Forms E Changes – Human Subjects and Clinical Trials Information

Research & Related Other Project Information Page

Section 1

Unchanged except for the addition of two new exempt categories. (They are not being used yet so don’t check 7 or 8.)
Answer the human subject questions as usual.

**NOTE:**
Even if you answer NO to the Human Subject involvement question, you will still need to complete the new form ‘PHS Human Subjects and Clinical Trials.’

PHS Human Subjects and Clinical Trials Information Page

The information contained in the box at the top of this form is what was entered into Section 1 of the RR Other Project Information page. These two forms are linked, so if you change data in this box, it will be changed on the other form.

If you answered NO to human subject involvement

Complete the first section ‘If No to Human Subjects.’
“Does the proposed research involved human specimens and/or data?”
If no, then nothing further to do.
If yes, then you need to provide an attachment on why the application does not involve human subjects research. Specific requirements for this justification are listed on page 94 of the new Forms E General Application Instructions.


DONE!

If you answered YES to human subjects’ involvement

You will need to provide at least 1 study record or 1 delayed onset study.

Definition of Delayed Onset Human Subject Study

Human subjects research is anticipated within the period of award but definite plans for this involvement cannot be described in the application.
^ Definition via NIH Glossary of Terms
*Not the same as “delayed start” where work is known up front but not completed in the initial budget period.
*If you have multiple delayed onset studies, you can include them together in a single Delayed Onset Study

Delayed Onset (3 items)

1) study title
a. Note: For multiple delayed onset studies, use “Multiple Delayed Onset Studies” as the title.

2) whether it’s an anticipated clinical trial
3) provide a justification that explains why detailed information can’t be provided at the time of application, assure all policies will be followed such as SIRB and a plan for the dissemination of NIH funded clinical trial info.

Study Record – Sub form of PHS Human Subjects and Clinical Trials Information page

Section 1 - Complete for both Human Subjects Studies and Clinical Trial Studies
1.5 is optional, as you aren’t required to register in ClinicalTrials.gov until 21 days after first participant enrolled.

Forms sections to be completed

<table>
<thead>
<tr>
<th>Form Section</th>
<th>IF you answered “yes” to ALL the questions in the Clinical Trial Questionnaire</th>
<th>If you answered “no” to ANY of the questions in the Clinical Trial Questionnaire</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section 2 – Study Population Characteristics</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Section 3 – Protection and Monitoring Plans</td>
<td>Required</td>
<td>Required</td>
</tr>
<tr>
<td>Section 4 – Protocol Synopsis</td>
<td>Required</td>
<td>Do not complete</td>
</tr>
<tr>
<td>Section 5 – Other Clinical Trial-related Attachments</td>
<td>Required if specified in the FOA</td>
<td>Do not complete</td>
</tr>
</tbody>
</table>

Instructions for completing the study forms sections can be found on the NIH web site.

Other Notable items

Section 2.1 of the Study Record (Conditions or Focus of Study)

At least 1 entry is required and up to 20 may be entered. Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study. If available, use appropriate descriptors from NLM's Medical Subject Headings (MeSH) so the application can be categorized. Include an entry for each condition.
https://www.nlm.nih.gov/mesh/

Section 4.7 of the Study Record (Dissemination Plan) – new –

Use this to describe how you plan to meet NIH’s new policies including the requirement to register and report in ClinicalTrials.gov.

* Good Clinical Practice (GCP) training expires after 3 years, so all those required to complete the basic GCP training course will need to complete a refresher course every 3rd year. - Documentation and training will be collected with other Just in Time (JIT) materials.