Icahn School of Medicine at Mount Sinai

Research IT

Instructions for InfoEd S2S NIH

Human Subjects and Clinical Trials Information Form

For NIH Applications with Due Dates On Jan 25, 2018 and After

The instructions for completing this form are on the NIH website. Please refer to the following resources.

1. Video (approx. 9 minutes)- A Walk-through of the PHS Human Subjects and Clinical Trials Information Form
2. Instructions – SF 424 Application Guide > G.500
   PHS Human Subjects and Clinical Trials Information Form

The instructions on the following pages supplement the NIH instructions to explain variations of the Human Subject and Clinical Trials Information Form in InfoEd and to highlight technical or other important requirements (e.g., term definition, character limit, unique title requirement, etc.). The links within these InfoEd instructions bring the user to the particular portion of the NIH instructions.

Other Resources

3. Podcast (approx. 12 minutes)- Understanding the Definition of a Clinical Trial and What That Means for You
4. Video (approx. 15 minutes) - Overview of New NIH Policies on Human Subjects Research and Clinical Trials

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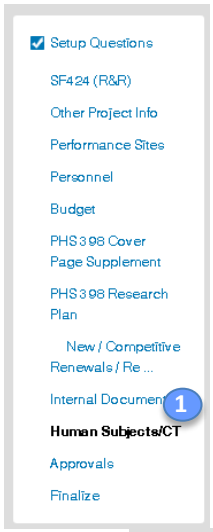
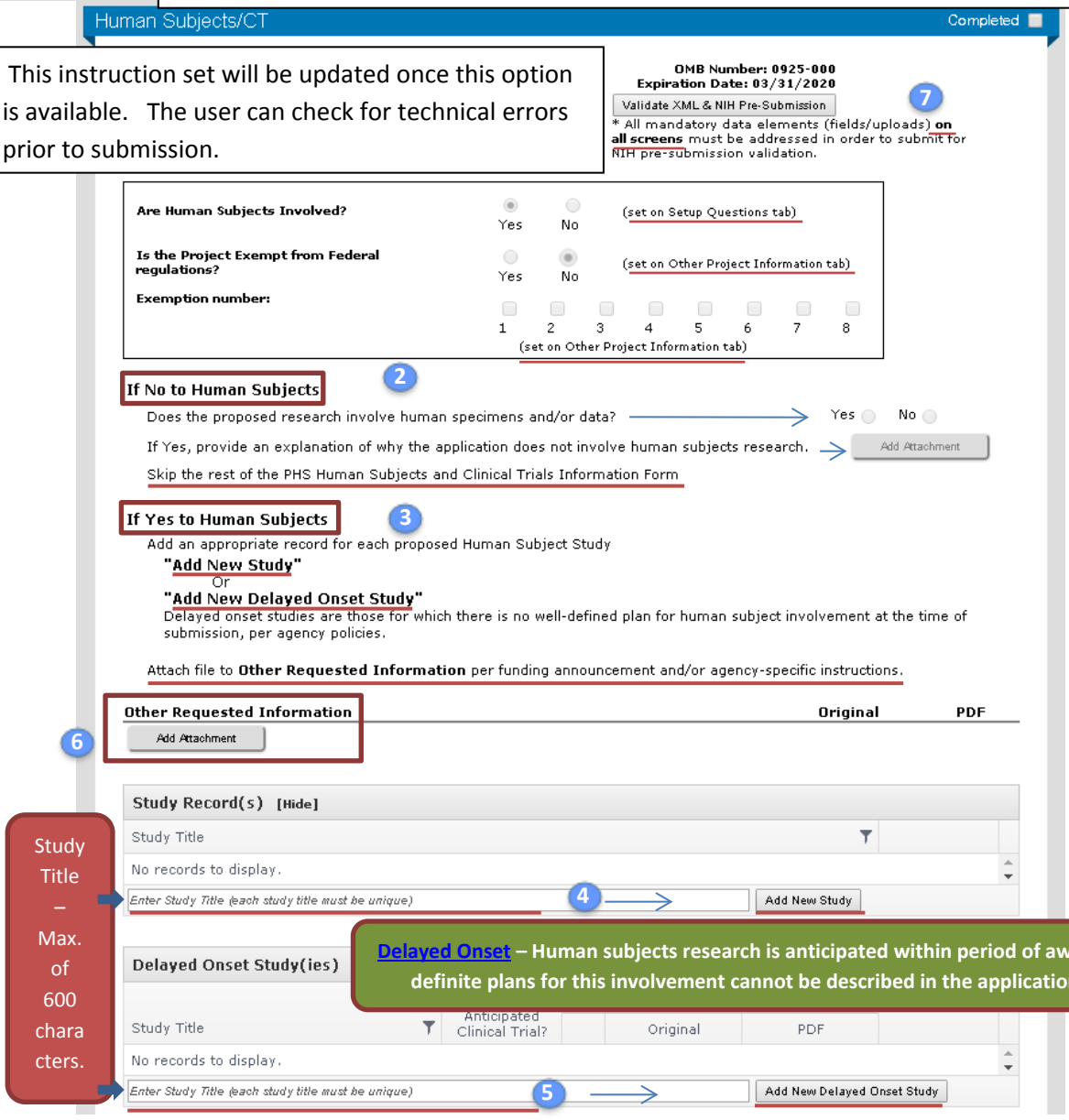
Last Updated: 1/19/2018

