MICHIGAN STATE UNIVERSITY

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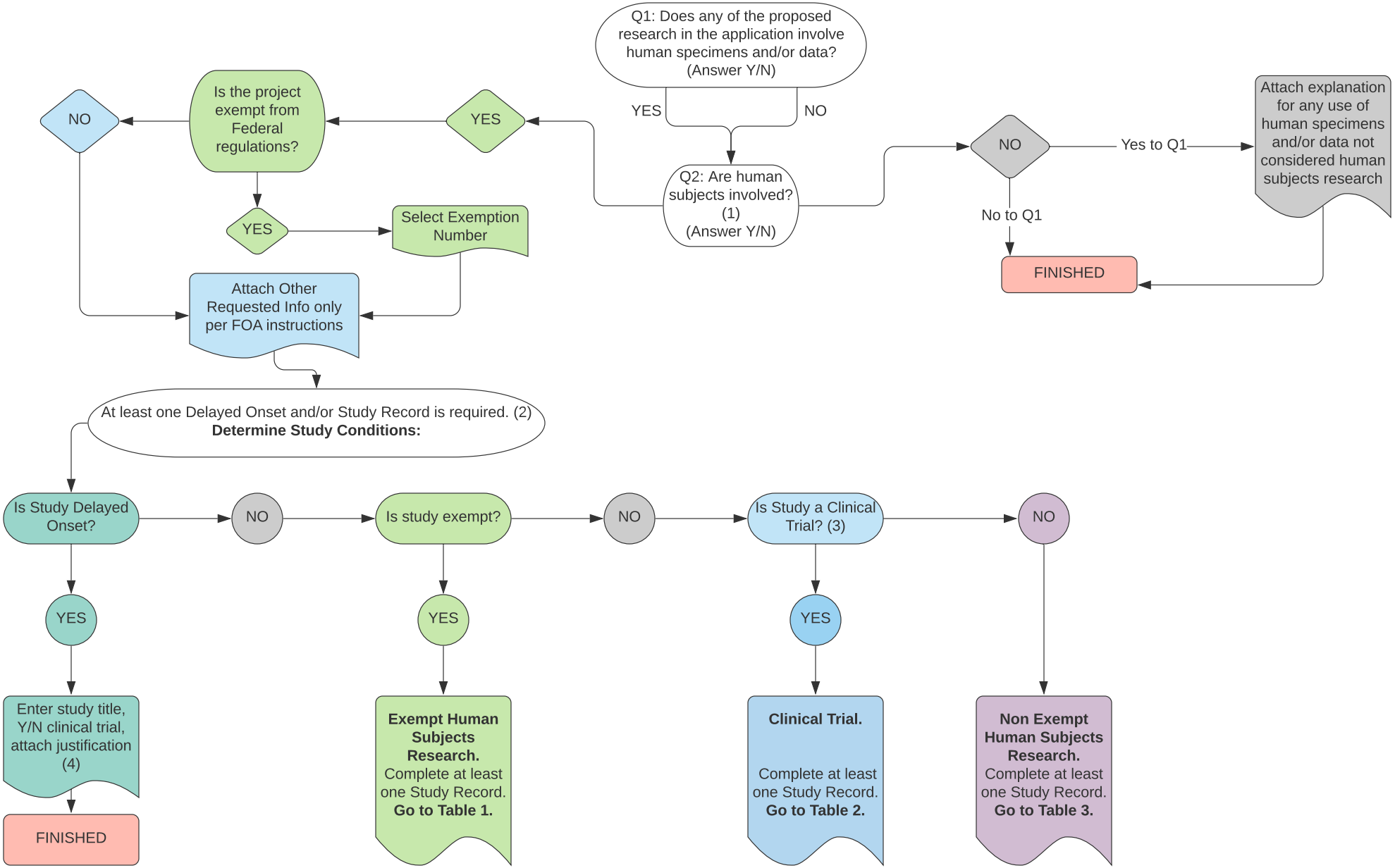
PHS Human Subjects and Clinical Trials Information
R-Series - Forms F



(1) Response to "Are Human Subjects Involved?" must match the response on the R&R Other Project Information.
(2) A proposal may include both Delayed Onsets and Study Records. Complete the appropriate sections for each portion of the project.
(3) See NIH definition of a clinical trial: https://grants.nih.gov/policy/clinical-trials/definition.htm
(4) Multiple delayed onset studies may be combined in a single delayed onset record.
These guidelines are generally applicable to R-series proposals. Please refer to the FOA for specific instructions. See also the NIH Application Guide Section G.500 for details on this form.

