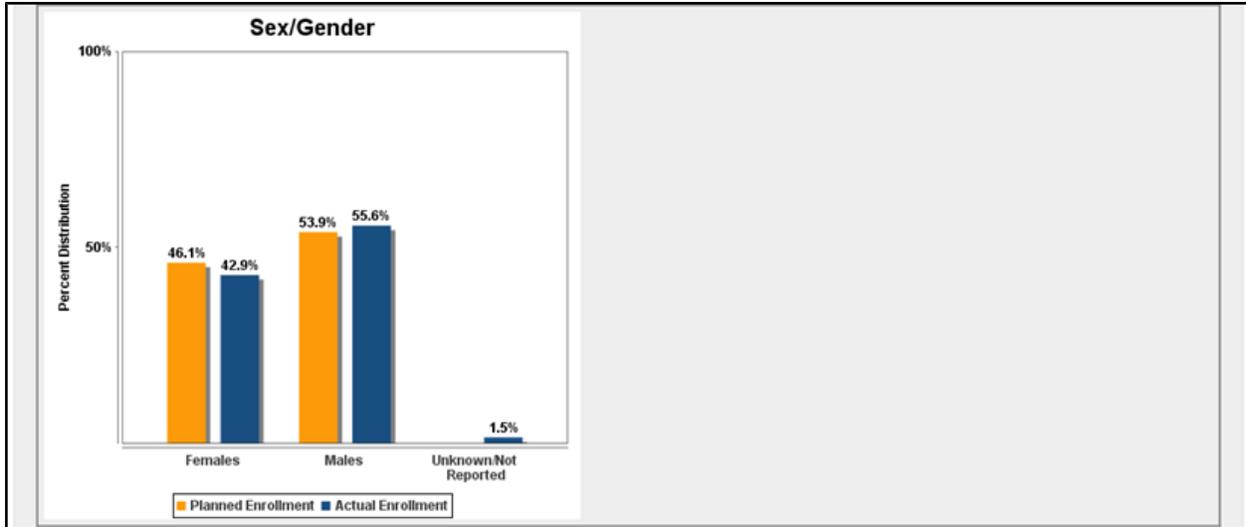


Figure 47: Sample Graph for Sex/Gender Category

Enrollment Distribution by Ethnicity

The graph shows the percent of total enrollment for each ethnicity category for both planned and actual enrollment for the IDR, as well as the Unknown/Not Reported category, which is reported for actuals only.

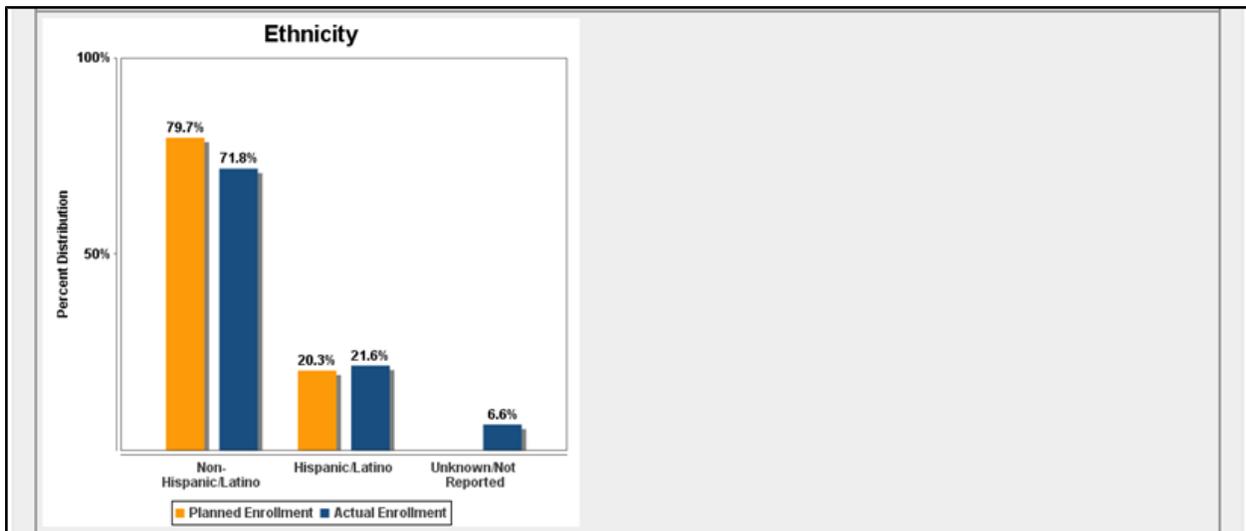


Figure 48: Sample Graph for Ethnicity Categories

Enrollment Distribution by Race

The graph shows the percent of total enrollment for each race category, for both planned and actual enrollment for the IDR, as well as the Unknown/Not Reported category, which is reported for actuals only.

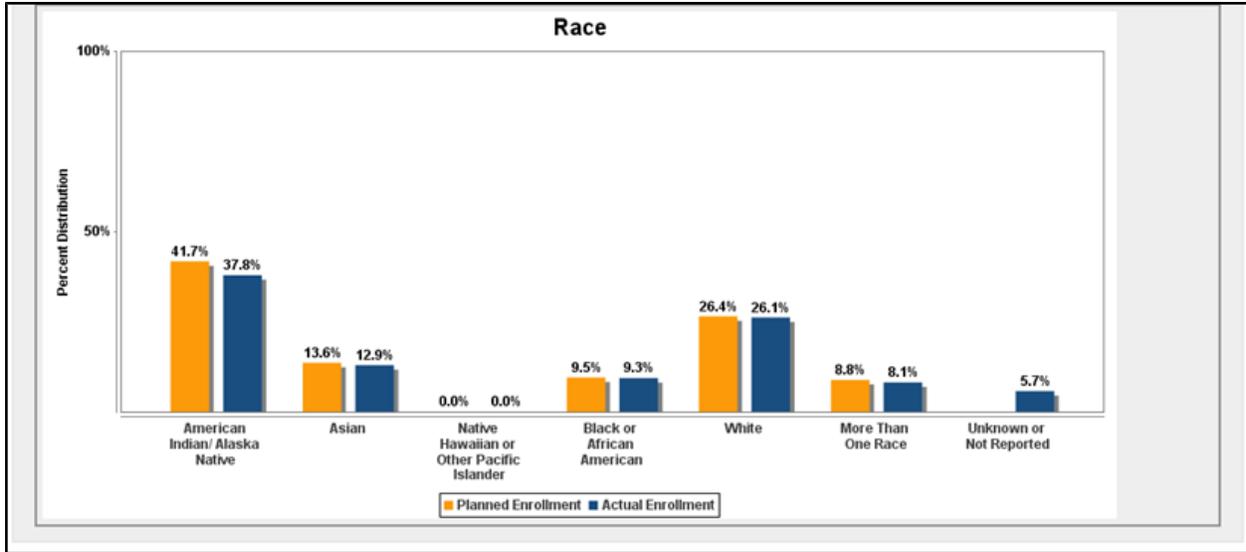


Figure 49: Sample Graph for Race Categories

IMPORTANT: In order for the data to be presented in these graphs, planned enrollment data must exist. If planned enrollment data do not exist, the following message will display with no graphs: *Because there is no planned enrollment associated with this IDR, the graphs cannot be generated.*

