Outline of NIH Human Subjects Section

*Full instructions are in the* [*SF424*](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.3)*, including additional instructions for career development and fellowship applications*

**Contents:**

[Section 1 – Basic Information.](#_SECTION_1_-)  Required for all studies.

[Section 2 – Study Population Characteristics.](#_SECTION_2_–) Required for all studies, unless using Exemption 4 only.

[Section 3 – Protection and Monitoring Plans.](#_SECTION_3_–) Sections 3.1 and 3.2 are required for all studies.

[Section 4 – Protocol Synopsis.](#_SECTION_4_–) For clinical trials only.

[Section 5 – Other Clinical Trial Related Attachments.](#_SECTION_5_–) Use only if specified in the FOA.

# SECTION 1 - BASIC INFORMATION

**Required for all studies.**

* 1. **Study Title**

*Use a unique title for each study. Maximum 600 characters.*

* 1. [**Exempt from Federal Regulations**](https://humansubjects.nih.gov/from-applicants#exemptions)**?**

*Answer Yes or No*

* 1. **Exemption Number**

*If not exempt, select “N/A.” If exempt provide the exemption number.*

*If using Exemption 4 and no other exemptions, Section 2 is not required.*

* 1. **Clinical Trial Questionnaire**

*Answer Yes or No for each. If all answers are yes, the study is considered a* [*clinical trial*](https://grants.nih.gov/grants/glossary.htm#ClinicalTrial)*.*

1. Human participants?
2. Prospectively assigned to an intervention?
3. Designed to evaluate the effect of the intervention?
4. Health-related biomedical or behavioral outcome?

**1.5 ClinicalTrials.gov identifier**

*Answer “N/A” if the study does not have a clinicaltrials.gov ID*

*Ancillary studies should use the ID for the ancillary study, not the parent study*

# SECTION 2 – STUDY POPULATION CHARACTERISTICS

**Section 2 is required for all studies, except those using Exemption 4 and no other exemptions.**

**2.1 Conditions or focus of study**

*Provide 1-20 key words, using* [*MeSH terms*](https://www.nlm.nih.gov/mesh/) *when available*

* 1. **Eligibility Criteria**

*Enter inclusion/exclusion criteria. Maximum 15,000 characters.*

*For bulleted lists, use a hyphen-space (“- “) at the start of each line, as follows*

Inclusion Criteria

* Inclusion 1
* Inclusion 2
* Etc

Exclusion Criteria

* Exclusion 1
* Exclusion 2
	1. **Age Limits**

*List the Minimum and Maximum age. If there is no limit, enter “N/A (No Limit)”.*

* 1. **Inclusion of women, minorities & children**

*Attach as a PDF.* [*Download instructions and sample*](http://octsi.ouhsc.edu/sites/default/files/2_4%20Human%20Subj%20Women%20Minorities%20Children.docx)*.*

* 1. **Recruitment & Retention Plan**

*Attach as a PDF. Describe how you will recruit and retain participants in your study. You should address both planned recruitment activities as well as proposed engagement strategies for retention.*

[*Download sample.*](http://octsi.ouhsc.edu/sites/default/files/2_5%20Human%20Subj%20Recruitment%20Retention.docx)

* 1. **Recruitment Status**

*Choose one:*

* not yet recruiting
* recruiting
* enrolling by invitation
* active not recruiting
* completed
* suspended
* terminated (halted prematurely)
* withdrawn (no participants enrolled)
	1. **Study Timeline**

*Attach as a PDF.* [*Download instructions and sample*](http://octsi.ouhsc.edu/sites/default/files/2_7%20Human%20Subj%20Clinical%20Trial%20Study%20Timeline.docx)*.*

* 1. **Enrollment date of first subject**

*Provide the date.*

**Is the provided date actual or anticipated?**

**Provide Inclusion Enrollment Report** (IER)

*Required unless using only Exemption 4.*

*Maximum of 20 IERs per study record; can be a combination of planned and cumulative.*

*Do not include an IER in a Revision application if there are no updates to the IER(s) in the original grant application. Instead, provide a comment in this field that previous IER(s) are still applicable. If you are revising the IER(s) in your original grant application, provide a comment here to that effect. See* FAQs on Monitoring Inclusion.

