

## Inclusion Re-engineering changes to eRA Systems for External Users

### **Principles Behind the Re-Engineering**

- Enhance focus on science
  - What are the appropriate proportions by sex/gender, race, and ethnicity for the scientific goals of the study?
  - Increase value of reporting on inclusion
- Simplify and streamline business processes
- Enhance communication

### **What does it mean for Grantees?**

The Inclusion Data will be submitted on the grant application in a structured format. Grants.gov packages will be enhanced to include the fillable PDF of the Inclusion Data forms.

Post-submission of original Inclusion Data will be managed by Grantees. eRA Systems will be enhanced to support the following tasks performed by Grantees:

- View Inclusion Data via eRA Commons for their grant applications
- View Inclusion Data for any grant application within the Institution
- Modifications of Inclusion Data based on requests from Agency
- Unsolicited submission of additional Inclusion Data post original submission of grant application or RPPR

Existing Target/Planned Enrollment Table Form

Program Director/Principal Investigator (Last, First, Middle):

### Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title:

Total Planned Enrollment:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	Females	Males	Total
Hispanic or Latino	<input type="text"/>	<input type="text"/>	<input type="text"/>
Not Hispanic or Latino	<input type="text"/>	<input type="text"/>	<input type="text"/>
<b>Ethnic Category: Total of All Subjects *</b>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Racial Categories			
American Indian/Alaska Native	<input type="text"/>	<input type="text"/>	<input type="text"/>
Asian	<input type="text"/>	<input type="text"/>	<input type="text"/>
Native Hawaiian or Other Pacific Islander	<input type="text"/>	<input type="text"/>	<input type="text"/>
Black or African American	<input type="text"/>	<input type="text"/>	<input type="text"/>
White	<input type="text"/>	<input type="text"/>	<input type="text"/>
<b>Racial Categories: Total of All Subjects *</b>	<input type="text"/>	<input type="text"/>	<input type="text"/>

\* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

Redesigned Target/Planned Enrollment Table Form

### Planned Enrollment Report

This report format should NOT be used for collecting data from study participants.

Study Title: \_\_\_\_\_

Domestic/Foreign: (D/F drop down) \_\_\_\_\_

Comments: \_\_\_\_\_

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

Existing Inclusion Enrollment Report

**Inclusion Enrollment Report**

This report format should NOT be used for data collection from study participants.

Study Title: \_\_\_\_\_  
 Total Enrollment: \_\_\_\_\_ Protocol Number: \_\_\_\_\_  
 Grant Number: \_\_\_\_\_

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
<b>Ethnic Category: Total of All Subjects*</b>				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
<b>Racial Categories: Total of All Subjects*</b>				*

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
<b>Racial Categories: Total of Hispanics or Latinos**</b>				**

... These totals must agree.  
 \*\* These totals must agree.

