HOW TO MAINTAIN & POPULATE
THE PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM
(HSCT 1.0)
IN KC PROPOSALS
NEW HSCT FORM & NIH APPLICATION PACKAGES

• New PHS Human Subjects and Clinical Trials Information form is a mandatory form in most NIH application packages

• Exceptions
  • Form not included in package
    • Training - T15, T32, T34, T35, T36, T37, D71, U2R, T01, T02, T03, T14, T42, T90, T90/R90, TU2
    • Shared Instrumentation – S10
    • Construction – C06/UC6, G20
    • Resource Awards – X01
  • Form optional
    • Admin Supp Type 3 – research, career dev, fellowship, institutional training (K12 and D43)
    • Type 6* & Type 7** – research, career dev, fellowship
      (*change in organization status, **change of grantee or training institution)
SELECTING THE CORRECT FUNDING ANNOUNCEMENT

• Many activity codes will have **two Parent Announcements**
  
  • one designated as "Clinical Trial Not Allowed"
  
  • another as "Clinical Trial Required"

• Have your PI verify which opportunity to use so you select correctly.
Does the research **prospectively assign** participants to an intervention? 
Yes → Is the research designed to evaluate an effect of the **intervention** on the participants? 
Yes → Is the effect being evaluated a **health-related biomedical or behavioral** outcome? 
Yes → **Study meets the NIH definition of clinical trial.** COUHES reviews research if the following criteria are met.

The research does **not** involve significantly **greater than minimal risk.** 
Yes → MIT has the **appropriate resources** necessary to facilitate the research. 
Yes → **Research required to follow policies and procedures set forth by the COUHES office.**

http://couhes.mit.edu/policies-procedures

**Contact COUHES**
617/253-6787

The study is **NOT** a clinical trial.
Prospectively assigned term refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

Intervention is defined as a manipulation of the subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

Health-related biomedical or behavioral outcome is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects’ biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors and, positive or negative changes to quality of life.

Significantly greater than minimal risk to subjects means that there is a probability of an event that is serious, prolonged and/or permanent occurring as a result of study participation or there is significant uncertainty about the nature or likelihood of adverse events.

Appropriate resources: see website COUHES.MIT.EDU for list of available resources at MIT.
This table indicates NIH target posting/reissue date for parent announcements and identifies the activity codes which will have a "Clinical Trial Required" parent announcement option.

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<thead>
<tr>
<th>Activity Code</th>
<th>Clinical Trial Not Allowed Parent</th>
<th>Clinical Trial Required Parent</th>
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<tr>
<td>T35</td>
<td>PA-18-404</td>
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</tbody>
</table>
In your KC system-to-system proposal:

Adding a Human Subjects Compliance entry checks the “Yes” box for the human subjects questions on both the R&R Other Project Info form and the new PHS HSC Tform.
**COMPLIANCE ENTRIES IN KC PROPOSALS**

Human Subjects = Yes for the KC S2S forms requires adding a human subjects Compliance entry. (Fields added to support the PHS HSCT form requirements.)
The PHS Human Subjects and Clinical Trials Information Form (HSCT form) is present in all NIH funding opportunities. It is required whether or not human subjects are a part of your project. The form consists of a “cover” page that includes an extractable Study Record, places to attach completed Study Record(s), and places where other form-specific narratives attach.

In your KC s2s proposal, this ‘cover’ page is populated from:
- **human subject compliance** detail entries & uploads for ‘yes’ - human subjects are involved
- or **S2S Questionnaire** answer and proposal attachments uploaded for use of specimens or specimen data.

The Study Record is an extractable multi-page form where the study details are defined, attachments added, and enrollment report details entered.
The 3 page Study Record consists of 5 sections, and expands if Inclusion Enrollment Reports are added. Narrative pdf files that previously attached to the Research Plan must now be uploaded to this extracted form before uploading to your KC proposal.
WHEN DO YOU NEED THE FULL STUDY RECORD?