1. **Using an** [**existing dataset**](https://grants.nih.gov/grants/glossary.htm#Existingdataset) **or resource?**

*Answer Yes or No*

*.*

1. **Enrollment Location Type**

*Select “US (Domestic)” or “non-US (Foreign)”*

*Use separate IERs for U.S. and non-U.S. sites. Multiple U.S. sites can be reported together in one IER. Foreign countries can be reported together in one IER.*

1. **Enrollment Country**
2. **Comments:** *OPTIONAL to provide additional information about the IER*

# SECTION 3 – PROTECTION AND MONITORING PLANS

**Sections 3.1 and 3.2 are required for all studies. Others are required for clinical trials.**

**3.1 Protection of Human Subjects**

*Attach as a PDF.* [*Download instructions and sample*](http://octsi.ouhsc.edu/sites/default/files/3_1%20Human%20Subj%20Protection.docx)*.*

**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?**

*Answer Yes or No.*

*Select N/A only if (a) the study is exempt, or (b) you are a career development, training, or fellowship applicant.*

**If yes, describe the single IRB plan.**

*Attach as a PDF.* [*Download instructions and sample*](http://octsi.ouhsc.edu/sites/default/files/3_2%20Human%20Subj%20sIRB.docx)*.*

* 1. **Data Safety Monitoring Plan**

*Required for clinical trials. Optional for other studies, unless otherwise specified in the application.*

*Attach as a PDF.* [*Download instructions and sample*](http://octsi.ouhsc.edu/sites/default/files/3_3%20Human%20Subj%20DSMP.docx)*.*

* 1. **Will a Data and Safety Monitoring Board by appointed for this study?**

*For clinical trials, answer Yes.*

*Optional for other studies.*

* 1. **Overall Structure of the Study Team**

*Required for clinical trials. Optional for other studies, unless otherwise specified in the application.*

*Attach as a PDF.* [*Download sample*](http://octsi.ouhsc.edu/sites/default/files/3_5%20Human%20Subj%20Study%20Team.docx)*.*

# SECTION 4 – PROTOCOL SYNOPSIS

**Section 4 is required for clinical trials. All other studies must skip Section 4.**

**4.1 Brief Summary**

*Maximum 5,000 characters. Enter a brief description of objectives of the protocol, including the primary and secondary endpoints*. *This can come from the study protocol or research strategy.*

**4.2 Study Design**

*See definitions and descriptions for Sections 4.2a – 4.2g in the* [*ClinicalTrials.gov Protocol Registration Data Element Definitions*](https://prsinfo.clinicaltrials.gov/definitions.html#StudyDesign)

**4.2a Narrative Study Description**

*Maximum 32,000 characters.*

*Enter a narrative description of the protocol. This can come from the study protocol or research strategy. Describe your plans for assignment of participants and delivery of interventions. You will also need to show that your methods for sample size and data analysis are appropriate given those plans. For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the* [*Research Methods Resources*](https://researchmethodsresources.nih.gov/) *webpage.*

**4.2b Primary Purpose**

*Choose one:*

* Treatment
* Prevention
* Diagnostics
* Supportive Care
* Screening
* Health Services Research
* Basic Science
* Device Feasibility
* Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

**4.2c. Interventions**

*Complete this section for each intervention to be used in your proposed protocol. List each intervention separately, even if multiple interventions are to be used for a single arm of the study (e.g., drug plus educational intervention). You can add up to 20 interventions.*

**Type (Choose one):**

* 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)
* Dietary Supplement (e.g., vitamins, minerals)
* [Combination Product](https://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm)
* Diagnostic Test
* Other

