Human Subject Addressing Errors Video Transcript

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Welcome to this video tutorial on how to address errors when uploading inclusion data using the Participant Level Data Template in the Human Subjects System (HSS).

To enter data on a Human Subject Study using the Participant Level Data Template, log into eRA Commons, find the award and go to the Human Subjects System. From the Application Information page, click on the HSCT Post Submission tab. Click on the Edit button at the top of the screen. Find the study record you want to update and click Edit in the Action column . Scroll down to Section 2 -Study Population Characteristics. At sub-section 2.9, Inclusion Enrollment Reports, click the Add New Enrollment Report to add a report, or click Edit to update an existing enrollment report.

To enter data using the template, scroll to the bottom of the screen. Download a spreadsheet template by clicking on the *'Download Participant Level Data Template'* button.

Delete the sample data and fill the template out with your data — race, ethnicity, sex or gender, age at enrollment, and age unit. Age at enrollment may be reported in units ranging from minutes to years. Acceptable values for the inclusion variables are shown in the sample data on the template, and on the Participant-level data tip sheet, which can be found on the eRA Training - Human Subjects System (HSS) web page at the URL shown here: https://era.nih.gov/help-tutorials/era-training-hss.htm.

It is very important not to change the template format in any way. Altering the format, category titles, or using unacceptable values results an error when uploading the data.

Once you have completed filling out the template, you upload the spreadsheet by clicking on the *'Upload Participant Level Data Attachment'* button. If there are no errors, the uploaded data will populate the cells in the report.

If the formatting of the template was altered in some manner when adding data, an error will result. Note the language of the error message. It provides some tips to troubleshoot the issue. In this error message it notes that Age must be a whole number between 0 and 9999.

So, in this example, when we look at the spreadsheet that was selected to be uploaded, we see a hidden column was accidently added to the spreadsheet. The error resulted because the system is expecting to have numbers in the fourth column for age. Instead it encountered text for Gender. The hidden column will need to be removed before trying again.

If you suspect a formatting change is the reason for the error, the best solution is to download a new version of the template and copy the data cells you completed in the previous spreadsheet to the new template, making sure to paste in the values only.

Another common error is using unacceptable values for variables such as ethnicity and age. In attempting to upload a completed Participant Level Data Template, you see we have encountered another error. The error message reminds us to 'Make sure columns were not modified, the file does not contain formulas, and only allowable category values are included.' When looking at the data, you will see that the last participant is listed as 'Spanish', when the correct value is 'Hispanic or Latino.'

After fixing the category for ethnicity data, and we attempt to upload the template again, a third error message is presented. This message notes 'If Ninety Plus or Unknown is specified as the Age Unit, the Age number must be blank'.

Looking again at the data, the last entry has 'unknown' entered for the age. In this case, the age number should be left blank, and only the age unit set to 'unknown.'

Once these values are corrected, the Participant Level Data can be successfully uploaded to the study.

Several resources are available to assist you with the Human Subjects System (HSS).

- Human Subjects System Overview page: https://era.nih.gov/hss-overview.htm
- HSS Training page: https://era.nih.gov/hss-training.htm
- Participant-Level Data Template Tip Sheet: https://grants.nih.gov/sites/default/files/Participant-level%20data%20template%20tip%20sheet.pdf

If you need additional help, please contact the eRA Service Desk: https://era.nih.gov/need-help

This concludes this tutorial on how to address errors when uploading inclusion data using the Participant Level Data Template in the Human Subjects System (HSS). Thank you for watching.