PHS STUDY RECORD FORM GUIDE

Minimum requirements for the extracted Human Subjects and Clinical Trial Information Form Study Record.

January 2018
IDENTIFY YOUR STUDY TYPE

• NIH now posts clinical trial specific funding opportunities. If you select a clinical trial required opportunity and do not include a clinical trial study report in your proposal, it will ERROR at eCommons.

• It is imperative to determine if your study meets the NIH definition of a clinical trial so you connect and submit with the correct funding opportunity.

• Use the Decision Tree on the next slide, review the NIH website resources, or contact the MIT COUHES office for help identifying if your project is defined as a Clinical Trial.

For more information and definitions, please refer to the NIH compliance website:
https://grants.nih.gov/policy/clinical-trials.htm
Does the research prospectively assign participants to an intervention? [Yes/No]

Is the research designed to evaluate an effect of the intervention on the participants? [Yes/No]

Is the effect being evaluated a health-related biomedical or behavioral outcome? [Yes/No]

The study is NOT a clinical trial.

**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/No]
- MIT has the appropriate resources necessary to facilitate the research. [Yes/No]

Research required to follow policies and procedures set forth by the COUHES office. [http://couhes.mit.edu/policies-procedures]

Contact COUHES 617/253-6787
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.
• For due dates on or after January 25, 2018, NIH requires that all applications involving one or more clinical trials be submitted through a Funding Opportunity Announcement (FOA) specifically designed for clinical trials.

• **New FOAs will specify allowability of clinical trials in the FOA title**
  - NIH Research Project Grant (Parent R01 - Clinical Trial Not Allowed)
  - Exploratory Clinical Trial Grants in Arthritis and Musculoskeletal and Skin Diseases (R21 - Clinical Trial Allowed)
  - Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Admin Supp - Clinical Trial Optional)
  - Ruth L. Kirschstein National Research Service Award (NRSA) Individual Postdoctoral Fellowship (Parent F32 - No Independent Clinical Trials)

• **All FOAs will specify the allowability of clinical trials in Section II. Award Information**
### Section II. Award Information

<table>
<thead>
<tr>
<th>Funding Instrument</th>
<th>Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity</th>
</tr>
</thead>
</table>
| Application Types Allowed | New  
Renewal  
Resubmission  
Revision  

The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types. |
| Clinical Trial? | Not Allowed: Only accepting applications that do not propose independent clinical trials. |
| Funds Available and Anticipated Number of Awards | The number of awards is contingent upon availability of funds and the submission of meritorious applications. |
CLINICAL TRIALS FOA DESIGNATIONS

- **Fellowship** Funding Opportunity Announcements (FOAs)
  - Not Allowed: Only accepting applications that do not propose independent clinical trials. Note: Applicants may propose to gain experience in a clinical trial led by a sponsor/co-sponsor as part of their research training.

- **Career Development** Funding Opportunity Announcements (FOAs)
  - Required: Only accepting applications that propose independent clinical trial(s)
  - Not Allowed: Only accepting applications that do not propose independent clinical trials Note: Applicants may propose to gain experience in a clinical trial led by a mentor/co-mentor as part of their research career development.

- **All Other FOAs** Funding Opportunity Announcements (FOAs)
  - Not Allowed: Only accepting applications that do not propose clinical trial(s)
  - Required: Only accepting applications that propose clinical trials
  - Optional: Accepting applications that either propose or do not propose clinical trial(s)
The 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?

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.

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

27 QC KC S2S PHS Study Record guide for the PHS HSCT TV1
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
Locate the **Human Subjects and Clinical Trial Information 1.0** form in the **RR Family** list screen at **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!)

You cannot extract the Study Record until you answer “YES” to Human Subject involvement question on the form— the “click here..” button is dimmed. Once ‘Yes’ is checked, the extract option is active.

Click to extract the Human Subject Study PDF file and save it to your computer.

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**PHS Human Subjects and Clinical Trials Information**

**View Burden Statement**

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and are included here for your reference. For changes to these items, contact the PHS HSCT V1 team at [hsctv1@phs.gov](mailto:hsctv1@phs.gov).

**If No to Human Subjects**

- [ ] Yes
- [ ] No

If No, provide an explanation of why the application does not involve human subjects.

- [ ] Yes
- [ ] No

Click to extract the Human Subject Study Record Attachment.

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**Are Human Subjects Involved?**

- [ ] Yes
- [ ] No

**Is the Project Exempt from Federal regulations?**

- [ ] Yes
- [ ] No

**Exemption number:**

- [ ] 1
- [ ] 2
- [ ] 3
- [ ] 4
- [ ] 5
- [ ] 6
- [ ] 7
- [ ] 8

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**If No to Human Subjects**

- [ ] Yes
- [ ] No

**Does the proposed research involve human specimens and/or data?**

- [ ] Yes
- [ ] No

If Yes, provide an explanation of why the application does not involve human subjects research.

