INSTRUCTIONS AND REMINDERS FOR COMPLETING UCLA CTSI'S COLLECTION FORM

FOR STUDIES PROPOSING CLINICAL TRIALS

The UCLA Clinical and Translational Science Institute (CTSI) Grants Submission Unit has created this worksheet to clarify the new human subjects and clinical trial policies—and subsequent changes to the SF424 (Forms Version E or FORMS-E)—for applications on or after January 25, 2018. This worksheet is meant solely to collect required information for the **NIH PHS Human Subjects and Clinical Trials Information Form** for studies that propose ***Clinical Trials***. It is not meant to replace your review of all applicable notices, guidelines, and updates from the NIH related to the specific funding opportunity being responded to. Investigators and research administration staff should continue to refer to NIH's official policies and guidelines available here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf.

This worksheet refers only to those sections of FORMS-E related to human subjects and clinical trials; it does not cover the entirety of the SF424 or other portions of the grant application process.

Investigators should always remember to refer to the specific Funding Opportunity Announcement (FOA) for any submission-specific information, including whether clinical trials are allowed and other FOA-specific requirements that may not be reflected on this form.

Please save this worksheet under a unique name on your hard drive or other HIPAA-compliant storage (e.g., Mednet shared drive). All attachments you upload to the worksheet will be saved automatically as part of the PDF. **These documents should be stored in the same location as your worksheet to ensure you can view your attachments while in the PDF at a later date**. Please ensure documents are closed before uploading to the PDF form.

Please note that this form is intended to collect information on the *study level*. If your application involves more than one proposed study within a single application, please fill out the relevant additional Collection Forms individually for each study.

Questions? Contact the UCLA CTSI Grants Submission Unit at gsu@mednet.ucla.edu or (310) 267-4258.

Clear form

Collection Form for Clinical Trials

Use this form if your study involves a Clinical Trial. If you are unsure if your study constitutes a Clinical Trial, please complete the questionnaire below (Question 1.4).

This interactive PDF form is meant to help researchers and staff collect relevant required information that will be input into the PHS Human Subjects and Clinical Trials Information Form.

Section 1. Basic Information

1.1 Study Title (each study title must be unique) (600 characters max; **first 150 display on official form**):

For additional studies, fill out this form with a unique filename.

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:

1.4.a Does this study involve human subject 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 (Optional) Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable.

If you selected NO to any of these questions, your study is NOT a clinical trial.

GSU is supported by the NIH National Center for Advancing Translational Science (NCATS) through UCLA CTSI grant UL1TR001881 | www.ctsi.ucla.edu

Section 2. Study Population Characteristics

2.1 Conditions or Focus of Study (minimum 1, maximum 20 conditions). Download and fill out form.

Add attachment | View attachments

2.2 Eligibility Criteria (15,000 characters max). Download and fill out form.

Add attachment | View attachments

2.3 Age Limits. Minimum Age: [ ] Years Maximum Age: [ ] Years

2.4 Inclusion of Women, Minorities, and Across the Lifespan. Download and fill out form.

Add attachment | View attachments

2.5 Recruitment and Retention Plan. Download and fill out form. Add attachment | View attachments

2.6 Recruitment Status: Not yet recruiting

2.7 Study Timeline. Download and fill out form. Add attachment | View attachments

2.8 Enrollment of First Subjects (enter date as MM/DD/YYYY). [ ] Anticipated

Inclusion Enrollment Report(s) (up to 20 reports). Download Inclusion (Planned) Enrollment report here and the Cumulative (Actual) Report here.

Add attachment | View attachments

Section 3. Protection and Monitoring Plans

3.1 Protection of Human Subjects. Download and fill out form. Add attachment | View attachments

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 ☐

If YES, describe the single IRB plan. Download and fill out form. Add attachment | View attachments

3.3 Data and Safety Monitoring Plan. Download and fill out form. Add attachment | View attachments

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

Yes ☐ No ☐

3.5 Overall Structure of the Study Team. Download and fill out form. Add attachment | View attachments

Section 4. Protocol Synopsis

4.1 Brief summary (5,000 characters max). Download and fill out form.

Add attachment | View attachments

4.2 Study design

4.2.a Narrative study description (32,000 characters max). Download and fill out form.

Add attachment | View attachments

4.2.b Primary purpose: Treatment

4.2.c Interventions (minimum 1, maximum 20 interventions). Download and fill out form.

Add attachment | View attachments

4.2.d Study phase (see phase definitions here): Early Phase 1 (or Phase 0)

If OTHER, provide a description in the space provided below (255 characters max):

Is this an NIH-defined Phase III clinical trial?

Yes ☐ No ☐

4.2.e Intervention model: Single Group

4.2.f Masking?

Yes ☐ No ☐

If YES, check all that apply (minimum 1 required if YES):

Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor ☐

4.2.g Allocation: N/A

4.3 Outcome measures (minimum 1, maximum 50 outcomes). Download and fill out form.

Add attachment | View attachments

4.4 Statistical Design and Power. Download and fill out form.

Add attachment | View attachments

4.5 Subject Participation Duration (255 characters max):

Section 4 (continued)

4.6 Will the study use an FDA-regulated intervention? Yes ☐ No ☐

4.6.a. If YES, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) Status. Download and fill out form.

Add attachment | View attachments

4.7 Dissemination Plan. Only one plan per application is allowed; this is true even if this project has multiple studies and/or interventions. Download and fill out form.

Add attachment | View attachments

Section 5. Other Clinical Trial Attachments

5.1 Other Clinical Trial-related Attachments (only if required by FOA, up to 10 allowed). If there are more than 10 attachments, combine remaining attachments into a single PDF and upload as 10th attachment together.

Add attachment | View attachments