**Name:** *Enter a unique name for each intervention. Maximum 200 characters.*

**Description:** *Maximum 1,000 characters*

**4.2d Study Phase (Choose one):**

* Early Phase 1 (or Phase 0)
* Phase 1
* Phase 1/2
* Phase 2
* Phase 2/3
* Phase 3
* Phase 4
* Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

**Is this an NIH-defined Phase III clinical trial?** Yes/No

**4.2e Intervention Model (Choose one):**

* Single Group
* Parallel
* Cross-Over
* Factorial
* Sequential
* Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

**4.2f Masking.** Yes/No

**If yes, select one or more types of masking/blinding to be used:**

* Participant
* Care Provider
* Investigator
* Outcomes Assessor

**4.2g Allocation (Choose one):**

* N/A
* Randomized
* Non-randomized

**4.3 Outcome Measures**

*Complete the "Outcome Measures" fields for each primary, secondary, and other important measures to be collected during your proposed clinical trial. You may have more than one primary outcome measure, and you can add up to 50 outcome measures.*

**Name:** *Enter a unique name for each individual outcome measure*

**Type (Choose one):**

* Primary - select this option for the outcome measures specified in your protocol that are of greatest importance to your study
* Secondary - select this option for outcome measures specified in your protocol that are of lesser importance to your study than your primary outcomes
* Other - select this option for additional key outcome measures used to evaluate the intervention.

**Time Frame:** *Indicate when a measure will be collected for analysis (e.g., baseline, post-treatment)*

**Brief Description:** *Describe the metric used to characterize the outcome measure if the metric is not already included in the outcome measure name. Maximum 999 characters.*

**4.4 Statistical Design and Power**

*Upload as a separate attachment.* [*Download sample*](http://octsi.ouhsc.edu/sites/default/files/4_4%20Hum%20Subj%20Stat%20Design.docx)*.*

*Specify the number of expected subjects, the expected effect size, the power, and the statistical methods for each outcome measure 4.3 Outcome Measures. The sample size and analysis methods should be appropriate given the interventions and assignment of participants. Trials that randomize groups or deliver interventions to groups require* [*special methods*](https://researchmethodsresources.nih.gov/)*.*

**4.5 Subject Participation Duration**

*Maximum 255 characters*. *Enter the time (e.g., in months) it will take for each individual participant to complete all study visits. If the participation duration is unknown or not applicable, write "unknown" or "not applicable."*

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

**Select “**Yes” or “No”

*See the definition of "FDA Regulated Intervention" under the* [*Oversight*](https://prsinfo.clinicaltrials.gov/definitions.html#oversight) *section of the* [*ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies*](https://prsinfo.clinicaltrials.gov/definitions.html) *page*

**If yes, describe the availability of Investigational Product and IND/IDE status**:

*Attach as a PDF.*

*Recommended length is 3,000 characters.*

*Describe the availability of study agents and support for acquiring and administering the study agent(s).*

*If applicable, indicate the IND/IDE status of the study agent, including whether the study is exempt from the IND/IDE requirement. Also indicate whether the investigators have had any interactions with the FDA (e.g., if the FDA has stated that research may proceed). Provide the IND/IDE number, if there is one.*

*Do not include the IND/IDE application, manufacturer's product specifications, study protocol, or protocol amendments in this attachment.*

*Check the FOA for additional requirements.*

**4.7 Dissemination Plan**

*Attach as a PDF.* [*Download instructions and sample*](http://octsi.ouhsc.edu/sites/default/files/4_7%20Hum%20Subj%20Dissemination.docx)*.*

# SECTION 5 – OTHER CLINICAL TRIAL RELATED ATTACHMENTS

**Complete this section only if your FOA specifically requests it.**

*Include only attachments requested in the FOA, and use requested file names. If a specific file name is not given in the FOA, use a meaningful file name since it will become a bookmark in the assembled application image.*

Date: 03/18/19

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