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**Other Requested Information**

Add Attachment | Delete Attachment | View Attachment

Skip the rest of the PHS Human Subjects and Clinical Trials Information form.

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**If Yes to Human Subjects**

Add a record for each proposed Human Subject Study by selecting “Add New Study” or “Add New Delayed Onset Study” as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, and are not to be conducted until the designated delay period. For delayed onset studies, you will provide the study name and a justification for omission of human subject study information.

**Other Requested Information**

Add Attachment | Delete Attachment | View Attachment

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**Study Record(s)**

Attach human subject study records using unique filenames.
Always launch **ADOBE READER**, then search to open the Human Subjects Study Record form. (You can corrupt the file and lose all your work if you use Adobe Pro or Adobe Acrobat, so don’t!)

Follow the opportunity instructions and NIH policies to complete 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**.
- The completed Study Record is uploaded to the KC Proposal > Compliance > Human Subjects details.
- If there are multiple studies, a separate Compliance entry is needed for each study.
REMINDER: FILENAME UNIQUENESS

- **Filenames must be unique within an application**
  - Given an application can have multiple study records, do not attach the same filename in different studies! Duplicate file names generate errors at Grants.gov.
  - As noted below, the file content may be the same, but the file NAME must be changed.

<table>
<thead>
<tr>
<th>4.7 Dissemination Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Format:</strong></td>
</tr>
<tr>
<td>Attach this information as a PDF file. See NIH’s <a href="#">Format Attachments</a> page.</td>
</tr>
<tr>
<td><strong>Content:</strong></td>
</tr>
<tr>
<td>For each study within an application, you must include a Dissemination Plan attachment. One Dissemination Plan per application is sufficient. You may attach the same Dissemination Plan to different studies within one application, but each file name must be unique.</td>
</tr>
<tr>
<td>Explain briefly your plan for the dissemination of NIH-funded clinical trial information and address how the</td>
</tr>
</tbody>
</table>
POSSIBLE REQUIRED PDF NARRATIVES

Attachment requirements vary based on FOA, type, and answers in the form.

<table>
<thead>
<tr>
<th>KC or Form</th>
<th>HS</th>
<th>CT</th>
<th>Mandatory or Optional</th>
<th>Description</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>KC</td>
<td>No</td>
<td>No</td>
<td>M</td>
<td>Specimen or Specimen data explanation</td>
<td>KC Proposal Attachments</td>
</tr>
<tr>
<td>KC</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Other Requested Information</td>
<td>KC Proposal Attachments</td>
</tr>
<tr>
<td>KC</td>
<td>Y</td>
<td>-</td>
<td>M</td>
<td>Delayed Onset Justification</td>
<td>KC PD &gt; Compliance Entry Details</td>
</tr>
<tr>
<td>KC</td>
<td>Y</td>
<td>Y</td>
<td>M</td>
<td>Study Title (max. 600 characters) Required for HS, DO, and CT</td>
<td>KC PD &gt; Compliance Entry Details - field</td>
</tr>
<tr>
<td>Form</td>
<td>Y</td>
<td>Y</td>
<td>M</td>
<td>Inclusion of Women, Minorities, and Children</td>
<td>Study Record extracted form, Item 2.4</td>
</tr>
<tr>
<td>Form</td>
<td>Y</td>
<td>Y</td>
<td>M</td>
<td>Recruitment &amp; Retention Plan</td>
<td>Study Record extracted form, Item 2.5</td>
</tr>
<tr>
<td>Form</td>
<td>Y</td>
<td>Y</td>
<td>M</td>
<td>Recruitment Status</td>
<td>Study Record extracted form, Item 2.6</td>
</tr>
<tr>
<td>Form</td>
<td>Y</td>
<td>Y</td>
<td>M</td>
<td>Study Timeline</td>
<td>Study Record extracted form, Item 2.7</td>
</tr>
<tr>
<td>Form</td>
<td>Y</td>
<td>Y</td>
<td>-</td>
<td>Protection of Human Subjects</td>
<td>Study Record extracted form, Item 3.1</td>
</tr>
<tr>
<td>Form</td>
<td>-</td>
<td>Y</td>
<td>M</td>
<td>Single IRB Plan</td>
<td>Study Record extracted form, Item 3.2</td>
</tr>
<tr>
<td>Form</td>
<td>-</td>
<td>Y</td>
<td>M</td>
<td>Data and Safety Monitoring Plan (optional for HS, required for CT)</td>
<td>Study Record extracted form, Item 3.3</td>
</tr>
<tr>
<td>Form</td>
<td>-</td>
<td>Y</td>
<td>O</td>
<td>Overall Structure of Study Team</td>
<td>Study Record extracted form, Item 3.5</td>
</tr>
<tr>
<td>Form</td>
<td>-</td>
<td>Y</td>
<td>M</td>
<td>Statistical Design and Power</td>
<td>Study Record extracted form, Item 4.4</td>
</tr>
<tr>
<td>Form</td>
<td>-</td>
<td>Y</td>
<td>-</td>
<td>Availability of Investigational Product &amp; Investigational New Drug/Device status</td>
<td>Study Record extracted form, Item 4.6.a</td>
</tr>
<tr>
<td>Form</td>
<td>-</td>
<td>Y</td>
<td>M</td>
<td>Dissemination Plan</td>
<td>Study Record extracted form, Item 4.7</td>
</tr>
<tr>
<td>Form</td>
<td>-</td>
<td>Y</td>
<td>O</td>
<td>Other Clinical Trial-related attachments (10 max) (Not allowed for HS)</td>
<td>Study Record extracted form, Item 5.1</td>
</tr>
</tbody>
</table>
A study record is considered a clinical trial if Yes to all Questionnaire questions AND FOA allows clinical trials.