7.3 Detailed Enrollment Report

The **Detailed Enrollment Report** tab of the *Inclusion Data Record (IDR) Details* screen displays a comprehensive table with all subject counts for planned and actual data integrated into the same display. The display of the information can be manipulated to hide or show information in a variety of ways.

Inclusion Data Record (IDR) Details ?

View Reported FY: 2015

Project #: [1P20MH345678-01](#) (paper)
 PI Name: [SHAKESPEARE, WILLIAM](#)
 Current Inclusion Data | Prior Versions: [09/19/2014](#)
 Project Title: A Midsummer Night's Dream and Other Sleep Disorders
 Appl. Status: Pending Award. Non-fellowships

Additional Project Information

Inclusion Data Record (IDR) |
 Enrollment Distribution |
 Detailed Enrollment Report |
 Enrollment Summary |
 Action History

Enrollment Report - Detailed View ?

View Options: [Hide Actuals](#) | [Show All Percentages](#)

View Percentages: [Actual/Planned](#) | [Planned/Category Total](#) | [Actuals/Category Total](#) | [Planned/Overall Study Total](#) | [Actuals/Overall Study Total](#) | [Planned/Ethnic Planned Total](#) | [Actuals/Ethnic Actual Total](#)

Show Racial Categories: [All](#) | Only Show: [American Indian/Alaska Native](#) | [Asian](#) | [Native Hawaiian or Other Pacific Islander](#) | [Black or African American](#) | [White](#) | [More Than One Race](#) | [Unknown/Not Reported](#)

Racial Categories	Ethnic Categories									Total	
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported				
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported		
American Indian/Alaska Native	Actuals:	33	60	0	25	5	0	2	1	0	126
	Planned:	35	58		25	5					123
Actuals/Overall Study Total:		10.4%	18.9%	0%	7.9%	1.6%	0%	0.6%	0.3%	0%	39.6%
Asian	Actuals:	21	20	0	0	0	2	0	0	0	43
	Planned:	20	20		0	0					40
Actuals/Overall Study Total:		6.6%	6.3%	0%	0%	0%	0.6%	0%	0%	0%	13.5%
Native Hawaiian or Other Pacific Islander	Actuals:	0	0	0	0	0	0	0	0	0	0
	Planned:	0	0		0	0					0
Actuals/Overall Study Total:		0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Black or African American	Actuals:	12	15	1	2	1	0	0	0	0	31
	Planned:	10	18		0	0					28
Actuals/Overall Study Total:		3.8%	4.7%	0.3%	0.6%	0.3%	0%	0%	0%	0%	9.7%
White	Actuals:	27	40	2	5	10	0	1	2	0	87
	Planned:	30	38		4	6					78
Actuals/Overall Study Total:		8.5%	12.6%	0.6%	1.6%	3.1%	0%	0.3%	0.6%	0%	27.4%
More Than One Race	Actuals:	3	4	0	10	10	0	0	0	0	27
	Planned:	2	4		10	10					26
Actuals/Overall Study Total:		0.9%	1.3%	0%	3.1%	3.1%	0%	0%	0%	0%	8.5%
Unknown or Not Reported	Actuals:	1	0	0	0	2	0	1	0	0	4
	Planned:	0	0		0	0					0
Actuals/Overall Study Total:		0.3%	0%	0%	0%	0.6%	0%	0.3%	0%	0%	1.3%
Totals (All Categories)	Actuals:	97	139	3	42	28	2	4	3	0	318
	Planned:	97	138		39	21					295

Planned Enrollment Report Comments: These are my comments

Cumulative Inclusion Enrollment Report Comments: These are my sample comments...

Figure 50: Default View–Detailed Enrollment Report Tab

Enrollment Report – Detailed View

Click an option's link to set a particular view. When an option is selected, its link will become bold as a visual indication of the current view. To unselect the view option, click the link again. The options on this screen allow you to change your view of displayed actual data, percentages, and/or racial categories.

NOTE: If the enrollment data in IMS came from the POP Tracking system, the following message will display on the screen in place of the detailed report: *Planned and/or cumulative and/or final enrollment data for this FY was entered in the previous OMB-approved layout in the eRA POP Tracking module. The Detailed View cannot be displayed for this FY.*

View Options

- **Hide Actuals**

Select this link to hide actuals data from the screen. When selected, the link becomes the **Show Actuals** link, which is used to show the actuals data.

Enrollment Report - Detailed View

View Options: **Show Actuals** Show All Percentages

View Percentages: [Actual/Planned](#) | [Planned/Category Total](#) | [Actuals/Category Total](#) | [Planned/Overall Study Total](#) | [Actuals/Overall Study Total](#) | [Planned/Ethnic Planned Total](#) | [Actuals/Ethnic Actual Total](#)

Show Racial Categories: [All](#) | Only Show: [American Indian/Alaska Native](#) | [Asian](#) | [Native Hawaiian or Other Pacific Islander](#) | [Black or African American](#) | [White](#) | [More Than One Race](#) | [Unknown/Not Reported](#)

Racial Categories		Ethnic Categories									Total	
		Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported				
		Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported		
American Indian/Alaska Native	Planned:	35	58		25	5						123
	Actuals/Overall Study Total:	10.4%	18.9%	0%	7.9%	1.6%	0%	0.6%	0.3%	0%		39.6%
Asian	Planned:	20	20		0	0						40
	Actuals/Overall Study Total:	6.6%	6.3%	0%	0%	0%	0.6%	0%	0%	0%		13.5%
Native Hawaiian or Other Pacific Islander	Planned:	0	0		0	0						0
	Actuals/Overall Study Total:	0%	0%	0%	0%	0%	0%	0%	0%	0%		0%
Black or African American	Planned:	10	18		0	0						28
	Actuals/Overall Study Total:	3.8%	4.7%	0.3%	0.6%	0.3%	0%	0%	0%	0%		9.7%
White	Planned:	10	10		4	4						70

Figure 51: Hide Actuals on Detailed Enrollment Report View

- **Show All Percentages**

When the **Show All Percentages** link is selected, the screen displays all percentages for every expanded racial category. The link is replaced with the **Hide All Percentages** link,

which is used to hide the percentages of all expanded racial categories.

