Transcript – IMS for PIs

Welcome to this tutorial on the Inclusion Management System (IMS).

The inclusion of women and minorities in clinical research is mandated by law.

IMS was developed by NIH to support the monitoring and oversight of inclusion policy, helping to ensure NIH supported research is in compliance with statutory and policy requirements for inclusion.

IMS allows grantees to directly manage their inclusion enrollment data throughout the awarded project period, as well it gives NIH staff the ability to monitor inclusion information more easily.

It also gives NIH staff the ability to see the same information the grantee sees to facilitate transparency.

The Inclusion Data Record (IDR) consists of the planned enrollment and/or the actual cumulative enrollment, as well as certain attributes that further describe the study.

IMS data can be accessed by grantees in one of two ways, via the eRA Commons Status screen, or via the Research Performance Progress Report (RPPR).

This tutorial will demonstrate accessing IMS via the eRA Commons Status, to create, access, and submit an Inclusion Data Record.

There are a number of reasons why you might need to access inclusion data through Commons Status rather than through the RPPR.

For example:

• Before the award of a competitive application, it may be necessary to make updates to the submitted enrollment information.

• After an award has started, the awarding agency may require the grantee to provide frequent updates to inclusion enrollment in addition to annual reporting associated with the RPPR.

• Grantees may also need to add new IDRs for studies that were not fully developed at the time of the competing application.

To access the IMS and IDR, log into eRA Commons as you normally would and click on the Status menu.

The grantee will then click on the List of Applications/Grants link.

Conversely, the SO will click on Status and can then select the Pending Inclusion Action link on the Status General Search screen.

For both the PI (or designee) and the SO: when the system returns the list of results, locate the desired grant and click on the Inclusion link in the Action column.

Clicking the Inclusion link opens the Manage Inclusion Data Records (IDRs) screen for the selected grant.

To create a new IDR, click on the Submit New Planned Inclusion Record link.

This link opens the Edit Planned Inclusion Data screen. The Planned Enrollment Report includes fields for the Study Title, designating the study as involving Foreign or Domestically located participants, and a free text field for Comments or notes.

All planned enrollment count information can be entered in the fields below and IMS will automatically total both the rows across and the columns down.

When all information has been added to the form, click the Save button to retain the enrollment report.

This will bring you back to the Manage Inclusion Data Records screen.

The Manage Inclusion Data Records screen displays information about the study in a table format.

It shows the IDR number, which is automatically generated by IMS, the IDR Status, the Study Title, last update date and time, and then the available actions.

To edit an existing IDR, select the Edit Planned Enrollment and/or Edit Cumulative Enrollment links in the Action column for the IDR that needs to be edited. Make the updates on the necessary screens. Be sure to click the Save button.

In order for the new or updated IDR to be visible to the agency, it must be sent to the PI's Signing Official, who will then submit it to the awarding agency for review.

Once the PI has finished the changes, the PI must select an SO to send the IDR to for approval.

This is accomplished by the PI clicking the Select SO link at the "Please select SO for Inclusion emails" field.

A drop down menu will appear with a list of the name of the registered SOs for the PI institution.

Clicking on the desired name updates to display the name of the SO next to the title Selected SO for Inclusion emails.

The Select SO button remains available on the screen and can be used to choose a different SO if necessary later.

With the SO now selected for the IDR, here is the workflow for submitting the IDR.

The PI completes the process to create or update the IDR as already described.

While the IDR is in control of the PI, it will have an IDR Status of "Grantee Updates in Progress."

The PI routes the IDR to their SO by going to the Action column and clicking the Route to SO link.

Once the PI does this, the IDR will have a status of "Pending SO."

The SO will receive an email notifying them that the IDR is available for them to review.

Using the View link, the SO can review all the details about the IDR.

Using one of the two edit links, they can make any changes to the IDR, if needed.

The SO can also return the IDR to the PI for additional work by clicking Return to PI link if there is a specific need to do so.

It is not a systematic requirement that the IDR be returned to the PI.

The PI can then make the requested changes and route it back to the SO for review again.

This is an option available should additional updates or corrections be needed prior to submission to the agency.

When an IDR is returned to the PI, the following actions occur:

• Email notification is sent to the PI

• IDR status updates to Grantee Updates in Progress

• The action is recorded in the Action History

When an IDR has a status of Pending SO, the SO can choose to use the Route to Agency link to officially submit the IDR to the NIH.

This action will alert the Program Official (PO) of the awarding agency that the IDR is ready for their review.

The IDR will then have a status of Received by Agency.

Remember, help is only a click away. Anywhere within the IMS, where you see a question mark (?) icon, simply click on it.

A new window will open to the online help for that topic with the option to explore all the other topics for that module.

This concludes this tutorial, IMS Access for PIs: Creating, Accessing, and Submitting IDRs.

Thank you for watching.