Redesigned Inclusion Enrollment Report

**Cumulative Inclusion Enrollment Report**

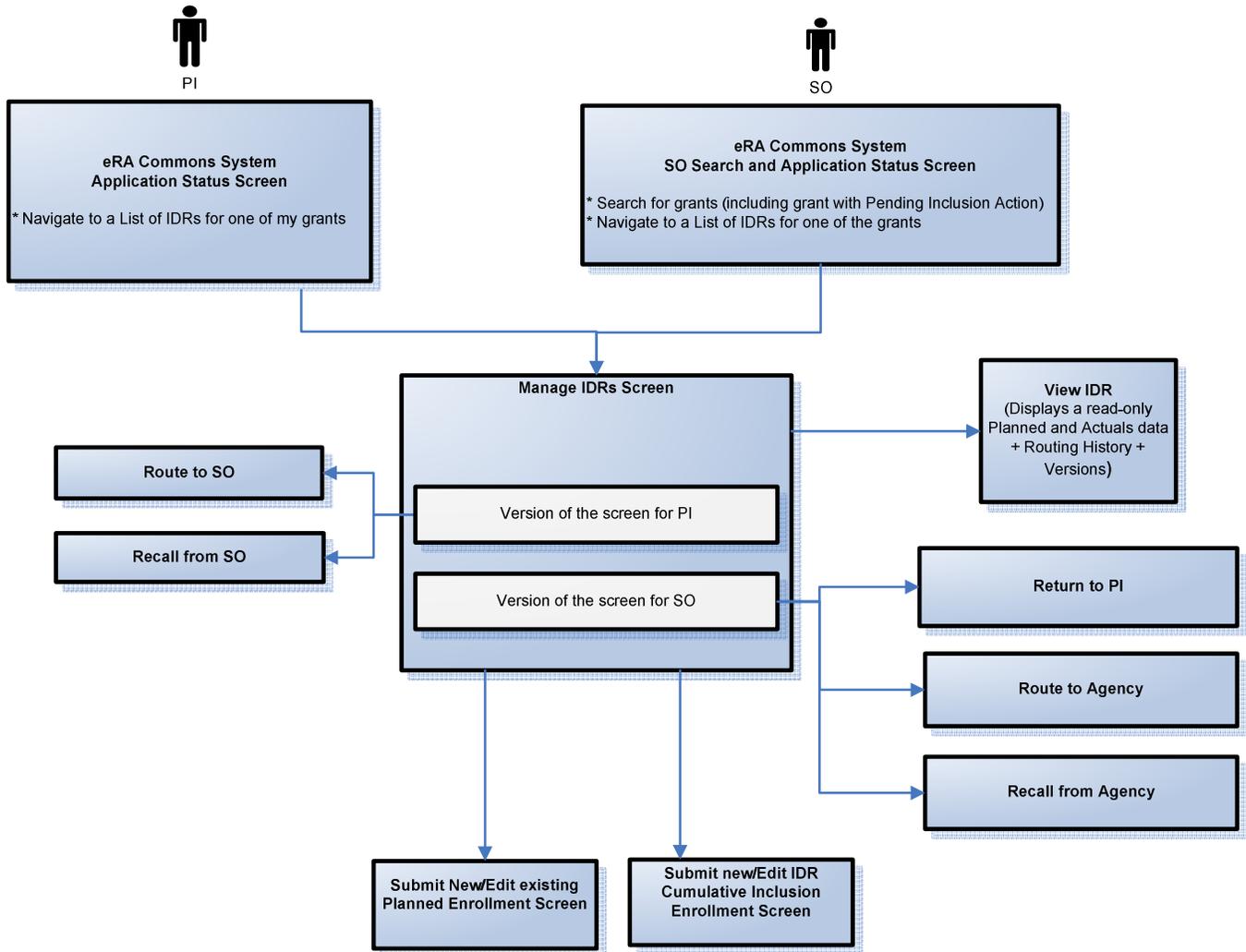
This report format should NOT be used for collecting data from study participants.

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										
Asian										
Native Hawaiian or Other Pacific Islander										
Black or African American										
White										
More Than One Race										
Unknown or Not Reported										
<b>Total</b>										