Study Record
Table 1

Exempt Human Subjects Research

Section 1 - Basic Information	**Required**	
1.1 Study Title	Required	
1.2 Exempt?	YES	
1.3 Exemption Number	Required	→ Should match selection on PHS Human Subjects and Clinical Trials Information form
1.4 Clinical Trial Questionnaire	At least one question NO	→ 1.4.a "Does the sudy involve human participants?" defaults to Yes and is not editable
1.5 ClinicalTrials.gov Identifier		

	Exemption Number (1.3 above)		
	E4[1] ONLY	**All other Exemptions[2]**	
		YES	
Section 2 - Study Population Characteristics	**Not Required**	**Required**	
2.1 Conditions or Focus of Study		Required	→ Up to 20 conditions, limited to 255 characters each
2.2 Eligibility Criteria		Required	→ Use dash+space for bulleted list
2.3 Age Limits		Required	
2.3.a. Inclusion of Individuals Across the Lifespan		Required	
2.4 Inclusion of Women and Minorities		Required	
2.5 Recruitmen and Retention Plan		Required	
2.6 Recruiment Status		Required	
2.7 Study Timeline		Required	
2.8 Enrollment of First Participant		Required	
2.9 Inclusion Enrollment Report(s)	**Not Required**	**Required**	→ Up to 20 reports can be added per study record
1. Inclusion Enrollment Report Title		Required	
2. Existing Dataset or Resource?		Required	
3. Enrollment Location Type		Required	
4. Enrollment Country(ies)		Optional	→ Autopopulates to USA for domestic
5. Enrollment Location(s)		Optional	→Type of location, not name
6. Comments		Optional	
Planned Table		Required if **NOT** using an existing dataset or resource	
Cumulative (Actual) Table		Required if using an existing dataset or resource	
Section 3 - Protection and Monitoring Plans	**Required**	**Required**	
3.1 Protection of Human Subjects	Required	Required	
3.2 Multi-site study?	Required	Required	→ Choose "N/A" for exempt
IRB Plan			
3.3 Data and Safety Monitoring Plan	Optional	Optional	
3.4 Data and Safety Monitoring Board?	Optional	Optional	
3.5 Overall Structure of Team	Optional	Optional	

Study Record
Table 1

Section 4 - Protocol Synopsis	**Do not complete**	**Do not complete**
Section 5 - Other Clinical Trial-related Attachments	**Do not complete**	**Do not complete**
	↓	↓
	Finished. Attach to PHS Human Subjects and Clinical Trials Information form.	Finished. Attach to PHS Human Subjects and Clinical Trials Information form.

[1]Exemption 4 ONLY

[2]Any exemption other than E4 only, or any combination of exemptions including E4.

Guidelines are generally applicable to NIH R-series proposals; please refer to the FOA for specific instructions.
Refer to the NIH Application Guide Section G.500 (link above) for details and content requirements:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

Study Record
Table 2

Clinical Trial

Section 1 - Basic Information	**Required**	
1.1 Study Title	Required	
1.2 Exempt?	NO	
1.3 Exemption Number		
1.4 Clinical Trial Questionnaire	All questions YES	→ 1.4.a "Does the sudy involve human participants?" defaults to Yes and is not editable
1.5 ClinicalTrials.gov Identifier	Optional	
Section 2 - Study Population Characteristics	**Required**	
2.1 Conditions or Focus of Study	Required	→ Up to 20 conditions, limited to 255 characters each
2.2 Eligibility Criteria	Required	→ Use dash+space for bulleted list
2.3 Age Limits	Required	
2.3.a. Inclusion of Individuals Across the Lifespan	Required	
2.4 Inclusion of Women and Minorities	Required	
2.5 Recruitmen and Retention Plan	Required	
2.6 Recruiment Status	Required	
2.7 Study Timeline	Required	
2.8 Enrollment of First Participant	Required	
2.9 Inclusion Enrollment Report(s)	**Required**	→ Up to 20 reports can be added per study record
1. Inclusion Enrollment Report Title	Required	
2. Existing Dataset or Resource?	Required	
3. Enrollment Location Type	Required	
4. Enrollment Country(ies)	Optional	→ Autopopulates to USA for domestic
5. Enrollment Location(s)	Optional	→Type of location, not name
6. Comments	Optional	
Planned Table	Required if **NOT** using an existing dataset or resource	
Cumulative (Actual) Table	Required if using an existing dataset or resource	
Section 3 - Protection and Monitoring Plans	**Required**	
3.1 Protection of Human Subjects	Required	
3.2 Multi-site study?	Required	→ If YES, contact IRB office to develop sIRB Plan (irb@ora.msu.edu)
IRB Plan	Not Required if NIH	→ If AHRQ and 3.2 is YES, attach IRB Plan (for NIH, plan will be required at JIT stage)
3.3 Data and Safety Monitoring Plan	Optional	
3.4 Data and Safety Monitoring Board?	Optional	
3.5 Overall Structure of Team	Optional	