Fields 1.1, 1.2, and 1.4 are required and enforced.

Optional, provide NCT# if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application.
2.1. Conditions or Focus of Study

2.1 required unless study is exemption 4. Up to 20 conditions at 255 characters each.

All Section 2 elements are required unless study is exemption 4 or otherwise noted in FOA.

2.2. Eligibility Criteria

Age limits are required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

If "N/A (No Limit)" selected, do not provide numerical min/max age.

2.3. Age Limits

Minimum Age

Maximum Age

2.4. Inclusion of Women, Minorities, and Children

2.5. Recruitment and Retention Plan

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)
Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource
   - [ ] Yes
   - [ ] No

2. * Enrollment Location Type
   - [ ] Domestic
   - [ ] Foreign

3. Enrollment Country(ies)
   - [ ]

4. Enrollment Location(s)
   - [ ]

5. Comments
   - [ ]

Remove Inclusion Enrollment Report

Answer required

Answer required

Answer required

Up to 500 characters
Planned enrollment required when “Using an Existing Dataset or Resource” = No.

Cumulative enrollment required when “Using an Existing Dataset or Resource” = Yes.
3.1 and 3.2 are required for human subject studies (3.3-3.5 are optional).

All fields in Section 3 are required for clinical trial studies.

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

☐ Yes  ☐ No  ☐ N/A  "N/A" is only a valid option for Exempt 4, fellowship, and career development applications

If yes, describe the single IRB plan

3.3. Data and Safety Monitoring Plan

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

☐ Yes  ☐ No

3.5. Overall Structure of the Study Team
### 4.1. Brief Summary

*Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.*

### 4.2. Study Design

#### 4.2.a. Narrative Study Description

*Up to 32,000 characters*

#### 4.2.b. Primary Purpose

Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; and Device Feasibility

#### 4.2.c. Interventions

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Up to 200 characters</td>
<td>Up to 1,000 characters</td>
</tr>
</tbody>
</table>

Add New Intervention

For each intervention, all fields are required (max 20).

Dropdown list: Drug (including placebo); Device (including sham); Biological/Vaccine; Procedure/Surgery; Radiation; Behavioral (e.g., Psychotherapy, Lifestyle Counseling); Genetic (including gene transfer, stem cell and recombinant DNA); and Dietary Supplement (e.g., vitamins, minerals)

#### 4.2.d. Study Phase

Dropdown list: Early Phase 1 (or Phase 0); Phase 1; Phase 1/2; Phase 2; Phase 2/3; Phase 3; Phase 4; and Other

#### 4.2.e. Intervention Model

Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other.

#### 4.2.f. Masking

- □ Yes
- □ No
- □ Participant
- □ Care Provider
- □ Investigator
- □ Outcomes Assessor

#### 4.2.g. Allocation

Dropdown list: N/A; Randomized; and Non-randomized
4.3. Outcome Measures

- **At least one Outcome Measure required** for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

<table>
<thead>
<tr>
<th>Name</th>
<th>Up to 255 characters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type</td>
<td>Dropdown list: Primary; Secondary, and Other</td>
</tr>
<tr>
<td>Time Frame</td>
<td>Up to 255 characters</td>
</tr>
<tr>
<td>Brief Description</td>
<td>Up to 999 characters</td>
</tr>
</tbody>
</table>

For each outcome measure, all fields are required.

4.4. Statistical Design and Power

- Required unless otherwise noted in opportunity.

4.5. Subject Participation Duration

- Up to 255 characters. Required unless otherwise noted in opportunity.

4.6. Will the study use an FDA-regulated intervention?

- Required unless otherwise noted in opportunity.

4.6a. If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status

- Required if 4.6 = Yes.

4.7. Dissemination Plan

- Required unless otherwise noted in opportunity.
Validations errors at eCommons prevent section 5 attachments for:
- non-CT study records (at least 1 No answer on Clinical Trial Questionnaire)
- Fellowship applications
- Career Dev applications to Clinical Trials Not Allowed FOAs

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Form supports up to 10 attachments.

**Attachments only allowed for CT studies.**
Only include attachments requested in opportunity.