# eRA Commons System Changes to support new Business Process

## Screen Map



## PI Status Screen Update

Application ID	Grants.gov Tracking #	Proposal Title	PD/PI Name	eSubmission Status	Current Application Status	Status Date	Action
<a href="#">1T32CA098617-01</a>		Training Program in Viruses and Oncogenesis.	LAIMINS, LAIMONIS A		Administratively Withdrawn by IC	05/02/2005	
<a href="#">1T32CA086792-01A1</a>		Training Program in Viral Oncology	LAIMINS, LAIMONIS A		Administratively Withdrawn by IC	05/02/2005	
<a href="#">1T32CA086792-01</a>		TRAINING PROGRAM IN VIRAL ONCOLOGY	LAIMINS, LAIMONIS A		Application withdrawn for amendment	01/01/2001	
<a href="#">2R01CA059655-16A1</a>	GRANT00486870P	Regulation of Human Papillomavirus Gene Expression	LAIMINS, LAIMONIS A	Submission Complete	Awarded. Non-fellowships only	03/10/2009	<a href="#">Transmittal Sheet</a>
<a href="#">4R37CA074202-16</a>		Life Cycle of Human Papillomaviruses	LAIMINS, LAIMONIS A		Council review completed	06/26/2012	
<a href="#">1R01CA142861-01</a>	GRANT10153066P	HPV and the DNA damage response	LAIMINS, LAIMONIS A	Submission Complete	Withdrawn by IC - Other Version Encumbered	06/17/2010	<a href="#">Transmittal Sheet</a>
<a href="#">5R01CA142861-03</a>		HPV and the DNA Damage Response	LAIMINS, LAIMONIS A	Submission Complete	Pending	06/01/2011	<a href="#">eSNAP</a>
<a href="#">1T32CA086792-01A2</a>		Training Program in Viral Oncology	LAIMINS, LAIMONIS A		Application has been entered into computer		
<a href="#">5R01CA142861-02</a>		HPV and the DNA Damage Response	LAIMINS, LAIMONIS A	Submission Complete	Awarded. Non-fellowships only	06/01/2011	<a href="#">Inclusion</a>

Inclusion link is added to Action column as follows:

1. For competing records, display Inclusion link for grants that require inclusion monitoring AND Summary Statement exists.
2. For non-competing records, for grants that require Inclusion monitoring, display Inclusion link at all times

SO Status Search Screen Update

The screenshot shows the 'General Search' form in the eRA Commons system. The 'Pending Inclusion Action' checkbox is highlighted with a red box. Other search criteria include Grant Number, Accession Number, PI Name, Application Status, Budget Start/End Dates, and Organization Hierarchy.

Clicking the Pending Inclusion Action check box will return grants that have inclusion data in “Pending PI”, “PI Updates in Progress”, “Pending SO”, or “SO Updates in Progress” status.

SO Status Hitlist Screen Update

The screenshot shows the 'Status Result - General Search' hitlist. The 'Inclusion' link in the Action column for the grant with Application ID 5R01DK065018-09 is highlighted with a red oval. The table lists various grants with their application IDs, tracking numbers, titles, PI names, and statuses.

Application ID	Grants.gov Tracking #	Proposal Title	PDI/PI Name	Application Status	Budget Start Date	FFATA	Show All Prior Errors	Action
<a href="#">1R01DK097702-01</a>	GRANT11056540P	High-Throughput Screening Assay for Novel Prokinetic Agents to Treat Constipation	PACK, MICHAEL A	Withdrawn	09/01/2012	Yes	<a href="#">Show All Prior Errors</a>	<a href="#">Transmittal Sheet</a>
<a href="#">5T32DK060455-09</a>		Renal and urologic biostatistics training grant	SHULTS, JUSTINE	Awarded. Non-fellowships only	07/01/2012			
<a href="#">5R37DK043806-22</a>		Thyroid hormone receptors - regulation and function	LAZAR, MITCHELL A	Awarded. Non-fellowships only	06/01/2012			
<a href="#">2R01DK060694-11</a>	GRANT11013350P	The Prx-1 transcription factor in pancreatic ductal biology	RUSTGI, ANIL K	Awarded. Non-fellowships only	07/01/2012		<a href="#">Show All Prior Errors</a>	<a href="#">JII Times Revised (1)   Transmittal Sheet</a>
<a href="#">5R01DK087874-03</a>		A Randomized Trial of Incentives and Peer Mentors to Improve Diabetic Outcomes	LONG, JUDITH A	Awarded. Non-fellowships only	05/01/2012			
<a href="#">5R01DK090505-02</a>		Fractalkine in Adipose Inflammation and Insulin Resistance	REILLY, MUREDACH P	Awarded. Non-fellowships only	06/01/2012	Yes		
<a href="#">5K24DK065018-09</a>		Improving the Effectiveness of Obesity Management	WADDEN, THOMAS A	Awarded. Non-fellowships only	02/01/2012			<a href="#">Inclusion</a>
<a href="#">5R01DK081342-03</a>		IMAGING AGENTS FOR BETA CELL MASS OF PANCREAS	KUNG, HANK F	Awarded. Non-fellowships only	04/01/2012			
<a href="#">1K08DK094968-01</a>	GRANT10896808P	Translating human PPARγ binding regions to gene regulation and metabolic disease	SOCCIO, RAYMOND EDWARD	Awarded. Non-fellowships only	04/15/2012	Yes	<a href="#">Show All Prior Errors</a>	<a href="#">Transmittal Sheet</a>
<a href="#">2P30DK050306-16</a>		Center for digestive and liver diseases	RUSTGI, ANIL K	Awarded. Non-fellowships only	07/01/2012			<a href="#">Inclusion</a>
<a href="#">5R01DK056645-13</a>		MicroRNAs and chromosome 22q in the colon	RUSTGI, ANIL K	Awarded. Non-fellowships only	06/01/2012			
<a href="#">5K08DK085152-03</a>		Elucidation of Novel Anti-apoptotic Pathways in	WANG, YONGPING	Awarded. Non-fellowships only	01/01/2012			

