Transcript for NIH's Human Subjects System Overview

**********DISCLAIMER!!!**********

THIS FILE MAY CONTAIN ERRORS. THIS IS NOT A LEGAL DOCUMENT AND IS NOT FOR USE IN A COURT OF LAW.

**********DISCLAIMER!!!**********

Welcome to this introduction to NIH's Human Subjects System

NIH is launching a new electronic system to manage human subjects and clinical trials information. This Human Subjects system replaces the Inclusion Management System (IMS) and will be used by grant applicants, recipients and NIH staff as of June 9, 2018.

The system allows principal investigators and signing officials to access and update all the human subjects and clinical trials data associated with their grants in one place. You can update participant and enrollment information, inform NIH of ClinicalTrials.gov registration, and revise other human subjects-related information as necessary, just-in-time for award or after a grant award is made.

The way it works is this — data is initially entered by the principal investigator, PI, on the Human Subjects and Clinical Trials Information form, in applications submitted for due dates of January 25, 2018, and beyond. The applications are retrieved by NIH, and once a grant number has been created, NIH automatically populates the Human Subjects system. This data is then made available to principal investigators and signing officials through a *Human Subjects* link that will be available on the eRA Commons Status screen and the Research Performance Progress Report (RPPR) as of June 9, 2018.

For projects submitted for due dates of January 25, 2018 and beyond, the system will display all the information the applicant included on the Human Subjects and Clinical Trials form. The system will also display additional form fields, beyond those from the original grant application, which may be required for progress reports. For recipients who submitted their application before January 25, 2018, only the inclusion enrollment section of the displayed form is populated.

Grant recipients with clinical trials registered at ClinicalTrials.gov will have the option to add their ClinicalTrials.gov identifier, the NCT number, in the form when they have completed registering the trial. Upon entry of the NCT number, the system will pre-populate several form fields, including study population characteristics and much of the protocol synopsis, from ClinicalTrials.gov. In the future, users will be able to use data from the Human Subjects system to initiate and populate their ClinicalTrials.gov registration.

This new system allows more transparent and real time updates of human subjects data, including inclusion records. You may be familiar with this type of approach from managing inclusion, where you can update the inclusion records directly in the system outside of the application or RPPR.

Study updates are possible through the system

- The most common use of this system will be for updates needed at the time of the Research Performance Progress Report (RPPR). Pre and post award changes may include:
- adding/updating study information
- updating enrollment data
- making off-cycle corrections or updates after application or RPPR submission
- Converting a delayed onset study to a full study record, once detailed study information is available
- Providing interim data as requested by NIH staff, in the funding opportunity announcement, or in the terms and conditions of award

After June 9, 2018 applicants and recipients will be able to access the human subject information in one of two ways:

- By way of a *Human Subjects* link on the *Status* screen in eRA Commons
- By way of a *Human Subjects* link in Section G of the RPPR form

Here is a quick demo of the key features. Clicking on the *Human Subjects* link takes you to a summary screen. From the summary screen, clicking on the Human Subjects tab will display a list of the human subjects studies for a given project. Principal Investigators and Signing Officials can drill down into the study details to update the human subjects study information, including inclusion data.

Here you can: Edit an existing study — For instance, if you want to update an existing Inclusion Enrollment Report, you can edit the cells in an existing enrollment report.

A new feature is that you can upload participant-level data in a CSV format (that is comma-separated values), which will automatically populate those cells. The data will be stored in the system and can be downloaded using the "Download Current Participant Level Data" button.

You can add a study by clicking the "Add New Study" button. And you can convert a delayed onset study to a full study record — by clicking the "Convert" button. Once a study is added or converted, you can add and save the necessary data in the Human Subjects and Clinical Trials Information Form.

Once the changes have been completed and saved, only the Signing Official can submit the form to NIH. The submission sends all study records associated with the application to NIH at one time.

On the NIH side, program officials and grants specialists are notified automatically if a study has been changed or added and have the ability to review the submission. Keep in mind some changes, including those that involve increased risk to human subjects, may require prior approval. Applicants and recipients should discuss such changes with their NIH program official.

How NIH staff will use the system…

Depending on their roles and privileges, NIH staff can use the Human Subjects system to:

- View and compare study records
- Associate, or link, projects to allow one primary project to report study information for other projects working on the same study
- Receive notifications
- Make limited corrections to study-level codes
- Delete duplicate or unfunded studies

The new system is one part of a larger initiative to help NIH manage human subjects and clinical trials information in a way that enhances the accountability and transparency of clinical research that it funds. Once the system becomes available on June 9, 2018, look for additional resources on using the new system at https://era.nih.gov/.

This concludes this overview of NIH's new Human Subjects system. Thank you for watching.