A. No Human Subjects, No Specimens/Specimen Data

B. No Human Subjects, YES Specimens/Specimen Data

C. Yes Human Subjects, YES Delayed Onset, Not Clinical Trial

D. Yes Human Subjects, Not Delayed Onset, Not Clinical Trial (study record required)

E. Yes Human Subjects, Not Delayed Onset, Yes Clinical Trial (study record required)

F. Yes Human Subjects, Yes Delayed Onset, Yes Clinical Trial

G. Multiple Studies

For scenarios D, E and possibly G, using human subjects, a completed PDF Study Record Form is required to complete the Compliance entry in the KC proposal. The Study Record is extracted from the HSCT form, available from Grants.gov. See next slides for download and extraction instructions.
The **Full Study** Record PDF form is part of the PHS Human Studies and Clinical Trials Information form, available for download at Grants.gov

Navigate to the Grants.gov Forms: [https://www.grants.gov/web/grants/forms.html](https://www.grants.gov/web/grants/forms.html)
Locate the **Human Subjects and Clinical Trial Information 1.0** form in the **RR Family** list screen at [Grants.gov](https://grants.gov).

Scroll down the list and click on the **PDF** hyperlink text in the form row to download the form.

Follow the method appropriate to your computer and browser to save the PDF file to your local computer.
Launch **ADOBE READER**, then use Reader to open the HSCT form.

(You can corrupt the file and lose all your work if you use Adobe Pro or Adobe Acrobat, so don’t!)
Researchers must follow the opportunity instructions and NIH policies to complete the study record.

FYI: Narrative uploads that had previously been submitted on the Research Plan have been relocated the study record.

A few tips on narrative attachments:
- NIH requires all uploads be in PDF format.
- PDFs should not be secured, or use special features, as these will error at Grants.gov.
- Each narrative file uploaded must have a unique name. (If not, the submission will error at Grants.gov)
- If you have more than one study record in your proposal, be careful to avoid repeating the file names in another study.

The completed Study Record is uploaded to the KC Proposal > Compliance > Human Subjects details. (Instructions in later slides.) If there are multiple studies, a separate Compliance entry is needed for each study.
KC Proposal instructions for populating the PHS HSCT Form with the following scenarios:

A. **No Human Subjects, No Specimens/Specimen Data**

B. **No Human Subjects, YES Specimens/Specimen Data**
   (S2S Questionnaire & PD Attatchment)

C. **Yes Human Subjects, YES Delayed Onset, Not Clinical Trial**
   (PD Compliance > Human Subjects > DO option checked > Justification PDF in Compliance entry)

D. **Yes Human Subjects, Not Delayed Onset, Not Clinical Trial**
   (PD Compliance > Human Subjects > Full Study extracted Form upload)

E. **Yes Human Subjects, Not Delayed Onset, Yes Clinical Trial**
   (PD Compliance > Human Subjects > CT option checked > Full Study extracted Form upload)

F. **Yes Human Subjects, YES Delayed Onset, Yes Clinical Trial**
   (PD Compliance > Human Subjects > CT option checked > Justification PDF in Compliance entry)

G. **Multiple Studies**
A. **No** HUMAN SUBJECTS AND **No** USE OF SPECIMENS OR SPECIMEN DATA

**In KC:**
If no Human Subjects compliance entry exists in your proposal, then both GG form questions are checked **No**.

**BUT:** the GG S2S questionnaire question regarding the use of specimens and/or data is mandatory.
If the answer is **No** to Specimen/Data question, then the ‘no’ box is checked on the HSCT form, and the related narrative will NOT transmit, even if it is uploaded in your proposal.
**Scenario A: No Human Subjects, No Human Specimens and/or data (cont’d.)**

**To enter in KC**

In your Proposal, navigate to the Questionnaire tab:

In the **Grants.gov S2S Questionnaire**: select ‘No’ for your response to the specimen/data question. This response supplies the answer for the HSCT form.

(Select answers for all the question & save to complete the GG S2S Questionnaire.)
Populated for as maintained for scenario A. NO human subjects, NO specimens/data
To enter in KC

**Step 1:**
Grants.gov S2S Questionnaire: - select ‘yes’ the specimen/data question

**Step 2:**
Proposal Attachments:
- upload the pdf to proposal attachment type: PHS_HumanSubjectsAndCT_InvolveHumanSpecimensExp

B. NO HUMAN SUBJECTS AND YES USE OF SPECIMENS OR SPECIMEN DATA

January 19, 2018

Populating the PHS Human Subjects Clinical Trial (HCT) form
PDF Preview in KC:
KC S2S Opportunity > Forms > print/preview PDF
Form populated for scenario B. NO human subjects, Yes to use of specimens/data, and PD attachment added.
New fields in the KC Compliance Entry window when Human Subjects is selected as the type. The Delayed Onset and Clinical Trial checkboxes are optional, based on your study details. If Delayed Onset is checked, the Study Title field presents, and must be provided. The Human Study Attachment is required for the HSCT form, but the type of upload depends on your study details.
Once added, you can edit your compliance entry.
- Click the trashcan icon to delete.
- Click on the row to expand

Once expanded, all fields are editable.
You can change the Human Study Attachment file with the ‘Replace’ button.
Choose a different file, and then click “Update” to save this change.
Add a Compliance Entry in your KC Proposal:

Select type: Human Subjects

Select the appropriate Approval status of your study

Enter/select the protocol and date information relevant to your study, as appropriate to type.