Inclusion Link is added. Same rules to display the link as for the PI Status screen

# Managing Inclusion Data for a Grant Application

## For PI

**Inclusion - Manage Inclusion Data Records (IDRs)**

Grant #: 1R01CA123411-01  
PI Name: Smith, John

[Submit new Planned Inclusion Form](#)

IDR #	IDR Status	Study Title	Last Updated Date	Actions
124	Pending PI	Some long Study title that spans 250 characters Some long Study title	12/21/2012 09:00 AM	<a href="#">View</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Edit Cumulative Inclusion Enrollment</a>
124	PI Updates in Progress	Some long Study title that spans 250 characters Some long Study title	12/25/2012 09:15 AM	<a href="#">View</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Edit Cumulative Inclusion Enrollment</a> <a href="#">Route to SO</a>
125	Received by Agency	Some long Study title that spans 250 characters Some long Study title	12/27/2012 08:00 AM	<a href="#">View</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Edit Cumulative Inclusion Enrollment</a>
128	Initiated	Some long Study title that spans 250 characters Some long Study title	12/20/2012 09:12 AM	<a href="#">View</a>   <a href="#">Delete</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Edit Cumulative Inclusion Enrollment</a> <a href="#">Route to SO</a>
128	Pending Agency	Some long Study title that spans 250 characters Some long Study title	12/29/2012 10:00 AM	<a href="#">View Current</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Edit Cumulative Inclusion Enrollment</a>
129	Pending SO	Some long Study title that spans 250 characters Some long Study title	12/29/2012 10:00 AM	<a href="#">View</a> <a href="#">Recall from SO</a>
433	SO Updates in Progress	Some long Study title that spans 250 characters Some long Study title	12/29/2012 10:00 AM	<a href="#">View</a>

## For SO

**Inclusion - Manage Inclusion Data**

Grant #: 1R01CA123411-01  
PI Name: Smith, John

[Submit new Planned Inclusion Form](#)

IDR #	IDR Status	Study Title	Last Updated Date	Actions
124	Pending PI	Some long Study title that spans 250 characters Some long Study title	12/21/2012 09:00 AM	<a href="#">View</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Edit Cumulative Inclusion Enrollment</a>
124	SO Updates in Progress	Some long Study title that spans 250 characters Some long Study title	12/25/2012 09:15 AM	<a href="#">View</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Edit Cumulative Inclusion Enrollment</a> <a href="#">Route to PI</a> <a href="#">Route to Agency</a>
125	Received by Agency	Some long Study title that spans 250 characters Some long Study title	12/27/2012 08:00 AM	<a href="#">View</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Edit Cumulative Inclusion Enrollment</a>
128	Initiated	Some long Study title that spans 250 characters Some long Study title	12/20/2012 09:12 AM	<a href="#">View</a>   <a href="#">Delete</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Route to PI</a> <a href="#">Route to Agency</a>
128	Pending Agency	Some long Study title that spans 250 characters Some long Study title	12/29/2012 10:00 AM	<a href="#">View Current</a> <a href="#">Recall from Agency</a>
129	Pending SO	Some long Study title that spans 250 characters Some long Study title	12/29/2012 10:00 AM	<a href="#">View</a> <a href="#">Edit Planned Enrollment</a> <a href="#">Edit Cumulative Inclusion Enrollment</a> <a href="#">Route to Agency</a> <a href="#">Return to PI</a>

