Coeus

How to Complete the PHS Human Subjects and Clinical Trials Information Form

Grants.gov FORMS-E January 2018
About the PHS Human Subject and Clinical Trial Information Form
NIH issues the *New* PHS Human Subjects and Clinical Trials Information Form (Grants.gov Forms-E)

- Effective on Applications with due dates on and after 1/25/18
- See NIH’s Webpage on the new form for further details and instruction.
Locating the *New* PHS Human Subjects and Clinical Trials form in Coeus

- You can verify whether or not this form is in the forms set for your proposal’s FOA.
- Once connected to Grants.gov, Check the Forms tab of the Grants.gov window in Coeus Premium.
- A few NIH FOA’s do not require this form- some training grants, instrumentation grants, etc.
Locating the *New* PHS Human Subjects and Clinical Trials form

- You may also check for required forms for your FOA directly at the Grants.gov website:
Initial Steps
Completing the *New* PHS Human Subjects and Clinical Trials form in Coeus

Getting Started

- Log in to Coeus Premium or Coeus Lite
- Create or copy a proposal development record
- Complete the Special Review tab
- Connect the proposal record to Grants.gov
Complete the Special Review tab

- Answer the human subjects question on the Special Review tab in Coeus Premium
- If “yes”, click the Add button and select status
- If “no”, leave blank
- Save the record
Connect to Grants.gov

- Connect to your proposal’s Grants.gov FOA
- Save the record
- The Human Subjects Forms link will then become available.
*New* Coeus Premium link to Human Subjects Forms in Lite

- Once you have connected the proposal record to Grants.gov
- From the Edit menu
- Click the new Human Subjects Forms link
Accessing the New Interface to Complete the Form
*New* Coeus Premium link to Human Subjects Forms in Lite

- Clicking the link in Premium will take you to the Coeus Lite login screen.
- Log in to Coeus Lite.
Coeus Lite opens to the Human Subjects and Clinical Trials Information form

<table>
<thead>
<tr>
<th>Proposal Summary</th>
<th>Investigator: Quinn, Jennifer L</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Info</td>
<td>Agency/Sponsor: 001820 - National Institute of Mental Health</td>
</tr>
<tr>
<td>Organization</td>
<td>Title: HE/CT Form-2: Task AM</td>
</tr>
<tr>
<td>Investigators/Key Persons</td>
<td>Proposal Period: 02/01/2018 - 01/31/2023</td>
</tr>
<tr>
<td>Credit Split</td>
<td>Least Unit: 000001: Brown University</td>
</tr>
<tr>
<td>Special Review</td>
<td>Least Updated: 2/18-31/18, 14:22:14.0 by Mual, Andrew M</td>
</tr>
<tr>
<td>Abstract</td>
<td>Add Human Subjects and Clinical Trials Information form</td>
</tr>
<tr>
<td>Science Code</td>
<td>Please add human subjects on the Special Review tab and identify the appropriate approval status and exemption.</td>
</tr>
<tr>
<td>Other</td>
<td>The following items are taken from the special Review tab and displayed here for your reference. Any changes to these fields must be made on the Special Review tab and may impact the data items you are required to complete on this form.</td>
</tr>
<tr>
<td>YNQ</td>
<td>Are Human Subjects Involved?</td>
</tr>
<tr>
<td>Proposal Roles</td>
<td>Is the Project Exempt from Federal Regulations?</td>
</tr>
</tbody>
</table>

If Yes to Human Subjects
You must add at least 1 of the following:
- A Human Subjects Study record for each proposed Human Subject Study by adding the description, choosing the file, and clicking the 'Add' button.
- A Delayed Onset Study in the Delayed Studies section by adding the study title, choosing the file, and clicking the 'Add' button.

Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on delayed onset studies. For delayed onset studies, you will provide the study name and a justification for omission of the human subject study information.

Human Subject Study Record(s) click here to extract Human Subject Study Record Attachment

<table>
<thead>
<tr>
<th>Description</th>
<th>File: Choose File, No file chosen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Add</td>
<td>Cancel</td>
</tr>
</tbody>
</table>

Other Requested Information

<table>
<thead>
<tr>
<th>File: Choose File, No file chosen</th>
<th>Add</th>
<th>Cancel</th>
</tr>
</thead>
</table>

Save
Completing the form in Lite

- Information from the Special Review tab will populate the initial three answers to the form in Lite.
Completing the Form for “No” Human Subjects Involved
Completing the form in Lite - No Human Subjects

Scenario:
- Human Subjects = NO
- Human specimens and/or data question must be answered
Completing the form in Lite