Need Help? Open Ticket with Research IT or click on the Support icon on the left side navigation bar.



1. Click on Human Subjects/CT.
2. If No to Human Subjects, you must answer the questions as indicated.
3. If Yes to Human Subjects, add a New Study or a New Delayed Onset Study.
4. If you are adding a new study, enter a unique title no longer than 600 characters and then click on the Add New Study button for each human subject study record. This form accommodates up to 150 separate New Study Records. Instructions continue in Step 8.
5. If you are adding a new delayed onset study, enter a unique title no longer than 600 characters. Instructions continue in Step 20.
6. Follow the other requested information instructions and any instructions in your Funding Opportunity Announcement (FOA) to determine whether you are permitted to include Other Requested Information. If it's not permitted, do not attach a file.

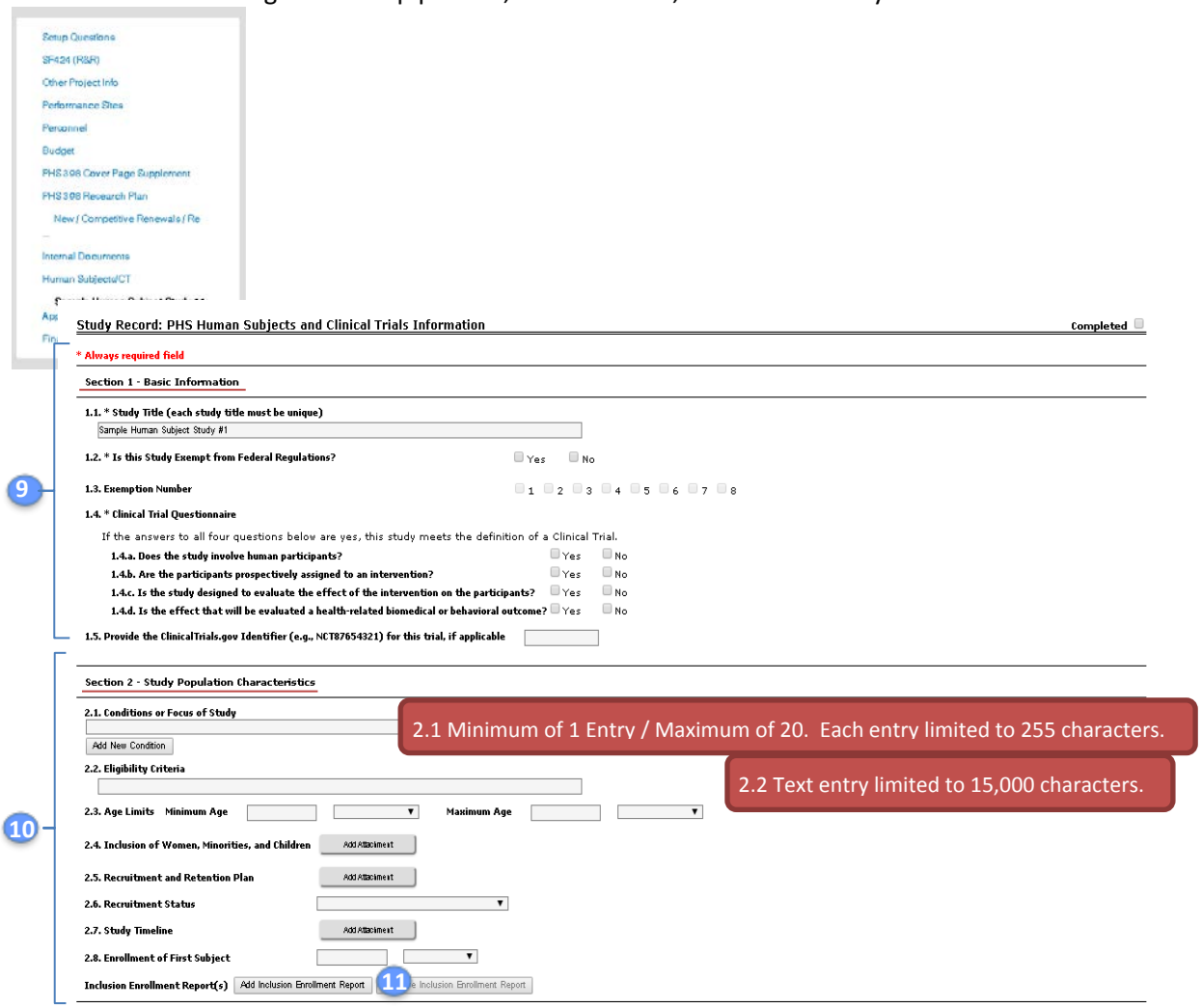
7. This instruction set will be updated once this option is available. The user can check for technical errors prior to submission.



8. After you add the New Study Record (see step 4), a link appears to the newly created record. Click on the link and complete the new Study Record sub-form. A screenshot of the Study Record sub-form is below.
9. Section 1 - All applications must have sections 1.1 – 1.4 completed. See 1.5 in the NIH Instructions for information about the Clinical Trials.gov identifier.
10. Section 2 – This entire section is required for most human subject studies. See section 2 of the NIH instructions for complete information.
11. An Inclusion Enrollment Report (IER) sub-form is required for all human subject studies unless it falls under Exemption 4 and no other exemptions. Click on the Add Inclusion Enrollment Report button to add the sub-form. Refer to NIH's Inclusion Enrollment Report instructions. The following page shows a screenshot of the IER.