## Actions for PI and SO

Actions for PI	Display if Inclusion Data Record is in following Status
View	Any status
Edit Planned Enrollment	Initiated, Pending PI, Pending SO, Received by Agency, PI Updates in Progress
Edit Cumulative Inclusion Enrollment	Initiated, Pending PI, Pending SO, Received by Agency, PI Updates in Progress
Delete	Available Anytime for any IDRS that have never been sent to Agency before.
Route to SO	PI Updates in Progress, Initiated
Submit New Planned Inclusion Form	Grant must not be awarded; for competing grants Summary Statement must be releases.
Recall from SO	Pending SO

Actions for SO	IDR Status
View	Any status except Initiated
Edit Planned Enrollment/ Edit Cumulative Inclusion Enrollment	Pending PI, Pending SO, Received by Agency, SO Updates in Progress
Delete	Available Anytime for any IDRS that have never been sent to Agency before.
Submit New Planned Inclusion Form	Grant not awarded; for competing grants Summary Statement is available.
Route to PI	Initiated, SO Updates in Progress
Return to PI	Pending SO, SO Updates in Progress
Route to Agency	Pending SO  SO Updates in Progress
Recall from Agency	Pending Agency

View Read-Only Inclusion Data

Inclusion Data Record Details

IDR #: 124  
 Study Title: Some long Study Title [for this version](#)  
 Accepted Date: 12/21/2012  
 Foreign/Domestic: Foreign

Routing History

Action Date/Time	Action Performed By	Action	Action Comments
12/21/2012 09:00 AM	<a href="#">Fox, Daniel</a>	Sent to Agency	This action comment, showing one line at a time, expanded by this link <a href="#">...more</a>
12/21/2012 08:05 AM	<a href="#">Smith, John</a>	Sent to SO	Please review and send to NIH.
12/21/2012 06:23 AM	<a href="#">Carter, James</a>	Sent to PI for Update	Reviewed, no problems, forwarding on to NIH

Target Enrollment Inclusion Report

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/ Alaska Native	1,000,000	1,000,000	1,000,000	1,000,000	4,000,000
Asian	1,000,000	1,000,000	1,000,000	1,000,000	4,000,000
Native Hawaiian or Other Pacific Islander	1,000,000	1,000,000	1,000,000	1,000,000	4,000,000
Black or African American	1,000,000	1,000,000	1,000,000	1,000,000	4,000,000
White	1,000,000	1,000,000	1,000,000	1,000,000	4,000,000
More Than One Race	1,000,000	1,000,000	1,000,000	1,000,000	4,000,000
<b>Total</b>	<b>6,000,000</b>	<b>6,000,000</b>	<b>6,000,000</b>	<b>6,000,000</b>	<b>24,000,000</b>

Comments: Sample Comments as submitted on this form

Cumulative Enrollment Inclusion Report

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	50,000	50,000	50,000	50,000	50,000	50,000	10,000	10,000	10,000	330,000
Asian	50,000	50,000	50,000	50,000	50,000	50,000	10,000	10,000	10,000	330,000
Native Hawaiian or Other Pacific Islander	50,000	50,000	50,000	50,000	50,000	50,000	10,000	10,000	10,000	330,000
Black or African American	50,000	50,000	50,000	50,000	50,000	50,000	10,000	10,000	10,000	330,000
White	50,000	50,000	50,000	50,000	50,000	50,000	10,000	10,000	10,000	330,000
More Than One Race	50,000	50,000	50,000	50,000	50,000	50,000	10,000	10,000	10,000	330,000
Unknown or Not Reported	50,000	50,000	50,000	50,000	50,000	50,000	10,000	10,000	10,000	330,000
<b>Total</b>	<b>350,000</b>	<b>350,000</b>	<b>350,000</b>	<b>350,000</b>	<b>350,000</b>	<b>350,000</b>	<b>70,000</b>	<b>70,000</b>	<b>70,000</b>	<b>2,310,000</b>