- Human specimens and/or data = YES
- A document supporting the “yes” answer to this question must be uploaded
- Choose file and then click the Add button
Completing the Form for “Yes” Human Subjects Involved
Completing the form in Lite - Yes to Human Subjects

Scenario:
- Human Subjects = YES
- And is not exempt
- Uploaded at least one Human Subject Study Record or enter at least one Delayed Onset Study.
The Study Record Attachment

To extract a Human Subject Study Record Attachment form

[Diagram showing the process of extracting a Human Subject Study Record Attachment form]
Completing the Study Record Attachment

- Button links you directly to the online form
- Download and complete
- Be sure that each Study Record has a unique study title
- Be sure each Study Record has unique Attachment Names

![Study Record Form](image)
Completing the Study Record Attachment

Important Note:

- If you see this screen, this is not a Coeus error/issue
- Please adjust your computer’s browser settings
- And/or adjust your Adobe Acrobat or Reader settings

Please wait...

If this message is not eventually replaced by the proper contents of the document, your PDF viewer may not be able to display this type of document.

You can upgrade to the latest version of Adobe Reader for Windows®, Mac, or Linux® by visiting http://www.adobe.com/go/reader_download.

For more assistance with Adobe Reader visit http://www.adobe.com/go/acrreader.

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Attaching the Human Subjects Study Record in Lite

- Once completed, add the Study Record(s) to the PHS Human Subjects and Clinical Trials form page in Coeus Lite
- Input the description, choose file to upload and click the Add button
Attaching the Human Subjects Study Record in Lite

- Confirm that the attached Study Record has green check marks under PDF and XML.
- Once an attachment is uploaded, you can view the Study Record(s) using the View Form link.
- Note: This form is not able to be printed from the Grants.gov window prior to submission. Use ‘View Form’ in Lite to confirm the information and appearance.
Completing the form in Lite

- Add an Other Requested Information attachment, if needed.
Completing the form in Lite - Yes to Human Subjects & Exempt

Scenario:
- Human Subjects = YES
- Exempt = YES
- Be sure that exemption(s) are listed in the Special Review tab with commas and no spaces
Completing the form in Lite- Yes to Human Subjects & Exempt

Scenario:

- Human Subjects = YES
- Exempt = YES
- Answers from Special Review populate form in Lite
- Add at least one Study Record or Delayed Onset Study record(s)
Coeus Lite Validations

Scenario:

- Human Subjects = NO
- Human specimens and/or data = YES
- No document added
- Upon save, validation reminds you to add an attachment

**Message from coeus-qas.brown.edu:**
Please attach an explanation of why the application does not involve human subjects research under 'Add Documents'.

Please add a document explaining the status and exemption.
Coeus Lite Validations

Scenario:
- Human Subjects = YES
- Exempt = YES or NO
- No Study Record or Delayed Onset Study attachment(s) uploaded
- Upon save, validation reminds you to add attachment(s)
Grants.gov Study Record Validations

Scenario:
- Human Subjects = YES
- Study Record attachment form(s) validates within the form itself
- Click ‘Check Form for Errors’ button to validate
Proposal Submission Validations

In Coeus Premium:

- Final validation before routing for approvals
- If form is missing required data, validation error appears
Final Recommendations
Final Recommendations

- Editing Human Subjects YES/NO Answer(s)
  - Cannot modify Special Review section in Lite when you log into Lite from the Human Subjects Forms link in Premium
    - Proposal is still open in ‘Edit’ mode in Premium. Lite is locked for editing except for the Human Subjects and Clinical Trials form page
  - Recommendation: change your YES/NO answer in Coeus Premium and save record.
Final Recommendations

Copying a previously submitted proposal development record:

- Review the following areas. Be sure to change answer(s) if needed
  - Special Review
  - Yes/No Questions
  - Questionnaire for S2S Grants.gov

- NO Human Subjects and Clinical Trials Form attachments will copy over. You will need to upload new attachments and review answers.
Proposal Hierarchies [Parent/child proposal(s)]

- Remember that:
  - Only the Parent gets connected to Grants.gov
  - Only the Parent will have the link from Premium to Lite to complete the Human Subjects and Clinical Trials form
    - Child proposal(s) will not have the link available. This is functioning correctly.
  - Properly complete the HS/CT form from the Parent proposal only
Final Recommendations

Issues with the Human Subjects Forms link or answers not appearing correctly:

- Be sure that you have connected the PD record to Grants.gov
- Be sure that this form is a required form in your Grants.gov forms package
- Have you completed the Special Review tab correctly
- Try saving and exiting the record, then re-opening the record.
- If it was a copy of a previous record, be sure that you have made all the correct changes first, then save.
Questions?


For further questions regarding this form’s function in Coeus
Contact RAIS@brown.edu