New Study Record Form

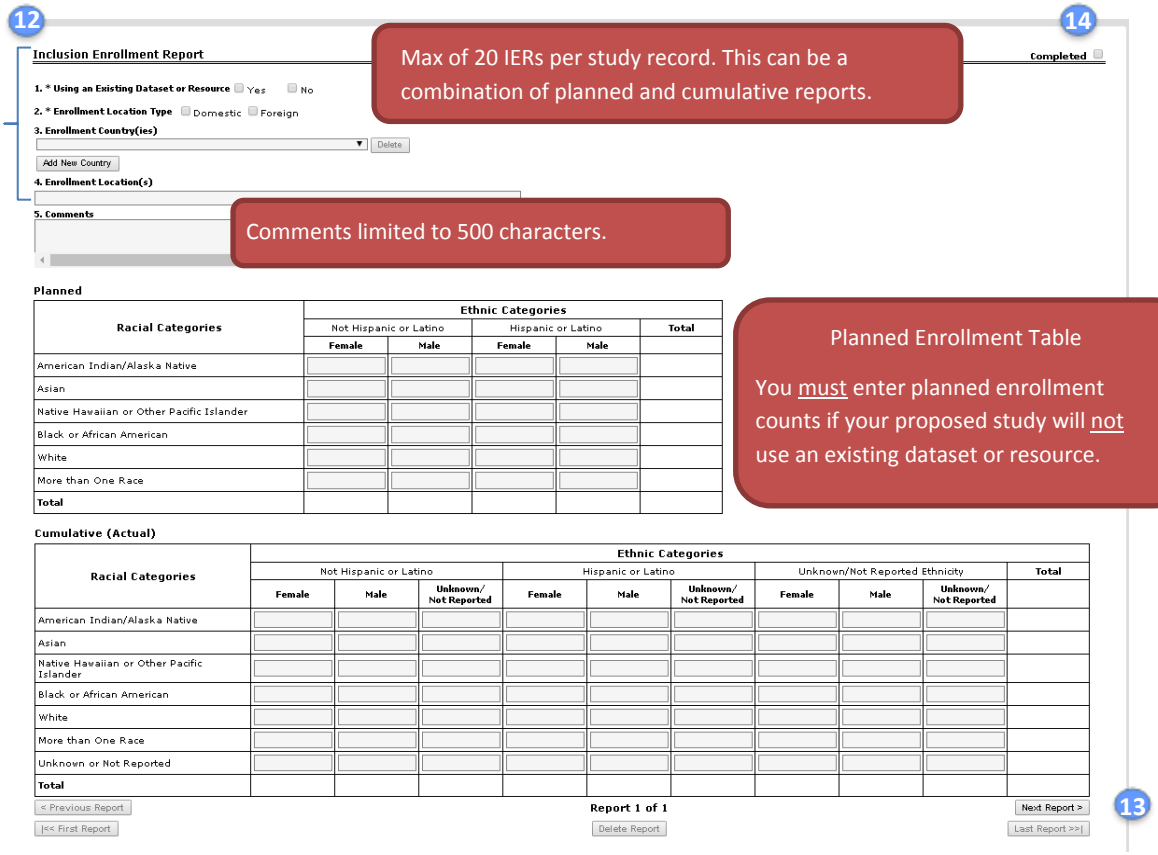
This is an image of the top portion, sections 1 – 2, of the New Study Record sub-form.



Inclusion Enrollment Report (IER)

The Inclusion Enrollment Report form is a sub-form within the Human Subjects and Clinical Trials Information > Add New Study Record form. See Step 11 on preceding page. Answer the questions as per the NIH instructions.

12. Questions 1-2 are required. 3-4 is optional. See notes in the screenshot below.
13. Click on Next Report to add more Inclusion Enrollment Reports.
14. Check Completed once the form is complete. To edit form, remove the checkmark.

