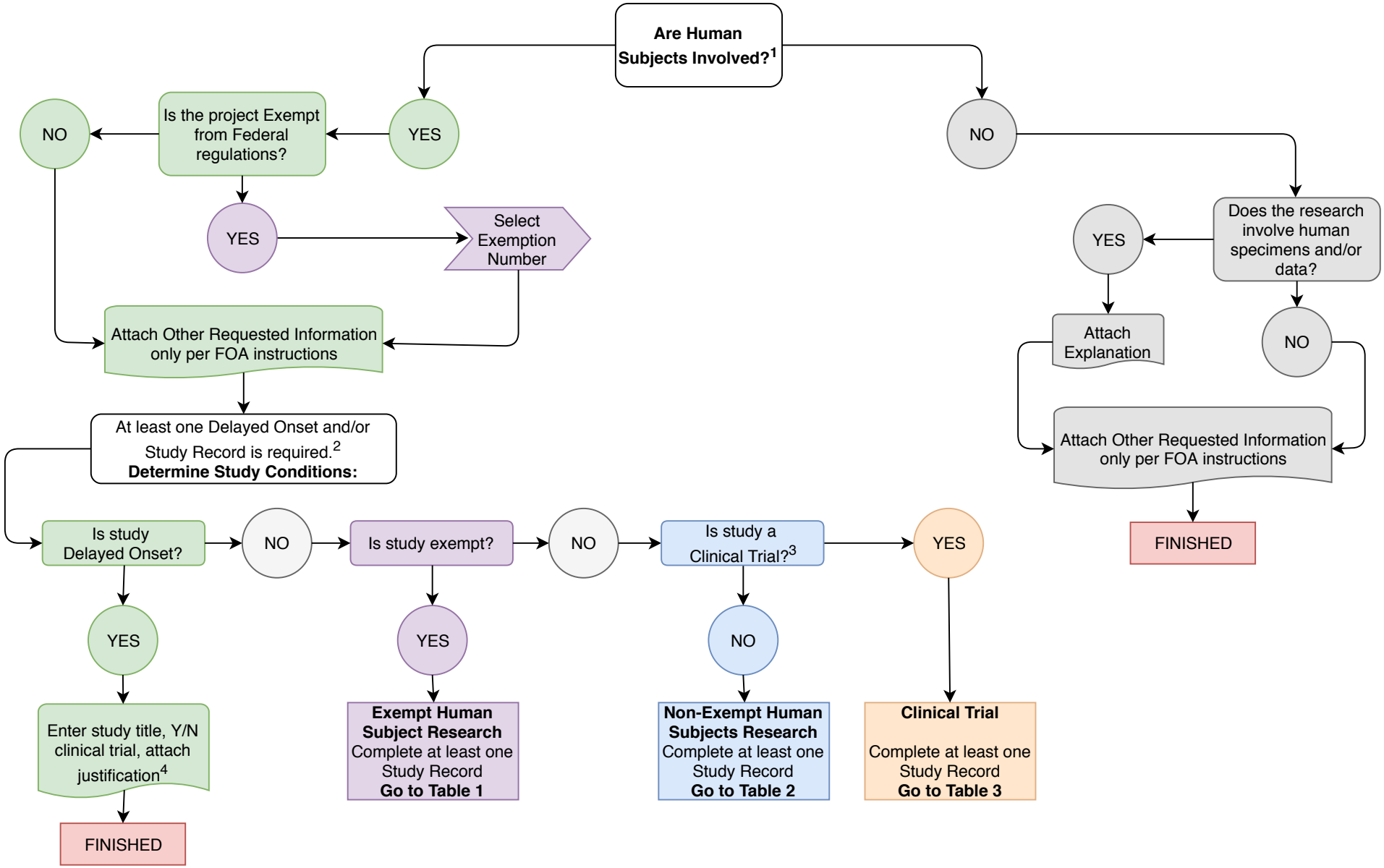
MICHIGAN STATE UNIVERSITY

Created By Theresa Couch, Last Updated 3/21/2019

PHS Human Subjects and Clinical Trials Information Form
R Series



[1] Response to "Are Human Subjects Involved?" must match the response on the R&R Other Project Information form.

[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 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 NIH R-series proposals. Please refer to the FOA for specific instructions.