By default, all percentages are hidden.

Enrollment Report - Detailed View

View Options: [Hide Actuals](#) | [Hide All Percentages](#) ←

View Percentages: [Actual/Planned](#) | [Planned/Category Total](#) | [Actuals/Category Total](#) | [Planned/Overall Study Total](#) | [Actuals/Overall Study Total](#) | [Planned/Ethnic Planned Total](#) | [Actuals/Ethnic Actual Total](#)

Show Racial Categories: [All](#) | Only Show: [American Indian/Alaska Native](#) | [Asian](#) | [Native Hawaiian or Other Pacific Islander](#) | [Black or African American](#) | [White](#) | [More Than One Race](#) | [Unknown/Not Reported](#)

Racial Categories	Ethnic Categories									Total	
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported				
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported		
American Indian/Alaska Native	Actuals:	33	60	0	25	5	0	2	1	0	126
	Planned:	35	58		25	5					123
Actuals/Overall Study Total:		10.4%	18.9%	0%	7.9%	1.6%	0%	0.6%	0.3%	0%	39.6%
Actuals/Planned:		94.3%	103.4%		100%	100%					102.4%
Planned/Category Total:		28.5%	47.2%	0%	20.3%	4.1%	0%	0%	0%	0%	100%
Actuals/Category Total:		26.2%	47.6%	0%	19.8%	4%	0%	1.6%	0.8%	0%	100%
Planned/Overall Study Total:		11.9%	19.7%	0%	8.5%	1.7%	0%	0%	0%	0%	41.7%
Planned/Ethnic Planned Total:		36.1%	42%		64.1%	23.8%					41.7%
Actuals/Ethnic Actual Total:		34%	43.2%	0%	59.5%	17.9%	0%	50%	33.3%		39.6%
Asian	Actuals:	21	20	0	0	0	2	0	0	0	43
	Planned:	20	20		0	0					40
Actuals/Overall Study Total:		6.6%	6.3%	0%	0%	0%	0.6%	0%	0%	0%	13.5%
Actuals/Planned:		105%	100%								107.5%
Planned/Category Total:		50%	50%	0%	0%	0%	0%	0%	0%	0%	100%
Actuals/Category Total:		48.8%	46.5%	0%	0%	0%	4.7%	0%	0%	0%	100%
Planned/Overall Study Total:		6.8%	6.8%	0%	0%	0%	0%	0%	0%	0%	13.6%

Figure 52: Show All Percentages on Detailed Enrollment Report

View Percentages

Select one or more of the links in the **View Percentages** section to display specific percentage data for the expanded racial categories. Selected links will display in bold type. Deselect a percentage option by selecting it a second time.

By default, the percentage links are unselected.

Enrollment Report - Detailed View ?									
View Options: Hide Actuals Hide All Percentages									
View Percentages: Actual/Planned Planned/Category Total Actuals/Category Total Planned/Overall Study Total Actuals/Overall Study Total Planned/Ethnic Planned Total Actuals/Ethnic Actual Total									
Show Racial Categories: All Only Show: American Indian/Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More Than One Race Unknown/Not Reported									
Ethnic Categories									Total
Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported			
Female	Male	Unknown/Not	Female	Male	Unknown/Not	Female	Male	Unknown/Not	

Figure 53: View Percentages Links on Detailed Enrollment Report

Percentage categories/links are as follows:

- **Actual/Planned**

The Actual/Planned value is calculated by dividing the Actuals enrollment count for each Ethnic category by the Planned enrollment count in that Ethnic category.

- **Planned/Category Total**

The Planned/Category value is calculated by dividing the Planned enrollment count for each Ethnic category by Total Planned enrollment count in that Racial category.

- **Actuals/Category Total**

The Actuals/Category value is calculated by dividing the Actuals enrollment count for each Ethnic category by the Total Actuals enrollment count for that Racial category.

- **Planned/Overall Study Total**

The Planned/Overall Study value is calculated by dividing the Planned enrollment count for each Ethnic category by Total Planned for all Racial categories.

- **Actuals/Overall Study Total**

The Actuals/Overall Study value is calculated by dividing the Actuals enrollment count for each Ethnic category by the Total Actuals for all Racial categories.

- **Planned/Ethnic Planned Total**

The Planned/Ethnic Planned value is calculated by dividing the Planned enrollment count for each Ethnic category by the Total Planned enrollment count in that Ethnic category.

- **Actuals/Ethnic Actual Total**

The Actuals/Ethnic Actual value is calculated by dividing the Actuals enrollment count for each Ethnic category by the Total Actuals enrollment count in that Ethnic category.

Show Racial Categories

- All

This view is the default view and displays information for all racial categories on the screen. Refer to the figure captioned *Default View–Detailed Enrollment Report Tab* above to see this view.

Click the link a second time to unselect this view and hide all racial categories. When hidden, only the **Total (All Categories)** record will display.

Enrollment Report - Detailed View											
View Options: Hide Actuals Show All Percentages											
View Percentages: Actual/Planned Planned/Category Total Actuals/Category Total Planned/Overall Study Total Actuals/Overall Study Total Planned/Ethnic Planned Total Actuals/Ethnic Actual Total											
Show Racial Categories: All Only Show: American Indian/Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More Than One Race Unknown/Not Reported											
Racial Categories		Ethnic Categories									Total
		Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported			
		Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
Totals (All Categories)	Actuals:	97	139	3	42	28	2	4	3	0	318
	Planned:	97	138		39	21					295

Planned Enrollment Report Comments: These are my comments

Cumulative Inclusion Enrollment Report Comments: These are my sample comments...

Figure 54: All Racial Categories Hidden on Detailed Enrollment Summary

- **Show Only**

Click the link for any option(s) to display data only for that specific racial category. When a category is selected, the link becomes bold and screen updates to display the data for the selected option(s). Click a category link a second time to unselect the view option and hide the corresponding racial category data.