Comments: Sample Comments as submitted on this form

[CLOSE]

Edit Inclusion Data (Planned)

**Create/Edit Planned Inclusion Data**

Grant #: 1R01CA123411-01  
 PI Name: Smith, John  
 IDR #: 123  
 IDR Status: Pending PI  
 Study Title: Some long Study Title

**Target Enrollment Inclusion Report**

\*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="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	4,000,000
Asian	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	4,000,000
Native Hawaiian or Other Pacific Islander	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	4,000,000
Black or African American	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	4,000,000
White	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	4,000,000
More Than One Race	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	<input type="text" value="1,000,000"/>	4,000,000
<b>Total</b>	6,000,000	6,000,000	6,000,000	6,000,000	24,000,000

[Save] [Cancel]

Edit Inclusion Data (Actual)

**Actuals Inclusion Data**

Grant #: 1R01CA123411-01  
 PI Name: Smith, John  
 IDR #: 123  
 IDR Status: Pending PI  
 Study Title: Some long Study Title

**Cumulative Inclusion Enrollment Report**

\*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="50,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	330,000					
Asian	<input type="text" value="50,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	330,000					
Native Hawaiian or Other Pacific Islander	<input type="text" value="50,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	330,000					
Black or African American	<input type="text" value="50,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	330,000					
White	<input type="text" value="50,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	330,000					
More Than One Race	<input type="text" value="50,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	330,000					
Unknown or Not Reported	<input type="text" value="50,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	<input type="text" value="10,00"/>	330,000					
<b>Total</b>	350,000	350,000	350,000	350,000	350,000	350,000	70,000	70,000	70,000	2,310,000

OMB approved form...

[Save] [Cancel]

Route to SO

**Route to SO**

**Grant #:** 1R01CA123411-01  
**PI Name:** Smith, John

**IDR #:** 123  
**IDR Status:** Pending PI  
**Study Title:** Some long Study Title

Action Comments (1000 characters max)

[Route to SO] [Cancel]

Route to Agency

**Route to Agency**

**Grant #:** 1R01CA123411-01  
**PI Name:** Smith, John

**IDR #:** 123  
**IDR Status:** Pending PI  
**Study Title:** Some long Study Title

Action Comments (1000 characters max)

[Route to Agency] [Cancel]

## **Submit Final Inclusion Data**

A link to Final Inclusion Data will be available for Awarded Grant Support years that do not have future non-competing grant support years. The link will be available on the Manage IDRs page, in-line with IDR Records, so users may submit Final Inclusion Data for each IDR under the awarded grant.

### **Inclusion - Manage Inclusion Data**

Grant #: 1R01CA123411-01  
PI Name: Smith, John

IDR #	IDR Status	Study Title	Last Updated Date	Actions
124	Accepted (Updated by PI)	Some long Study title that spans 250 characters Some long Study title	12/21/2012 09:00 AM	<a href="#">View</a> <a href="#">Submit Final Inclusion Data</a>
124	Accepted (Updated by PI)	Some long Study title that spans 250 characters Some long Study title	12/25/2012 09:15 AM	<a href="#">View</a> <a href="#">Submit Final Inclusion Data</a>

Note that Submit New Planned Inclusion Form link is not available for Inclusion Data Records on awarded grants.

Once Submit Final Inclusion Data link is clicked, the system will take users to Actual Inclusion Enrollment Data Form, where users will be able to modify the final inclusion counts and then route the form to SO.

The process of Routing the Final Inclusion Data to Agency is the same as for any other updates of the Inclusion Data.

Once received by Agency, the status of the Inclusion Data Record will be set to "Received by Agency" status..