Study Record
Table 2

Section 4 - Protocol Synopsis	Required	
4.1.a Detail Description	Required	→ Up to 32,000 characters
4.1.b Primary Purpose	Required	
4.1.c Interventions	Required	→ Up to 20 interventions allowed
4.1.d Study Phase	Required	→ Select Y/N NIH Phase III
4.1.e Intervention Model	Required	
4.1.f Masking	Required	→ aka Blinding; if Yes, select type(s)
4.1.g Allocation	Required	
4.2 Outcome Measures	Required	→ At least 1, up to 50 allowed
4.3 Statistical Design and Power	Required	
4.4 Subject Participation Duration	Required	
4.5 FDA-regulated intervention?	Required	→ If yes, 4.5.a explanation required
4.6 Applicable clinical trial under FDAAA?	Required	
4.7 Dissemination Plan	Required	→ Same can be used for multiple studies; filename must be unique for each study record
Section 5 - Other Clinical Trial-related Attachments	**Only include per FOA**	

↓

Finished.
Attach to PHS Human Subjects and Clinical Trials Information form.

Guidelines are generally applicable to NIH R-series proposals; please refer to the FOA for specific instructions.
Refer to the NIH Application Guide Section G.500 (link above) for details and content requirements:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

Study Record
Table 3

Non-Exempt Human Subejcts Research

Section 1 - Basic Information	**Required**	
1.1 Study Title	Required	
1.2 Exempt?	NO	
1.3 Exemption Number		
1.4 Clinical Trial Questionnaire	At least one question NO	→ 1.4.a "Does the sudy involve human participants?" defaults to Yes and is not editable
1.5 ClinicalTrials.gov Identifier		
Section 2 - Study Population Characteristics	**Required**	
2.1 Conditions or Focus of Study	Required	→ Up to 20 conditions, limited to 255 characters each
2.2 Eligibility Criteria	Required	→ Use dash+space for bulleted list
2.3 Age Limits	Required	
2.3.a. Inclusion of Individuals Across the Lifespan	Required	
2.4 Inclusion of Women and Minorities	Required	
2.5 Recruitmen and Retention Plan	Required	
2.6 Recruiment Status	Required	
2.7 Study Timeline	Optional	
2.8 Enrollment of First Participant	Required	
2.9 Inclusion Enrollment Report(s)	**Required**	→ Up to 20 reports can be added per study record
1. Inclusion Enrollment Report Title	Required	
2. Existing Dataset or Resource?	Required	
3. Enrollment Location Type	Required	
4. Enrollment Country(ies)	Optional	→ Autopopulates to USA for domestic
5. Enrollment Location(s)	Optional	→Type of location, not name
6. Comments	Optional	
Planned Table	Required if **NOT** using an existing dataset or resource	
Cumulative (Actual) Table	Required if using an existing dataset or resource	
Section 3 - Protection and Monitoring Plans	**Required**	
3.1 Protection of Human Subjects	Required	
3.2 Multi-site study?	Required	→ If YES, contact IRB office to develop sIRB Plan (irb@ora.msu.edu)
IRB Plan	Not Required if NIH	→ If AHRQ and 3.2 is YES, attach IRB Plan (for NIH, plan will be required at JIT stage)
3.3 Data and Safety Monitoring Plan	Optional	
3.4 Data and Safety Monitoring Board?	Optional	
3.5 Overall Structure of Team	Optional	
Section 4 - Protocol Synopsis	**Do not complete**	
Section 5 - Other Clinical Trial-related Attachments	**Do not complete**	

↓

Finished.
Attach to PHS Human Subjects and Clinical Trials Information form.