Enrollment Report - Detailed View											
View Options: Hide Actuals Show All Percentages											
View Percentages: Actual/Planned Planned/Category Total Actuals/Category Total Planned/Overall Study Total Actuals/Overall Study Total Planned/Ethnic Planned Total Actuals/Ethnic Actual Total											
Show Racial Categories: All Only Show: American Indian/Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More Than One Race Unknown/Not Reported											
Racial Categories		Ethnic Categories									Total
		Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported			
		Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/Alaska Native	Actuals:	33	60	0	25	5	0	2	1	0	126
	Planned:	35	58		25	5					123
Black or African American	Actuals:	12	15	1	2	1	0	0	0	0	31
	Planned:	10	18		0	0					28
White	Actuals:	27	40	2	5	10	0	1	2	0	87
	Planned:	30	38		4	6					78
Totals (All Categories)	Actuals:	97	139	3	42	28	2	4	3	0	318
	Planned:	97	138		39	21					295
Planned Enrollment Report Comments: These are my comments											
Cumulative Inclusion Enrollment Report Comments: These are my sample comments...											

Figure 55: Show Multiple Racial Categories on Detailed Enrollment Summary

Racial categories/links are as follows:

- **American Indian/Alaska Native**
- **Asian**
- **Native Hawaiian or Other Pacific Islander**
- **Black or African American**
- **White**
- **More Than One Race**
- **Unknown/Not Reported**

7.4 Enrollment Summary

The **Enrollment Summary** tab of the *Inclusion Data Record (IDR) Details* screen displays a table providing a summary of all project application records within the project and corresponding fiscal year as well as Inclusion Total Counts for the IDR.

For multi-year funded awards, the table displays a list of fiscal years of the multi-year funded award as well as the Inclusion Total Counts for this IDR only.

Single-year funded and multi-component grants and contracts

The following information is displayed for single-year funded and multi-component awards:

- **Project No.**

For grants, the grant number is displayed as a link to the Grant Snapshot report and includes an additional link (folder icon) for accessing the Grant Folder. These links are not available for subprojects.

For contracts, the contract number is displayed as a link to the *Contract Details* pop-up screen.

For intramural projects, **Project No.** is not hyperlinked.

- **PI Name**

The name is displayed as a link, which opens the PI Details pop up screen.

For intramural projects, **PI Name** is not hyperlinked.

- **Project FY**

Fiscal year of the project.

- **Inclusion Total Counts (This IDR Only)**

Inclusion total counts are represented separately for Planned and Actual total counts.

- **Last Budget Period Data as reported by PI**

When a [Last Budget Period type IDR](#) exists, this row displays the Planned and Actual counts for that IDR. The row only exists for projects with a Last Budget Period type IDR.

Inclusion Data Record (IDR) Details ⓘ

View Reported FY: 2015

Project #: [1P20MH345678-01](#) 📁 (paper)

PI Name: [SHAKESPEARE, WILLIAM](#)

Current Inclusion Data | Prior Versions: [09/22/2014](#) [09/19/2014](#)

Project Title: A Midsummer Nights' Dream and Other Sleep Disorders

Appl. Status: Pending Award. Non-fellowships

Additional Project Information

Inclusion Data Record (IDR)	Enrollment Distribution	Detailed Enrollment Report	Enrollment Summary	Action History
Enrollment Summary (All Years, This IDR Only) ⓘ				
Project No.	PI Name	Project FY	Inclusion Total Counts (This IDR Only)	
			Planned	Actuals
1 P20MH345678-01 📁	SHAKESPEARE, WILLIAM	2015	295	318

Figure 56: Enrollment Summary Tab of IDR Details (Single Project)

Inclusion Data Record (IDR) Details ?

View Reported FY: 2015

Project #: [1P20MH345678-01](#) 📁
 PI Name: [SHAKESPEARE, WILLIAM](#)
 Current Inclusion Data | Prior Versions: [09/22/2014](#) [09/19/2014](#)
 Project Title: A Midsummer Nights' Dream and Other Sleep Disorders
 Appl. Status: Pending Award. Non-fellowships

+ Additional Project Information

Inclusion Data Record (IDR) | Enrollment Distribution | Detailed Enrollment Report | **Enrollment Summary** | Action History

Enrollment Summary (All Years, This IDR Only) ?

Project No.	PI Name	Project FY	Inclusion Total Counts (This IDR Only)	
			Planned	Actuals
1 P20MH345678-01 📁	SHAKESPEARE, WILLIAM	2015	295	318
Last Budget Period Data as reported by PI:			295	318

Figure 57: Enrollment Summary Showing Last Budget Period Data

Inclusion Data Record (IDR) Details ?

View Reported FY: 2014

Project #: [1234012000071-0-12300005-1](#)
 PI Name: [VALJEAN, JEAN](#)
 Current Inclusion Data
 Project Title: This Project Title Represents an Example of a Contract PROJECT Title Displayed in IMS System
 Appl. Status: Not Applicable

+ Additional Project Information

Inclusion Data Record (IDR) | Enrollment Distribution | Detailed Enrollment Report | **Enrollment Summary** | Action History

Enrollment Summary (All Years, This IDR Only) ?

Project No.	PI Name	Project FY	Inclusion Total Counts (This IDR Only)	
			Planned	Actuals
1234012000071-0-12300005-1	VALJEAN, JEAN	2014	54	60

Figure 58: Enrollment Summary for Contracts

Multi-year funded grants

- **IDR FY**

Represents the fiscal year of the IDR

- **Inclusion Total Counts (This IDR Only)**

Inclusion total counts are represented separately for Planned and Actual total counts.