Delayed Onset option selected

Study Title entered (600 character maximum)

Human Study Attachment field, upload the PDF justification document per sponsor instructions.

Add Entry.
PDF Preview in KC:

KC S2S Opportunity > Forms > print/preview PDF
Form populated for scenario C. Yes human subjects, Yes delayed onset, NO clinical trial.

Following page is the Justification document PDF file.
Add a Compliance Entry in your KC Proposal:
Select **type**: Human Subjects
Select the appropriate **Approval status** of your study
Enter/select the protocol and date information relevant to your study, as appropriate to type.

**Human Study Attachment** field, upload the completed **extracted Study form**.

Add Entry.
PDF Preview in KC:

KC S2S Opportunity > Forms > print/preview PDF

Form populated for scenario D. YES human subjects, No Delayed, No Clinical Trial.

Form preview pages populate from uploaded Study file(s) and attachments.
Add a Compliance Entry in your KC Proposal:
Select type: Human Subjects
Select the appropriate Approval status of your study
Enter/select the protocol and date information relevant to your study, as appropriate to type.

Clinical Trial option checked

Human Study Attachment field, upload the completed extracted Study form.
Add Entry.
PDF Preview in KC:

KC S2S Opportunity > Forms > print/preview PDF

Form populated for scenario E: YES human subjects, No Delayed, YES Clinical Trial.

Form preview pages populate from uploaded Study file(s) and attachments.
Add a Compliance Entry in your KC Proposal:
Select type: Human Subjects
Select the appropriate Approval status of your study
Enter/select the protocol and date information relevant to your study, as appropriate to type.

Clinical Trial option checked
Delayed Onset option checked

Human Study Attachment field, upload the PDF justification document.
Add Entry.
PDF Preview in KC:
KC S2S Opportunity > Forms > print/preview PDF
Form populated for scenario E: YES human subjects, YES Delayed, YES Clinical Trial.

Form preview pages populate from uploaded Study file(s) and attachments.
**G. MULTIPLE STUDIES**

If you need to detail more than one study, and/or study type, you must add a separate Compliance item for each study/upload.

The data from the compliance entries and the attachments will populate in the appropriate sections of the HSCT form.

*Delayed Onset Studies*

<table>
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<tr>
<th>Study Title</th>
<th>Anticipated Clinical Trial?</th>
<th>Justification</th>
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<tbody>
<tr>
<td>Delayed onset study test</td>
<td>No</td>
<td>1 Delayed_Onset_Justif.pdf</td>
</tr>
<tr>
<td>Study2</td>
<td>No</td>
<td>2 Delayed_Onset_study_2.pdf</td>
</tr>
</tbody>
</table>

Unique file names!
OTHER REQUESTED INFORMATION

Only use for information if it is specifically requested in FOA or application guide instructions.

Per NIH, this attachment will most likely ONLY be used for cross-referencing when studies are shared across multiple components in multi-project applications.
In KC: to include the Other Requested Information attachment:

1. Add the human subject compliance entry, with required elements
2. Add your PDF file to Attachments > Proposal > type PHS_HumanSubjectsAndCT_OtherRequestedInfo

Then KC S2S Opportunity > Forms > print/preview PDF populates the HSCT form this way:

(YES human subjects (as maintained) with the Attachment)
FORM TIPS …

• ALWAYS use Adobe Reader with Grants.gov forms & extracted forms!

• Delayed Onset studies usually require a written justification uploaded as a PDF, not the completed extracted Study Form. Follow the instructions in the funding opportunity.

• If you have a Compliance entry for Human Subjects, the Proposal Attachment for specimen data will not be submitted. NIH programmed this form to only transmit the specimen/data attachment if there are NO human subjects.

• Please take care to review the attached documents in the extracted Study Form. They all must be PDF files, and they all must have unique file names. If there are any duplicate file names, the submission will error at Grants.gov and a changed/corrected proposal must be prepared.

Getting Help

For questions or problems using this Quick Reference Card, email the Support Team at RA-Help@mit.edu Include your Name, Contact Information, your Proposal Number, and your question!