Guidelines are generally applicable to NIH R-series proposals; please refer to the FOA for specific instructions.
Refer to the NIH Application Guide Section G.500 (link above) for details and content requirements:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

Complete human subjects section of R&R Other Project Information form prior to completing this form.

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 02/28/2023

Use of Human Specimens and/or Data

* Does any of the proposed research in the application involve human specimens and/or data? ☐ Yes ☐ No

Answer required for all applications.

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Only include attachment if proposed research uses human specimens and/or data not considered to be human subjects research.

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 data 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

Information populated from R&R Other Project Information form.

If No to Human Subjects

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

If Yes to Human Subjects

Steps for adding a study record will vary based on submission method used (ASSIST, system-to-system solution, Grants.gov Workspace).

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, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide a study name and justification for omission of human subject study information.

Other Requested Information

Only provide an Other Requested Information attachment when specifically requested in the funding opportunity announcement text or application guide.

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

1) Please attach Human Subject Study 1 | Add Attachment | Delete Attachment | View Attachment

Delayed Onset Study(ies)

Cannot add a Delayed Onset Study if you answer No to human subjects question on R&R Other Project Information form.

Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). Multiple delayed onset studies can be grouped in a single record.

	Study Title	Anticipated Clinical Trial?	Justification
		☐	Add Attachment | Delete Attachment | View Attachment

Required and system enforced for each delayed onset study. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

If Anticipated Clinical Trial box is checked, funding opportunity announcement must allow clinical trials. When multiple studies are included in the same delayed onset record, select Yes if it is anticipated that any study will be a clinical trial.

Required and system enforced for each delayed onset study. In addition to justification, must include information regarding how the study will comply with the NIH single Institutional Review Board (sIRB) policy prior to initiating any multi-site study, as well as, a plan for the dissemination of NIH-funded clinical trial information.

Cannot add a Study Record if you answer No to Human Subjects question on R&R Other Project Information form.

HS = Human Subjects
CT = Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 02/28/2023

* Always required field

Section 1 - Basic Information

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

Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

1.2. * Is this Study Exempt from Federal Regulations? ☐ Yes ☐ No ← Answer required and system enforced.

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

If Study Exempt is Yes, must provide exemption number. Exemption must also be selected on Other Project Information form.

1.4. * Clinical Trial Questionnaire ← Answers to questionnaire required and system enforced.

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

1.4.a defaults to Yes and is not editable.

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

If four questions are all Yes AND FOA allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.*

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Optional. Provide NCT# for this study, if available. Newly proposed studies do not need to be entered in ClinicalTrials.gov at time of application. If building on an existing study, enter NCT# for ancillary study (if available), not the parent study.

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Required and system enforced unless exemption 4 is only exemption selected. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria

Required and system enforced unless exemption 4 is only exemption selected or otherwise noted in opportunity.

Required and system enforced unless exemption 4 is only exemption selected or otherwise noted in opportunity.

2.3. Age Limits **Minimum Age** [ ] [ ] **Maximum Age** [ ] [ ]

Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

Dropdown list: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

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

2.3.a. Inclusion of Individuals Across the Lifespan Required and system enforced unless exemption 4 is only exemption selected. Attachment | View Attachment

2.4. Inclusion of Women and Minorities Required and system enforced unless exemption 4 is only exemption selected. Attachment

2.5. Recruitment and Retention Plan Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in opportunity. Attachment

2.6. Recruitment Status Required and system enforced unless exemption 4 is the only exemption selected or otherwise noted in opportunity.

2.7. Study Timeline Required and system enforced for CT study unless 4 is the only exemption selected or otherwise noted in opportunity. Attachment | View Attachment

2.8. Enrollment of First Participant [ ] [ ]

Date: MM/DD/YYYY.

Dropdown list: Anticipated, Actual

Enrollment of First Participant field is required and system enforced unless exemption 4 is only exemption selected or using existing dataset.

2.9. Inclusion Enrollment Report(s)

Inclusion Enrollment Reports required and system enforced unless exemption 4 is only exemption selected or otherwise noted in opportunity.

Add Inclusion Enrollment Report

Up to 20 Inclusion Enrollment Reports can be added.