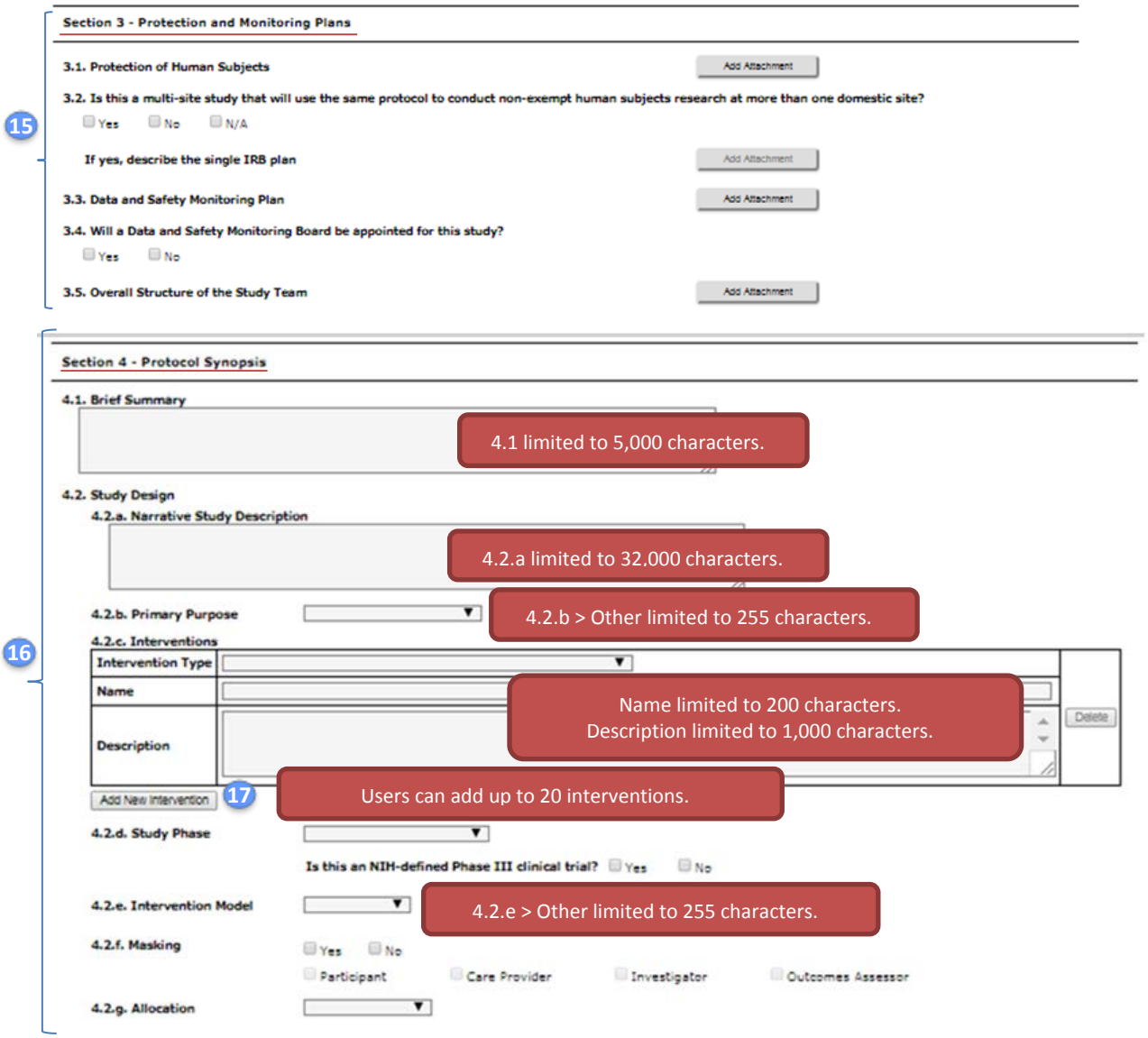


New Study Record Form (continued)

This is section 3 – 4.2, the middle portion, of the New Study Record form.

Section 4 continues on the next page.

15. Section 3 – This entire section is required for all studies involving human subjects, unless otherwise noted in the NIH instructions.
16. Section 4 – This entire section is required for all studies that include the answer Yes in 1.4 the Clinical Trial Questionnaire. See Step 9 of these instructions. Refer to the NIH instructions for complete information. Do not complete this section if you answered No to any question in 1.4. If you do, this will result in errors and will prevent your application from being accepted.
17. Click to Add New Intervention. Review section 4 instructions (link above) for applicability.