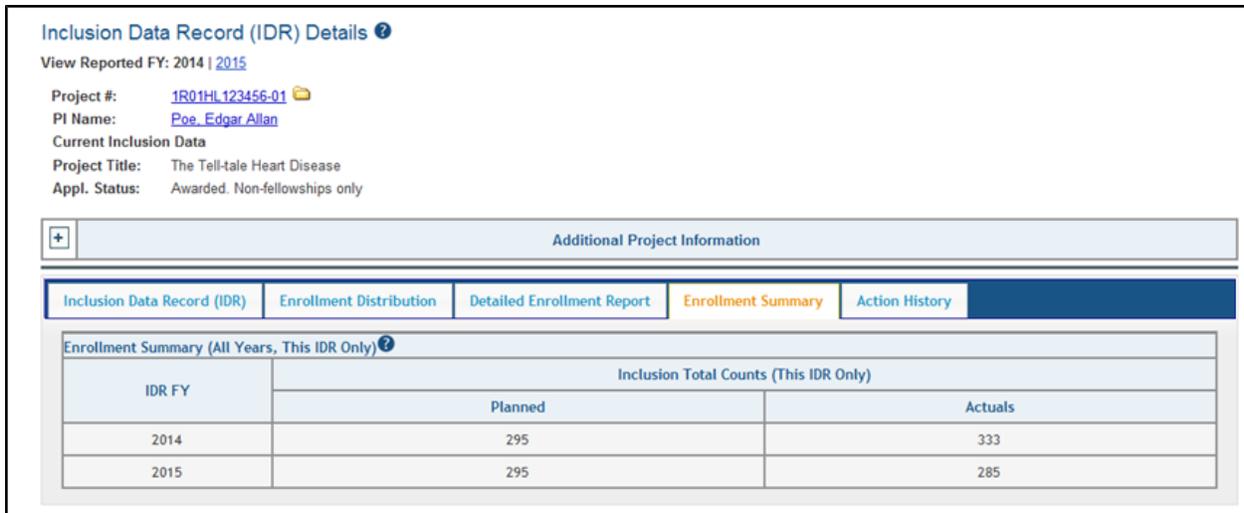


Figure 59: Enrollment Summary for Multi-Year Funded Award

7.5 Action History

The **Action History** tab of the *Inclusion Data Record (IDR) Details* screen provides a list of actions performed against the IDR, including the person who performed the action.

NOTE: In the case of viewing a Last Budget Period type IDR, the screen only displays the action history of that IDR. It does not include the history of the associated regular IDR.

Action History

The information is displayed in a table with the following fields:

- **Action Date/Time**

Displays the date and time on which the action was performed in the system.

- **Action Performed By(link)**

Provides the name of the individual who performed the action. The name is displayed as a link, which opens the *PI Details* pop up screen.

- **Action**

Displays the type of action performed against the IDR. Below is a list of possible actions and their definitions.

- *Accepted by Agency:* A system-generated status update upon rollover of a multi-year funded award. The user in this event will display as System.

- *Copied from prior year:* The IDR was created when the next budget period began.
- *Created:* The IDR form (Planned or Actual) was received as part of the electronic application submission process, was created in the Inclusion Management System, or was migrated from POP Tracking.
- *Created Via RPPR:* The Grantee user has created the IDR by selecting the Submit New Planned Inclusion Form link after accessing the IDR via RPPR.
- *Created Via Web Service:* The IDR was inserted via web service.
- *Cumulative Enrollment is Updated for Progress Report:* The Grantee user has updated the actual enrollment counts after accessing the IDR via RPPR.
- *Data Locked for Reporting:* A system-generated status update upon freezing FY for contracts or intramural projects.
- *Grant is Awarded:* A system-generated status update upon release of the award. The user in this event will display as System.
- *Grant is Awarded, IDR is Not Rolled Forward:* A system-generated status update upon release of the award when the IDR is marked as *Not Funded* or *Type 2 Progress Report*. The user in this event will display as System.
- *Grantee Updates in Progress:* The Grantee user initiated updates for the IDR by editing the planned or actuals data.
- *Inclusion Data Accessed Via RPPR:* Indicates that a Grantee user has accessed the IDR by selecting the Inclusion link from the RPPR Section G. Special Requirements.
- *Planned Enrollment is Updated for Progress Report:* The Grantee user has updated the planned enrollment counts after accessing the IDR via RPPR.
- *Returned to PI:* The SO returned a routed IDR back to the PI.
- *Sent to Agency:* The SO (or delegate) routed the IDR to Agency.
- *Sent to Agency as Part of the Progress Report:* The IDR is submitted within a submitted RPPR.
- *Sent to SO:* The PI (or delegate) routed the IDR to the SO.
- *Updated by Internal Staff:* Data on the planned or actual enrollment form was updated by agency staff.
- *Updated Via Web Service:* The IDR was updated via web service.

Inclusion Data Record (IDR) Details ?

View Reported FY: 2015

Project #: [5R01MH654321-03](#) 

PI Name: [Austen, Jane](#)

Current Inclusion Data | Prior Versions: [09/22/2014](#)

Project Title: Pride & Prejudice and the Human Psyche

Appl. Status: Awarded. Non-fellowships only

+ Additional Project Information

[Inclusion Data Record \(IDR\)](#) | [Enrollment Distribution](#) | [Detailed Enrollment Report](#) | [Enrollment Summary](#) | [Action History](#)

Action History ?

Action Date/Time	Action Performed By	Action
09/22/2014 02:42 PM	Austen, Jane	Created via RPPR
09/22/2014 02:42 PM	Austen, Jane	Cumulative Enrollment is Updated for Progress Report
09/22/2014 03:10 PM	Woodhouse, Emma	Sent to Agency as part of the Progress Report
09/24/2014 11:24 AM	Bennet, Elizabeth	Grantee Updates in Progress
09/24/2014 11:24 AM	Bennet, Elizabeth	Sent to SO
09/24/2014 11:39 AM	Woodhouse, Emma	Sent to Agency

Figure 60: Sample Action History for an Inclusion Data Record

8 Viewing IDRs via the Grant Folder

Agency staff (and anyone with access to the *Grant Folder*) can view the *Inclusion Data Records (IDRs)* screen for all existing versions of IDRs for a grant record. The report is accessed by selecting the **Inclusion** link from *Grant Folder*.

The resulting screen varies depending on whether the grant is a single-project, multi-project, or multi-year funded grant.

- **Single-project awards:** Lists all IDRs for the grant.
- **Multi-project awards:** Lists all IDRs for the parent and its subprojects.
- **Multi-year funded awards:** Lists all IDRs grouped by fiscal year

IMPORTANT: The **Inclusion** link in *Grant Folder* is not available for contracts and intramural projects.

8.1 Inclusion Data Records via Grant Folder (Single-Project Awards)

The *Inclusion Data Record(s)* screen is accessed via the *Grant Folder* and provides a list of all IDRs for the grant application along with links for accessing the IDR details of those records. Where applicable, the screen also allows viewing of prior versions of the IDR(s).

IDR#	IDR IC ID	Last Updated Date	Study Title	Actions
54720	04-130	11/04/2009 (Current)	Measure for Measure and Other Scientific Methodol (...more)	View
54721	04-316	11/04/2009 (Current)	All's Well That Ends Well with advancements in m(...more)	View
54724	04-257	11/04/2009 (Current)	A Winter's Tale: A comprehensive study of the co(...more)	View
54725	05-023	11/04/2009 (Current)	The Life and Death of King John: Determining risk fac(...more)	View
54726	919-04	11/04/2009 (Current)	The Merry Hives of Windsor	View

Figure 61: Inclusion Data Record for Single Project via Grant Folder

Header information includes the following:

- **Grant #**
- **PI Name**
- **Project Title**
- **Application Status**

The hit list portion of the screen contains the following information:

IDR #

The **IDR#** is the unique Inclusion Management System-generated identifier for the inclusion data record (IDR). This number remains unchanged throughout the lifetime of the grant.