## Modifications to eRA Commons – RPPR

As part of the Progress Report Submission, Grantees also submit Cumulative Inclusion Enrollment Report, indicating the number of subjects used within the last awarded grant support year. This existing module will need to be modified to support changes in business as follows:

1. Existing screen that comes up when users click .on the eSnap -> Manage eSnap -> Special Reporting Req menu needs to be adjusted to:
  - a) Modify the language on the boiler plate of the page to be adjusted to new adopted terminology (note that actual language changes will be documented in the detailed requirements).
  - b) Adjust business rules that govern the display of the links to the studies that require the Inclusion Enrollment Report to be in-line with the overall business process of the re-engineered Inclusion business flow (as explained in the Process Overview section of this document).

Here is the existing screenshot:

Home Admin Institution Profile Personal Profile Status eSNAP Internet Assisted Review xTrain Admin Supp eRA Partners  
Grant List Manage eSNAP  
A Cover Page B Accomplishments C Products D Participants E Impact F Changes G Special Reporting Req H Budget

### G. Special Reporting Requirements

**G.1 Special Notice of Award Terms and Funding Opportunity Announcement Reporting Requirements**

Address any special reporting requirements specified in the award terms and conditions in the [Notice of Award \(NoA\)](#) or Funding Opportunity Announcement (FOA).

Nothing to Report  
or upload file(s)

**G.2 Not Applicable**

**G.3 Not Applicable**

**G.4 Human Subjects**

G.4.a Does the project involve human subjects?  Yes  No

Is the research exempt from Federal regulations?  Yes  No  
If yes, check appropriate exemption number(s).  
 E1  E2  E3  E4  E5  E6

Does this project involve a clinical trial?  Yes  No  
If yes, is this an NIH-defined Phase III Clinical Trial?  Yes  No

**G.4.b Inclusion Enrollment Data**

Please review the box below to determine if this project meets the definition of clinical research and requires the reporting of cumulative enrollment of subjects and the distribution of sex/gender, ethnicity and race. [Click here](#) for complete instructions about this requirement. Please contact the NH Program Official James Panagis at [grATest@mail.nih.gov](mailto:grATest@mail.nih.gov) with any questions.

**Inclusion Enrollment**

Please click the "Save" button at the bottom of the page before proceeding to the Inclusion Enrollment Reports. Otherwise, any entered data will be lost.

Inclusion Enrollment Report is required for the following study(ies):

[To reveal an etiological factor of functional ankle instability-PROTOCOL-000](#)

**G.4.c ClinicalTrials.gov**

Does this project include one or more applicable clinical trials that must be registered in ClinicalTrials.gov under FDAAA?  
 Yes  No

If yes, provide the ClinicalTrials.gov identifier, NCT number (e.g., NCT00654321) for those trials.

**G.5 Human Subjects Education Requirement**

- Modify the existing Inclusion Enrollment Report screen in RPPR to be in-line with new design of the Actual Inclusion Enrollment form explained above. Here is the screenshot of existing form in RPPR:

**5/01 Inclusion Enrollment Report Table** ?

Program Director/Principal Investigator Name: LIU, WEN

Grant Number: 5R21AR062205-02	Optional Institution Information
NIH Study Title: To reveal an etiological factor of functional ankle instability-PROTOCOL-000	Study Title: <input type="text"/>
NIH Protocol Number:	Protocol Number: <input type="text"/>

This study does not involve enrollment from foreign population. **Total Enrollment: 0**

Comment for NIH ?

**PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race** ?

Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino ?	0	0	0	0
Not Hispanic or Latino	0	0	0	0
Unknown (Individuals not reporting ethnicity)	0	0	0	0
<b>Ethnic Category: Total of All Subjects*</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Racial Categories				
American Indian or Alaska Native	0	0	0	0
Asian	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	0	0	0	0
White	0	0	0	0
More than one race	0	0	0	0
Unknown or not reported	0	0	0	0
<b>Racial Categories: Total of All Subjects*</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

**PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)** ?

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	0

**MUST MATCH**

- Modify other existing business rules that govern the submission of the inclusion data within the RPPR to be in-line with the new re-engineered process.

Once Inclusion Data Record with updated Actuals data is received as part of the RPPR at NIH, the status of the record will be set to "Received by Agency".