NIH Updates: FORMS-E and Single IRB Requirements Effective 1/25/2018

NIH has adopted new Human Subjects research regulations and a revised Application Package (FORMS-E) effective for proposals with due dates on or after 1/25/2018.

Warning: NIH Funding Opportunity Announcements (FOA) have been updated so that they either accept or do not accept proposals for Clinical Trials (see image below). The participating organizations may vary between the "Clinical Trial Not Allowed" Parent FOA and the "Clinical Trial Required" Parent FOA for the same activity code. It is very important to double check the FOA requirements because if the proposal is submitted to the wrong FOA, it can be rejected. Read the details of each FOA carefully.

WHAT DOES THIS MEAN? Principal Investigators must determine early on whether or not their proposal includes a clinical trial under NIH’s new definition to ensure they apply to the correct FOA. If unsure, they must contact the NIH Program Officer to determine if the proposal includes clinical trial.

NIH Research Project Grant (Parent R01 Clinical Trial Required)

NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)

Table for Parent Announcements that identifies the activity codes with the “Clinical Trial Required” option.

Example of FOA with clinical trial required.
**NEW Definition of “Clinical Trial”**

**The information below does not include every detail regarding NIH’s new definition of clinical trials. Please refer to the NIH policy links below for a full description.**

NIH now defines a clinical trial as:

- “A research study in which one or more human subjects are **prospectively assigned** to one or more **interventions** (which may include placebo or other control) to evaluate the effects of those interventions on **health-related biomedical or behavioral outcomes**”
  - **Prospectively assigned**: a pre-defined process (e.g. randomization) by which research participants are assigned to one or more arms (e.g. intervention, placebo, or other control) of a study
  - **Intervention**: a manipulation of the research participant or their environment that modifies their behavior (e.g. use of a wearable device such as a Fitbit, diet or exercise, surgical technique, diary logs)
    - Note: Surveys, interviews, focus groups, and collecting biological samples are not “interventions” if the participants’ biomedical and behavioral status is not monitored or evaluated.
  - **Health-related biomedical or behavioral outcome**: a pre-specified goal or condition that reflects the effect of the intervention(s) on participants’ biomedical or behavioral status or quality of life (e.g. improvement of lung capacity, changes to psychological well being)

- Indicate if the proposal is a clinical trial on the PHS Human Subjects and Clinical Trials Information, Section 1.4 (see picture below)

**Policy:**


**Case Studies** (Examples for determining if a study is a clinical trial)


**New form: PHS Human Subjects and Clinical Trials Information**

- Required for all NIH applications with due dates on or after 1/25/2018.
- Removes human subjects questions from the PHS 398 Research Plan and Cover Page Supplement

**Please note that this form is **required** even if the study does not have human subjects.**
**PHS Human Subjects and Clinical Trials Information**

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 displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the date items you are required to complete on this form.

- **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

**If No to Human Subjects**

- **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.

**Add Attachment**

**Delete Attachment**

**View Attachment**

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

**Study Record: PHS Human Subjects and Clinical Trials Information**

*Always required field*

**Section 1 - Basic Information**

1.1. **Study Title (each study title must be unique)**

1.2. **Is this Study Exempt from Federal Regulations?** □ Yes □ No

1.3. **Exemption Number** □ 1 □ 2 □ 3 □ 4 □ 5 □ 6 □ 7 □ 8

1.4. **Clinical Trial Questionnaire**

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

- 1.4.a. **Does the study involve human participants?** □ Yes □ No
- 1.4.b. **Are the participants prospectively assigned to an intervention?** □ Yes □ No
- 1.4.c. **Is the study designed to evaluate the effect of the intervention on the participants?** □ Yes □ No
- 1.4.d. **Is the effect that will be evaluated a health-related biomedical or behavioral outcome?** □ Yes □ No

1.5. **Provide the ClinicalTrials.gov identifier (e.g., NCT07654321) for this trial, if applicable**
When filling out the form above:

- FOAs with “Clinical Trial Required”, all 4 questions in Section 1.4 “Clinical Trial Questionnaire” must be “Yes”
- FOAs with “Clinical Trial Not Allowed”, the questions in Section 1.4 “Clinical Trial Questionnaire” must not all say “Yes” (“Yes” and “No” OK)
- It is very important to double check these questions because if they are not answered correctly, the proposal can be mislabeled as a clinical trial and be rejected.

**Additional Single IRB (sIRB) Requirement for all Human Subjects Research**

Effective January 25th with the FORMS-E changes above, the NIH will require proposals to delegate one IRB to be responsible for conducting an ethical review of, and coordinating, all human participant research performed at all the locations on a multi-site study (i.e. when UCSB has a subaward or is a subawardee on an NIH proposal). The following exclusions apply:

- The human subjects research must be **non-exempt**
- The **same research protocol** is conducted at more than one domestic site.
- Single sIRB rule **does not apply** to Career Development (K), Research Training (T), or Fellowship (F) mechanisms.

**Responsibilities are divided between sIRB site and participating site as follows:**

- **Reviewing Site**
  - Conducts the IRB review for studies at all sites
- **Participating Site(s)**
  - Reports to the sIRB
  - Meets all IRB requirements for a study at their site
  - May need to include a line on the budget for costs allocated to a sIRB review
  - UCSB prefers to be a participating site.

**Impact on preparing NIH proposals:**

- **Proposal Stage**: If the NIH proposal involves conducting the same research at multiple locations, the proposal must include a **sIRB Plan** which indicates the sIRB, includes sIRB costs, and describes communication between site.
- **Award Stage**: All participating sites must execute an Authorization Agreement and the sIRB Plan will be incorporated into the Notice of Award (NOA) as a term and condition.
Single IRB question is now on **PHS Human Subjects and Clinical Trials Information**: Section 3.2 (see below)

*Screenshot of section of PHS Human Subjects and Clinical Trial Info form pertaining to sIRB.*

<table>
<thead>
<tr>
<th>Section 3 - Protection and Monitoring Plans</th>
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<tbody>
<tr>
<td>3.1. Protection of Human Subjects</td>
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<tr>
<td>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?</td>
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<td>□ Yes □ No □ N/A</td>
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<td>If yes, describe the single IRB plan</td>
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*Screenshot of where to include sIRB costs on the budget: “F. Other Direct Costs” lines 8-10*

<table>
<thead>
<tr>
<th>F. Other Direct Costs</th>
<th>Funds Requested ($)</th>
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<tbody>
<tr>
<td>1. Materials and Supplies</td>
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<td>2. Publication Costs</td>
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<td>3. Consultant Services</td>
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<td>4. ADP/Computer Services</td>
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<td>5. Subawards/Consortium/Contractual Costs</td>
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<td>6. Equipment or Facility Rental/User Fees</td>
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<td>7. Alterations and Renovations</td>
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<td>9.</td>
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<td>10.</td>
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<tr>
<td>Total Other Direct Costs</td>
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<thead>
<tr>
<th>G. Direct Costs</th>
<th>Funds Requested ($)</th>
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<tbody>
<tr>
<td>Total Direct Costs (A thru F)</td>
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