The words (*Last Budget Period*) appear after the IDR number to indicate that the IDR is a [Last Budget Period](#) type IDR.

The word (*Final*) appears after the IDR number to indicate that the IDR is a final type IDR. Currently, this concept only exists for intramural projects.

IDR IC ID

The **IDR IC ID** is an identification number entered by Agency staff as one of the optional IDR attributes. This value is not the same as the system-generated IDR #. This field could be blank if an IDR IC ID number was not assigned.

Last Updated Date

The date that this version of the IDR was created.

Study Title

Displays the study title associated with the IDR. Some study titles do not fit in the default row size. For these titles, select the **more...** link to display the entire title.

Actions

Displays the available actions for the specific record.

- **View:** Links to the *Inclusion Data Record (IDR) Details* screen. Refer to the topic titled [Inclusion Data Record \(IDR\) Details on Page 66](#) for information on this screen.
- **Show Prior Versions:** Expands the screen to show prior versions of the IDR, where applicable.
- **Hide Prior Versions:** Collapses the screen to hide prior versions of the IDR, where applicable.

8.2 Inclusion Data Records via Grant Folder (Multi-Project Awards)

The *Inclusion Data Record(s)* screen is accessed via the *Grant Folder* and provides a list of all IDRs for the parent application and all subprojects, along with links for accessing the IDR details of those records. Where applicable, the screen also allows viewing of prior versions of the IDR(s).

The parent record always displays at the top of the list with all parent IDRs grouped beneath it. Subprojects follow the parent record, along with their own IDRs.

IDR#	IDR IC ID	Last Updated Date	Study Title	Actions
Inclusion Data Records (IDRs)				
Grant #: 5P50MH123456-07				
PI Name: AUDEN, W.H.				
Project Title: The Age of Anxiety Disorders				
Appl. Status: Pending Council Review				
<hr/>				
5P50MH123456-07				
54720	04-130	11/04/2009 (Current)	An Open Phase I Study of Anxiety Disorders and th(...more)	View
54721	04-316	11/04/2009 (Current)	Phase I Clinical Trial of Anxiety	View
54724	04-257	11/04/2009 (Current)	Phase II Trial of Patients with Multiple Symptoms(...more)	View
54725	05-023	11/04/2009 (Current)	Another Great Study on Anxiety (...more)	View
54726	919.04	11/04/2009 (Current)	Anxiety Triggers in Technical Writers with Tight Deadlines	View
5P50MH123456-07/01 Proj 1				
127315	06-150	11/04/2009 (Current)	Project 1 Study 1	View
127318	06-147	11/04/2009 (Current)	Project 1 Study 2	View
5P50MH123456-07/02 Proj 2				
127311	06-096	11/04/2009 (Current)	Project 2 Study 2	View
5P50MH123456-07/03 Proj 3				
No Inclusion Data Records				
5P50MH123456-07/04 Proj 4				
No Inclusion Data Records				

Figure 62: Inclusion Data Record for Parent Project (and Subprojects) via Grant Folder

Header information includes the following:

- **Grant #**
- **PI Name**
- **Project Title**
- **Application Status**

The Hit list portion of the screen contains the following information:

Grant #

Displays the grant number of the parent record, with subprojects following below.

IDR #

The **IDR#** is the unique Inclusion Management System-generated identifier for the inclusion

data record (IDR). This number remains unchanged throughout the lifetime of the grant.

The words (*Last Budget Period*) appear after the IDR number wherever displayed to indicate that the IDR is a [Last Budget Period](#) type IDR.

The word (*Final*) appears after the IDR number to indicate that the IDR is a final type IDR. Currently, this concept only exists for intramural projects.

IDR IC ID

The **IDR IC ID** is an identification number entered by Agency staff as one of the optional IDR attributes. This value is not the same as the system-generated IDR #. This field could be blank if an IDR IC ID number was not assigned.

Last Updated Date

The date that this version of the IDR was created.

Study Title

Displays the study title associated with the IDR. Some study titles do not fit in the default row size. For these titles, select the **more...** link to display the entire title.

Actions

Displays the available actions for the specific record.

- **View:** Links to the *Inclusion Data Record (IDR) Details* screen. Refer to the topic titled [Inclusion Data Record \(IDR\) Details on Page 66](#) for information on this screen.
- **Show Prior Versions:** Expands the screen to show prior versions of the IDR, where applicable.
- **Hide Prior Versions:** Collapses the screen to hide prior versions of the IDR, where applicable.

8.3 Inclusion Data Records via Grant Folder (Multi-Year Funded Awards)

The *Inclusion Data Record(s)* screen is accessed via the *Grant Folder* and provides a list of all IDRs for the multi-year funded award, along with links for accessing the IDR details of those records. Where applicable, the screen also allows viewing of prior versions of the IDR(s).

IDRs are grouped together by fiscal year, with the most recent fiscal year displayed at the top of the screen.

Inclusion Data Records (IDRs) ?				
Grant #: 1R01HL123456-01				
PI Name: Poe, Edgar Allan				
Project Title: The Tell-tale Heart Disease				
Appl. Status: Awarded. Non-fellowships only				
IDR#	IDR IC ID	Last Updated Date	Study Title	Actions
2015				
1026222		09/23/2014 (Current)	Tell-Tale Heart Disease: Study Number Three	View
1010477		09/12/2014 (Current)	Tell-Tale Heart Disease: Study Number Two	View
1010414		09/12/2014 (Current)	Tell-Tale Heart Disease: Study Number One	View
2014				
1010477		09/12/2014 (Current)	Tell-Tale Heart Disease: Study Number Two	View
1010414		09/12/2014 (Current)	Tell-Tale Heart Disease: Study Number One	View

Figure 63: Inclusion Data Record for Multi-Year Funded Award via Grant Folder

Header information includes the following:

- **Grant #**
- **PI Name**
- **Project Title**
- **Application Status**

The Hit list portion of the screen contains the following information:

FY

Displays the fiscal years associated with the grant, with the latest year at the top. IMS groups IDRs by fiscal year and displays the **FY** header for each group.

IDR #

The **IDR#** is the unique Inclusion Management System-generated identifier for the inclusion data record (IDR). This number remains unchanged throughout the lifetime of the grant.

