Human Subjects System (HSS)

Quick Guide for Warnings and Errors

This guide describes some of the warnings and errors commonly encountered by users in the Human Subjects System, or HSS. The guide provides instructions on how to resolve the warnings and errors, and general tips on getting information updated and submitted.

Tip Sheet: HSS inclusion policy warnings and errors

Errors: data issues that prevent submission. ***Warnings***: data issues that warrant review and potential correction, but submission is still allowed.

Warning or error	What it means	What to do
Inclusion monitoring is required, but no IER exists.	All clinical research, which includes almost all exempt and non-exempt human subjects research (except exemption 4) requires inclusion monitoring. This error will come up when your project has a study record that requires inclusion monitoring, but an inclusion enrollment report has not been created.	Add an inclusion enrollment report. Planned enrollment is required for all prospective research. When using an existing dataset or resource, be sure to mark “yes” to this option on the IER and provide data only in the cumulative enrollment table instead.
Enrollment has begun, but inclusion data have not been provided.	Once the Enrollment of First Participant Date is set to “actual,” the system will check for inclusion data in the inclusion enrollment report. The warning will display if a start date is given but enrollment is not reported.	Provide the required inclusion enrollment data. If the Enrollment of First Participant Date is incorrect and the study has been registered in ClinicalTrials.gov, use the Populate button to pull the date from ClinicalTrials.gov into your study record. If your study is not a clinical trial or has not been registered yet, contact your NIH Program Officer for assistance with correcting the date.
Participant-level data, including age at enrollment, is required.	For all studies that came in on applications on/after January 25, 2019, participant-level data are required for inclusion enrollment reporting. The warning comes up if participant-level data have not been provided in an inclusion enrollment report that describes prospective enrollment.	Use the participant-level data template to provide the sex or gender, race, ethnicity, and age for each participant on your study. Upload the completed spreadsheet to your inclusion enrollment report in HSS.

Tip Sheet: HSS clinical trial policy warnings and errors

Warning or error	What it means	What to do
Some of the information provided in study “Example Study Title" (HSS field) does not match the information in Clinicaltrials.gov for the Clinicaltrials.gov identifier provided "NCT######".	For clinical trials, HSS checks some fields in ClinicalTrials.gov to make sure they match. The warning displays if any of the applicable fields are different between the two systems. The warning message lists the fields that do not match to point you directly to the problem.	Review the fields mentioned in the warning. Use the Populate button in Section 1 to update information in HSS with the information in ClinicalTrials.gov. If ClinicialTrials.gov needs to be updated, have the information there updated first.
Enrollment of 1st participant is more than 21 days ago and no NCT has been provided.	Per the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information, NIH-defined clinical trials must register and report in ClinicalTrials.gov.* Registration is due within 21 days of the enrollment of the first study participant. Once registered, the funding recipient provides the NCT in the relevant clinical trial study record. This message displays as a warning or error** when a study record has an “actual” Enrollment of First Participant that is 21 or more days in the past, and an NCT has not been provided in the study record. *NIH is delaying enforcement of the requirement to register and report in ClinicalTrials.gov for BESH studies that applied through a BESH FOA. See NOT-OD-22-205. **21 – 30 days = warning. More than 30 days = error.	Register the study in ClinicalTrials.gov, or contact the responsible party to do so. Provide the NCT in the appropriate study record after registering. If registration was completed but the NCT hasn’t been assigned yet, attach the receipt. See the eRA news item for recipients for more information. If enrollment has not actually begun, contact your NIH program officer to request assistance with correcting the Enrollment of First Participant Date.
Primary completion date is more than 12 months ago and no results have been provided.	The NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information requires results to be provided in ClinicalTrials.gov within 12 months of the study’s primary completion date. The error fires when the study has an “actual” primary completion that is more than 12 months in the past, and results are not available in ClinicalTrials.gov for the study.	Complete the submission of results in ClinicalTrials.gov, or contact the responsible party to do so. Once the results are submitted to ClinicalTrials.gov, this error should clear. If the study record’s primary completion date is incorrect, you will need to correct the date to clear the error. Confirm that the date is correct in ClinicalTrials.gov, then use the “Populate” button to update your NIH study record with this information.

Tip Sheet: common HSS data quality warnings and errors

Warning or error	What it means	What to do
The required form is incomplete.	Information has not been provided in a required field(s). For most clinical studies, information is required in Sections 1 – 3. Section 4 is only required for clinical trials. More detailed information regarding required fields can be found in the application guide.	Review the study record and confirm that information has been provided where necessary. Refer to the application guide or other resources for guidance on responding to the required items.
Information is provided for [field name] but the response to questions 1.4a – 1.4d are not all Yes.	Some fields, such as those in Section 4 of the study record, are only required for clinical trials. If a study record that is not representing a clinical trial has responses to these items, this error will come up. Remember, study records that have all 4 of the clinical trial questions (items 1.4a – 1.4d in Section 1) answered with "yes" are considered clinical trial study records.	If the study is not a clinical trial, remove information from fields that are only required for clinical trials. See the application guide for detailed information about which fields are required for your study.
[Milestone percentage] enrollment date is not greater than or equal to the Enrollment of the First Participant (Study Start) Date	Dates entered in the system need to be sequential. Therefore, an error will be produced if a date is entered for a field, such as the 25% enrollment date, that is later than the date of a milestone that should come after it. For example, if the 25% enrollment date is set to 06/01/2023, the 75% enrollment date cannot be set to an earlier date such as 05/01/2023.	Review the dates that are entered on the study record, and update them for accuracy.
The Enrollment of First Participant date is set to "anticipated," but the date is no longer in the past. Please set the date to "actual" or provide a new anticipated date.	The system utilizes the current date to understand how to interpret dates that are entered in your study record. By definition, an "anticipated" date must be a date that hasn't occurred yet, while an "actual" date must be a date that already passed. (In other words, an actual date is the date that X actually happened, while an anticipated date is a date that you are estimating for an event to occur.) Therefore, while working in the system, if you have a date that you previously entered in a field as an anticipated date, but now that date has passed, the system will identify that as an error.	Review the date that is currently entered. If the first participant has been enrolled, update the field to reflect the date that this occurred and set the field to "actual." Note that the system locks the field once it is saved as "actual" if the study is a clinical trial, so be sure to confirm before saving! If the first participant has not been enrolled, change the date to the new anticipated enrollment start date, and confirm that the date is set to "anticipated."

General Tips!

Unable to edit?

- Check the Submission Status. Change it to “Work in Progress” in order to edit.
- Confirm your permissions. Contact your signing official to make sure you have necessary role(s) assigned to you.

Read the error or warning details!

- Most of the errors and warnings contain information about the study record, inclusion enrollment report, and specific field that is responsible for the message.

General Tips! (cont.)

Changes must be submitted!

- NIH staff cannot see changes that you make until they are submitted by the signing official or designee.
- If you are making updates for an RPPR, submit your HSS changes ***before*** submitting your RPPR to make sure your RPPR reflects them. This will also clear RPPR warnings about data changes that are needed.

Unresolved warnings may still require your attention after submission!

- Though you can still submit while there are warnings about the data, you may still be required to address them prior to receiving your award or to closeout your grant. You may avoid delays if you address warnings prior to submission.

Need Help?

Check out these resources and contacts:

- eRA Service Desk
- HSS Online Help or PDF HSS User Guide
- HSS Training website
- NIH application guide website
- NIH Grants Conference Dec. 2022 PreCon Event on Human Subjects, Clinical Trials, and Inclusion HSS Training recording, transcript, and slide deck
- Your NIH Program Officer