* Fellowship (F) and Career Development (K) applications to FOAs that do not allow clinical trials cannot propose independent clinical trial studies led by applicant PD/PI. However, proposing studies under the leadership of a sponsor/mentor that allows for clinical trials research experience is encouraged. Answering Yes to all four Clinical Trial Questionnaire questions will not flag the study as a clinical trial. These studies must include HS information, but will receive a system error if information is included in study fields in sections 4 or 5 of form.

Inclusion Enrollment Report

1. * Inclusion Enrollment Report Title

Required. Up to 600 characters.

2. * Using an Existing Dataset or Resource ☐ Yes ☐ No — Answer required and system enforced.

3. * Enrollment Location Type ☐ Domestic ☐ Foreign — Answer required and system enforced. Do not mix domestic and foreign enrollment data on the same inclusion enrollment report.

4. Enrollment Country(ies)

Multi-select from list of countries.

5. Enrollment Location(s)

6. Comments

Up to 500 characters.

Planned

Planned enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is No. System enforcement relaxed if Comment is provided.

Racial Categories	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		**Total**
	Female	**Male**	**Female**	**Male**	
American Indian/ Alaska Native	0	0	0	0	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	0	0	0	0	0
White	0	0	0	0	0
More than One Race	0	0	0	0	0
Total	0	0	0	0	0

Cumulative (Actual)

Cumulative (Actual) enrollment information is required and system enforced when answer to "Using an Existing Dataset or Resource" question is Yes. System enforcement relaxed if Comment is provided.

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			**Total**
	Female	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	**Female**	**Male**	**Unknown/ Not Reported**	
American Indian/ Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Report 1 of 1

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects — Required and system enforced. | Add Attachment | Delete Attachment | View Attachment

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 — Answer required and system enforced. "N/A" is only a valid option if study is not exempt from federal regulations (i.e., Question 1.2 is No).

If yes, describe the single IRB plan — NIH: If Yes, not required. AHRQ: If Yes, required. | Add Attachment | Delete Attachment | View Attachment

3.3. Data and Safety Monitoring Plan — Required and system enforced for CT study. Optional for HS study. | Add Attachment | Delete Attachment | View Attachment

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

☐ Yes ☐ No — Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

3.5. Overall Structure of the Study Team — Optional. | Add Attachment | Delete Attachment | View Attachment

Section 4 - Protocol Synopsis — You are not allowed to complete fields in Section 4 (i.e., will receive system error) if FOA does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Study Design

4.1.a. Detailed Description

Up to 32,000 characters.

4.1.b. Primary Purpose — Dropdown list: Treatment; Prevention; Diagnostics; Supportive Care; Screening; Health Services Research; Basic Science; Device Feasibility; and Other

4.1.c. Interventions — Up to 20 Interventions allowed.

Intervention Type	
Name	Up to 200 characters.
Description	Up to 1,000 characters.

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)

4.1.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 N/A

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

4.1.e. Intervention Model — Dropdown list: Single Group; Parallel; Cross-Over; Factorial; Sequential; and Other

4.1.f. Masking ☐ Yes ☐ No

☐ Participant ☐ Care Provider ☐ Investigator ☐ Outcomes Assessor

If Masking is Yes, you must select at least 1 of the Participant/Care Provider/Investigator/ Outcomes Assessor check boxes.

4.1.g. Allocation — Dropdown list: N/A; Randomized; and Non-randomized

4.2. Outcome Measures At least one Outcome Measure required and system enforced for CT studies unless otherwise noted in opportunity. Up to 50 Outcome Measures allowed.

Name	Up to 255 characters.
Type	Dropdown list: Primary; Secondary; and Other
Time Frame	Up to 255 characters.
Brief Description	Up to 999 characters.

4.3. Statistical Design and Power ☐ Required and system enforced for CT study unless otherwise noted in opportunity. Attachment | Delete Attachment | View Attachment

4.4. Subject Participation Duration Up to 255 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.5. Will the study use an FDA-regulated intervention? ☐ Yes ☐ No Answer required and system enforced for CT study unless otherwise noted in opportunity.

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

☐ Required and system enforced if Yes. Add Attachment | Delete Attachment | View Attachment

4.6. Is this an applicable clinical trial under FDAAA? ☐ Yes ☐ No

4.7. Dissemination Plan ☐ Required and system enforced for CT study. Generally one Dissemination Plan per application is sufficient. Can attach same plan (unique filenames) in multiple studies.

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments Add Attachments | Delete Attachments | View Attachments

Form supports up to 10 attachments. Attachments only allowed for CT studies. Only include attachments requested in opportunity.