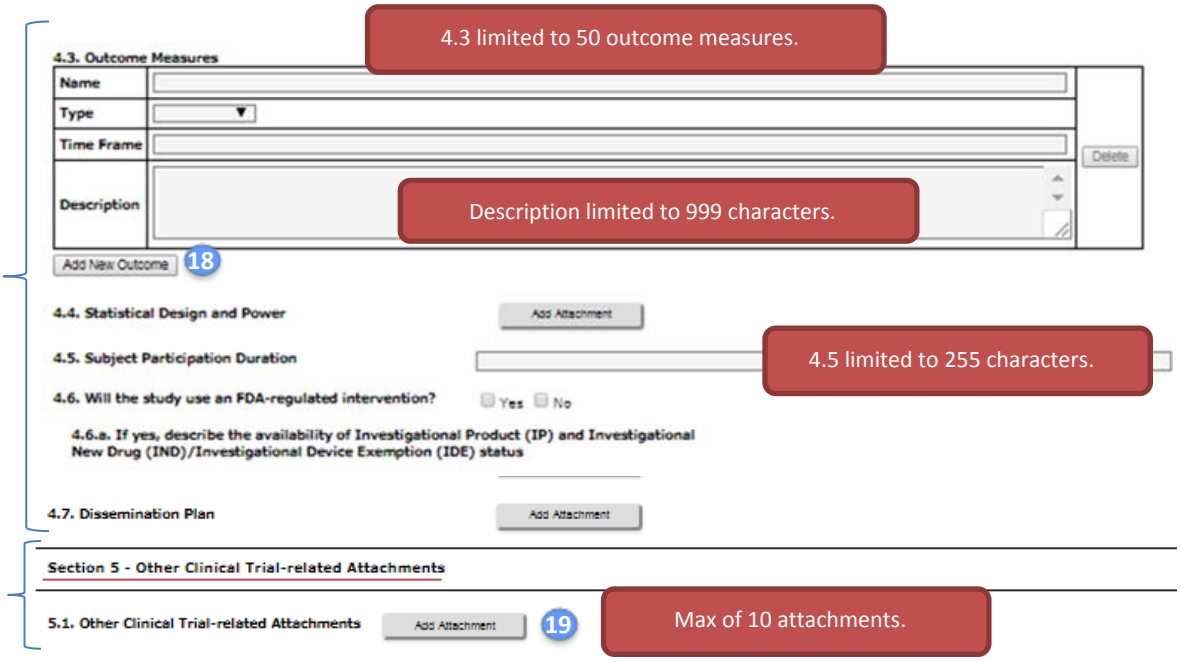


New Study Record Form (continued)

This is section 4.3 - 5, the bottom portion, of the New Study Record form. See Step 16 overall re: section 4 requirements.

18. Click to Add New Outcome (i.e., Primary, Secondary, Other).
19. Section 5 – This section is required for all studies if two criteria are met.
    1) You've included the answer Yes to all questions in 1.4 the Clinical Trial Questionnaire, and
    2) The funding opportunity announcement specifies that an attachment(s) is required or permitted.

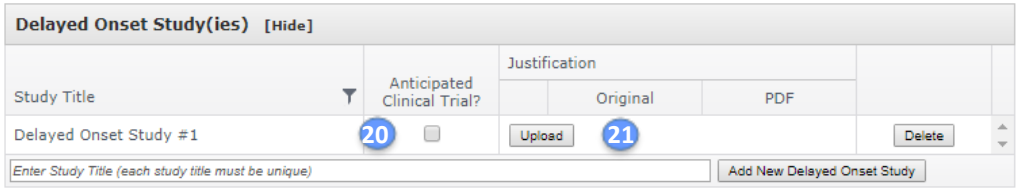
    Do not complete this section if you answered No to any question in 1.4. If you do, this will result in errors and will prevent your application from being accepted.



New Delayed Onset Study

This is a continuation from Step 5. Refer to the NIH instructions for more information about delayed onset studies.

20. Check this box if you anticipate that this study will be a clinical trial.
21. Upload the justification. If you are including more than one delayed onset study in any given delayed onset study entry, address all the included studies in a single justification attachment.



Final Step on Human Subjects and Clinical Trials Information Form

22. Place checkmark in Completed box once complete. To edit the form, remove the checkmark.