Transcript - HSS Study Record Export

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

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

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Welcome to this tutorial on the steps to export study record data from the Human Subjects System (HSS), to facilitate the registration of the study at ClinicalTrials.gov.

One of the requirements of award recipients when conducting clinical trials, is to register their study at ClinicalTrials.gov within 21 days of enrolling their first patient. To reduce this burden on award recipients, the Office of Extramural Research (OER) has developed a feature in HSS that permits users to export study record entries that correspond to fields in ClinicalTrials.gov as an XML file.

With the exported study data, you will then be able to more easily, quickly and reliably upload that data to ClinicalTrails.gov as part of your study registration process, without manually having to enter all the study information. For example, the Narrative Study Description in HHS will populate the Detailed Description field in clinicaltrials.gov, saving quite a bit of data entry.

Here are some important points to remember before we get into the steps to export data from HSS, so that it can be uploaded to ClinicalTrials.gov…

Use of the feature is optional.

The export XML functionality is only available for clinical trial studies. This means only study records listed as clinical trial will have the Export XML button.

Each study record uploaded to ClinicalTrials.gov must have a unique title if the process is to be successful.

Only XML records can be uploaded to clinicaltrials.gov. The system will not accept PDFs, word documents, text documents, or spreadsheets.

You must provide the following information to complete the process:

An Organization Name. This is the one-word Organization Name is assigned when you created the account in the Protocol Registration and Results System (PRS)

Unique Identification Protocol Number: Any unique identifier assigned to the Protocol by the Sponsor

The Human Subject/Clinical Trial (HSCT) form does not contain all the information required by ClinicalTrials.gov, therefor you will need to provide the missing information in order to eliminate the resulting errors.

The first part of the process is to export the desired study data from eRA Commons as an XML file. This starts by finding the application or grant in eRA Commons.

The signing official, Principal Investigator or their delegate will go to the Status tab and conduct a search using the search tool provided and relevant search criteria.

From the search results page, click on the Human Subjects link. This will take you to the Human Subjects System, and specifically the Application Information screen. From here, click on the HSCT Post Submission tab.

Study records listed as clinical trials will include the Export XML button in the Action column. Click this button.

"The CT GOV Export Info" screen is presented. Provide the one-word organization name and the Unique Protocol Identification Number in the corresponding fields. When done, click the Export button. This will download the XML file to your desktop.

With the XML study record successfully downloaded, go to ClinicalTrials.gov's PRS login page, at register.clinicaltrials.gov. Log into the Protocol Registration and Results System.

From the landing page, click on the Records button near the top left of the screen. From the drop down menu, select the Upload Record (XML) option. This will open the Upload Record (XML) screen.

On the Upload Record screen, click the Choose file button. Navigate to the XML study file you exported from HSS. With the file selected, on the Upload Record screen, click the Upload button.

The Record Summary screen will open. In the Protocol Section you will see errors and warnings from the missing information that ClinicalTrials.gov requires but was not included in the XML export. Use the Open link along the left side to expand the Protocols section. From this screen, you can click the Edit links for each subsection to complete the missing information.

Additional information about the registration process can be found on the Clinical Trials.gov website.

And you will find more resources on the eRA Intranet at inside, dot e r a, dot N I H, dot gov, forward slash HSS, forward slash training. You can also access the Online Help at the link displayed here https://era.nih.gov/erahelp/ASSIST/Default.htm#cshid=99

This concludes this tutorial on the steps to export study record data from HSS. Thank you for watching.