The words (*Last Budget Period*) appear after the IDR number to indicate that the IDR is a [Last Budget Period](#) type IDR.

The word (*Final*) appears after the IDR number to indicate that the IDR is a final type IDR. Currently, this concept only exists for intramural projects.

IDR IC ID

The **IDR IC ID** is an identification number entered by Agency staff as one of the optional IDR attributes. This value is not the same as the system-generated IDR #. This field could be

blank if an IDR IC ID number was not assigned.

Last Updated Date

The date that this version of the IDR was created.

Study Title

Displays the study title associated with the IDR. Some study titles do not fit in the default row size. For these titles, select the **more...** link to display the entire title.

Actions

Displays the available actions for the specific record.

- **View:** Links to the *Inclusion Data Record (IDR) Details* screen. Refer to the topic titled [Inclusion Data Record \(IDR\) Details on Page 66](#) for information on this screen.
- **Show Prior Versions:** Expands the screen to show prior versions of the IDR, where applicable.
- **Hide Prior Versions:** Collapses the screen to hide prior versions of the IDR, where applicable.

9 Contracts

Contracts data entry is handled by Agency staff through manual entry or web service upload. If an IDR is created by staff in IMS, it can be edited in IMS, and it will be rolled forward. If an IDR is created via web service, it can be edited only via WS and not rolled forward. Investigators and contractors do not currently create records or enter data into IMS.

Agency staff responsible for managing inclusion enrollment data for contracts uses the same screens and features used for grants when entering data directly into IMS, although some differences exist for contracts. For steps on viewing and updating inclusion enrollment data for contracts, refer to the specific topic (e.g., Search Parameters, Manage IDRs, etc.). Information relevant only to contracts or only to grants is indicated in each topic where applicable.

A key difference between contracts and grants is the process of locking IDRs for editing. Whereas inclusion data are locked in a grant when the award is issued in a given FY, contracts follow a process of locking the data at a certain point in time. This process is called *freezing* in IMS and can only be performed by certain OER staff. Frozen contract inclusion data has a status of *Data Locked for Reporting* and can be viewed but not edited. Generally, this administrative action to lock the data will occur just after the close of the FY. [IC IOPW](#) members will be notified of a deadline to confirm all data are entered into IMS for contracts and when the data will be frozen for that FY.

Where contracts are concerned, two types of projects exist: the contract **parent** and the contract **project**. Contract parents and projects share the same contract document number within the same FY. If a contract number ends in zero (e.g., N01DE32636-0-0-0) it is a contract parent. If the contract number ends with any number other than zero (e.g., N01DE32636-0-0-1) it is a contract project.

Contract parents and projects share the same contract document number within the same FY. When searching for contracts using the **Contract Document Number** field on the *Search Parameters* screen, IMS will display contract parent and contract project records for the same FY. Refer to the example below.

+ Search Parameters 12 items found, displaying all items.							
Flag	Project#	Any IDR in Received by Agency Status?	FY	PI Name	HS	Inclusion Monitoring Required?	PO Name
-	1234012000071-0-12300005-0 IDRs Exist: N Manage IDRs GUM	No	2014	VALJEAN, JEAN	30	No-CTP	HUGO, VICTOR
Project Title: This Project Title Represents an Example of a Contract Parent Title Displayed in IMS System ...More							
No Inclusion Data Records							
-	1234012000071-0-12300005-1 IDRs Exist: Y Manage IDRs GUM	No	2014	VALJEAN, JEAN		Yes	
Project Title: This Project Title Represents an Example of a Contract PROJECT Title Displayed in IMS System ...More							
Flag	IDR#	IDR IC ID	IDR Status	Planned Data Last Upd Date/ID	Actual Data Last Upd Date/ID		
P	1045392		Accepted by Agency Study Title: Sample Study Title 1	03/26/2015 / GRINGOIRE, PIERRE			
P	1045391		Accepted by Agency Study Title: Sample Study Title 2	03/26/2015 / VALJEAN, JEAN	03/26/2015 / VALJEAN, JEAN		
P	1045393	Foreign IDR	Accepted by Agency Study Title: Sample Study Title 3	03/26/2015 / VALJEAN, JEAN			
+	1234012000071-0-12300004-0 IDRs Exist: N Manage IDRs GUM	No	2014	VALJEAN, JEAN	30	No-CTP	HUGO, VICTOR
Project Title: Another Sample Contract Parent							
+	1234012000071-0-12300004-1 IDRs Exist: N Manage IDRs GUM	No	2014	VALJEAN, JEAN		Yes-POL	
Project Title: Another Sample Contract Project							

Figure 64: Sample Search Results for Contracts (Parent and Project)

In general, inclusion enrollment is monitored on the contract project level if the Human Subject code for this project is set to *Yes*. Inclusion enrollment is typically not monitored on the contract parent level. IMS automatically sets the inclusion monitoring code to *No-CTP* for the contract parent record. If monitoring must take place on the contract parent, NIH staff can work with their [IC IOPW](#) members to update the contract parent with the appropriate monitoring code.

Contract IDRs are rolled into the current year of the contract when the contract record is created.

9.1 Contract Details

Contract numbers displayed as links in IMS lead to the *Contract Details* for that specific contract. *Contract Details* includes the following read-only details:

- Contract Document Number
- Project #
- Fiscal Year
- PI Name (displayed as a link to the PI Details)
- Project Title
- Org Name
- Contracting Officer
- FOA
- PO Name

Contract Details

Contract Information

Contract Document Number: N01CA012345
Project#: N01CA012345-0-0-0
Fiscal Year: 2002
PI Name: [PIRRIP, PHILIP](#)
Project Title: GREAT EXPECTATIONS IN SCIENCE AND MEDICINE
DRUG I-261025119
Org Name: CHARLES DICKENS UNIVERSITY
Contracting Officer: ABEL MAGWITCH
FOA: PA-00-000
PO Name: MISS HAVISHAM

[Close](#)

Figure 65: Contract Details Pop-up

10 Intramurals

Intramural inclusion data entry is handled by Agency staff through manual entry into an intramural data system. Data from that system will then be uploaded via web service into IMS at least annually. Investigators and contractors do not currently create records or enter data into IMS.

There are some additional pieces of information used for parsing intramural project inclusion data that are described elsewhere in this document. For steps on viewing inclusion enrollment data for intramural projects, refer to the specific topic (e.g., Search Parameters, Manage IDRs, etc.). Intramural projects more closely resemble grants, in terms of how they are displayed in IMS. Certain IMS features and functionality, such as the Grant Update Module, may not be functional given how information for intramural projects is received into IMS. Last Budget Period functionality is not applicable.

A key difference between intramural projects and grants is the process of locking IDRs for reporting. Whereas inclusion data are locked in a grant when the award is issued in a given FY, intramural records follow a process of locking the data at a certain point in time like contracts. This process is called freezing in IMS and can only be performed by certain OER staff. Frozen intramural inclusion data has a status of Data Locked for Reporting and can be viewed but not edited directly in IMS or by upload via web service. Generally, this administrative action to lock the data will occur just after the close of the FY. [Intramural IOPW](#) members will be notified of a deadline to confirm all intramural data are entered into IMS and when the data will be frozen for that FY.

When searching for intramural, the specific Z number field on the *Search Parameters* screen may be used much like for grants. Alternatively, there is a filter box on the Search Parameters screen that permits filter to only intramural projects, if desired.

The screenshot shows the 'Search Parameters' form. At the top, there is a 'Basic Search' section. The 'Grant #' row contains several input fields: 'Type' (value: 1), 'Activity' (value: Z01), 'IC' (value: CA), 'Serial #' (value: 123456), and 'Year' (value: 14). These five fields are enclosed in a red oval. Below this, there are fields for 'PI Name' (Last, First, Middle), 'Project FY' (with a search icon), 'Council Round' (YYYYMM), and 'Project Status' (with a search icon). The 'Project Class' section has three radio buttons: 'Grant', 'Intramurals' (which is selected and circled in red), and 'Contracts'. At the bottom of the form, there are 'Search' and 'Clear' buttons. Below the form is an 'Advanced Search' section.

Figure 66: Intramurals Filter Box on Search Parameters

Appendix A: Glossary of Related Terms

The following terms are found in this user guide or are related to the content therein.

A

Agency

The organization responsible for administering a grant via eRA modules. Agency may refer to NIH or one of the partnering HHS Operating Divisions (see OpDiv).

Appl ID

The unique, system identifier number assigned to an application.

E

eRA

Electronic Research Administration. The NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. May also refer to the group responsible for this infrastructure.

Error

A message displayed by the system to show that action must be taken before further processing can continue. An error represents a 'hard stop' in the system.

Existing Data Set (or Resource)

An existing dataset may be constructed of different types of data including but not limited to survey data, demographic information, health information, genomic information, etc. Also included would be data to be derived from existing samples of cells, tissues, or other types of materials that may have been previously collected for a different purpose or research question but will now be used to answer a new research question. In general, these will be studies meeting the NIH definition for clinical research with a prospective plan to analyze existing data and/or derive data from an existing resource and where no ongoing or future contact with participants is anticipated.

F

FOA

A publicly available document by which a Federal Agency makes known its intentions to award discretionary grants or cooperative agreements, usually as a result of competition for funds. Funding opportunity announcements may be known as program announcements,

requests for applications, notices of funding availability, solicitations, or other names depending on the Agency and type of program.

Foreign/Domestic Indicator

Indicates whether the IDR involves participants from a non-US site (i.e., foreign) or a US site (i.e., domestic). It is a required attribute for an IDR.

FY

Fiscal Year

G

Grant Folder

The official repository of grant-related documents and reports, which includes Summary Statements, Notice of Award (NoA), electronic Streamlined Non-Competing Award Process (eSNAP) Reports, and other grant-related information.

GUM

Grants Update Module

H

HS

Also Human Subjects Code. Code that reflects the status of human subjects inclusion categories on summary statements of grant applications and on the grants management and program officer worksheets.

Human Subject

A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.

I

IC

Institute/Center. The NIH organizational component responsible for a particular grant program or set of activities.

IDR

Inclusion Data Record

IDR #

Also, IDR number. The IDR# is the unique Inclusion Management System-generated identifier for the inclusion data record (IDR). This number remains unchanged throughout the lifetime of the grant.

IDR IC ID

The IDR IC ID is an identification number entered by Agency staff as one of the optional IDR attributes. This value is not the same as the system-generated IDR #. This field could be blank if an IDR IC ID number was not assigned.

IMS

Inclusion Management System

IOPW

The Inclusion Operating Procedures Workgroup (IOPW) is a trans-NIH group of staff members involved in managing policies and procedures for inclusion monitoring at the ICs. These individuals are the primary points of contact at each IC. The roster can be obtained at the following site: <http://nih-extramural-intranet.od.nih.gov/d/nih/committees/iopw/iopw.htm>. <<MEREDITH: I cannot format text in the Flare glossary feature, this includes creating hyperlinks. Sorry.>>

L

Last Budget Period IDR

IDRs created by the Grantee for reporting changes in enrollment data or newly started studies for the research performed during the period of time between award of the last support year and the end of the project period. There are two types of Last Budget Period IDR: 1) those associated with a regular IDR and reflect updated enrollment and 2) those newly created that are not associated with a regular IDR.

N

NCT No.

Also, National Clinical Trial number. This unique number is also referred to as the ClinicalTrials.gov registry number. The format for the number is NCT followed by an 8-digit number (e.g., NCT12345678).

NIH

National Institutes of Health. A Federal agency whose mission is to improve the health of the people of the United States. NIH is a part of the Public Health Service, which is part of the U.S. Department of Health and Human Services.

No Planned Enrollment Reason

Indication why there is no planned enrollment data for the Inclusion Data Record (i.e., planned enrollment counts are equal to zero).

O

OpDiv

Operating Division. A HHS Operating Division is an agency that provides services to carry out the HHS mission. NIH's electronic Research Administration (eRA) currently partners with the Agency for Healthcare Research and Quality (AHRQ), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Substance Abuse & Mental Health Services Administration (SAMHSA), and the Department of Veterans Affairs (VA) to provide electronic grants management processing.

P

PCC

Program Class Code. The internal code, unique to each IC, indicating that IC's scientific interest. It is used to identify internal programs, branch classifications, the science or disease area, and sometimes program officials.

PHS

Public Health Service. Umbrella organization in the U.S. Federal Government consisting of eight HHS health Agencies, the Office of Public Health and Science, and the Commissioned Corps (a uniformed service of more than 6,000 health professionals). The NIH is the largest Agency within the PHS.

PO (PO name)

Program Official. The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.

S

SMS

Subproject Management System

U

User Role

(sometimes, Role). A specific set of permissions assigned to a system user to set the limitations of that user's available system functions and features.

W

Warning

An informational message displayed by the system to show that an item or issue should be reviewed and verified before continuing the process. An warning is informational only and does not represent a 'hard stop' in the system.