Please refer to the NIH Application Guide Section G.500 for details on this form: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

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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 Study Involve Human Participants?" should be answered YES
1.5 ClinicalTrials.gov Identifier		

	Expemption Number (1.3 above)		
	E4 ONLY[1]	**All other Exemptions[2]**	
		YES	
Section 2 Study Population Characteristics	**Not Required**	**Required**	
2.1 Conditions or Focus of Study		Required	→ Up to 20 Entries
2.2 Eligibility Criteria		Required	→ Use dash+space for bulleted list
2.3 Age Limits		Required	
2.4 Inclusion of Women, Minorities & Children		Required	
2.5 Recruitment and Retention Plan		Required	
2.6 Recruitment Status		Required	
2.7 Study Timeline		Required	
2.8 Enrollment of First Subject		Required	
Inclusion Enrollment Report	**Not Required**	**Required**	→ Up to 20 reports per study record
1. Existing Dataset or Resource?		Required	
2. Enrollment Location Type		Required	
3. Enrollment Countries		Optional	→ Autopoulates USA for domestic
4. Enrollment Locations		Optional	→ Type of location, not name
5. Comments		Optional	
Planned Table		Required if not using an existing dataset or resource	
Cumulative Table		Required if using existing dataset or resource	
Section 3 Protection and Monitoring Plans	**Required**	**Required**	
3.1 Protection of Human Subjects	Required	Required	
3.2 Multisite Study?	Required	Required	→ Select "N/A" for Exempt Studies
IRB Plan			
3.3 Data Safety Monitoring Plan	Optional	Optional	
3.4 DSM Board?	Optional	Optional	
3.5 Overall Structure of the Study Team	Optional	Optional	

Section 4 Protocol Synopsis	**Do Not Complete**	**Do Not Complete**
Section 5 Other Clincial 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.

These guidelines are generally applicable to NIH R-series proposals. Please refer to the FOA for specific instructions.

Please refer to the NIH Application Guide Section G.500 for details and content requirements:

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

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Study Record
TABLE 2

Non-Exempt Human Subjects 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 Study Involve Human Participants?" should be answered YES
1.5 ClinicalTrials.gov Identifier		
Section 2 Study Population Characteristics	**Required**	
2.1 Conditions or Focus of Study	Required	→ Up to 20 Entries
2.2 Eligibility Criteria	Required	→ Use dash+space for bulleted list
2.3 Age Limits	Required	
2.4 Inclusion of Women, Minorities & Children	Required	
2.5 Recruitment and Retention Plan	Required	
2.6 Recruitment Status	Required	
2.7 Study Timeline	Required	
2.8 Enrollment of First Subject	Required	
Inclusion Enrollment Report	**Required**	→ Up to 20 reports per study record
1. Existing Dataset or Resource?	Required	
2. Enrollment Location Type	Required	
3. Enrollment Countries	Optional	→ Autopoulates USA for domestic
4. Enrollment Locations	Optional	→ Type of location, not name
5. Comments	Optional	
Planned Table	Required if not using an existing dataset or resource	
Cumulative Table	Required if using existing dataset or resource	
Section 3 Protection and Monitoring Plans	**Required**	
3.1 Protection of Human Subjects	Required	
3.2 Multisite Study?	Required	→ If YES, contact IRB office to develop sIRB Plan (irb@ora.msu.edu)
IRB Plan	Required if 3.2 = YES	
3.3 Data Safety Monitoring Plan	Optional	
3.4 DSM Board?	Optional	
3.5 Overall Structure of the Study 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.

These guidelines are generally applicable to NIH R-series proposals. Please refer to the FOA for specific instructions.
Please refer to the NIH Application Guide Section G.500 for details and content requirements:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm

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Study Record
TABLE 3

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	
1.5 ClinicalTrials.gov Identifier	Optional	
Section 2 Study Population Characteristics	**Required**	
2.1 Conditions or Focus of Study	Required	→ Up to 20 Entries
2.2 Eligibility Criteria	Required	→ Use dash+space for bulleted list
2.3 Age Limits	Required	
2.4 Inclusion of Women, Minorities & Children	Required	
2.5 Recruitment and Retention Plan	Required	
2.6 Recruitment Status	Required	
2.7 Study Timeline	Required	
2.8 Enrollment of First Subject	Required	
Inclusion Enrollment Report	**Required**	→ Up to 20 reports per study record
1. Existing Dataset or Resource?	Required	
2. Enrollment Location Type	Required	
3. Enrollment Countries	Optional	→ Autopoulates USA for domestic
4. Enrollment Locations	Optional	→ Type of location, not name
5. Comments	Optional	
Planned Table	Required if not using an existing dataset or resource	
Cumulative Table	Required if using existing dataset or resource	
Section 3 Protection and Monitoring Plans	**Required**	
3.1 Protection of Human Subjects	Required	
3.2 Multisite Study?	Required	→ If YES, contact IRB office to develop sIRB Plan
IRB Plan	Required if 3.2 = YES	(irb@ora.msu.edu)
3.3 Data Safety Monitoring Plan	Required	
3.4 DSM Board?	Required	
3.5 Overall Structure of the Study Team	Required	

Section 4 Protocol Synopsis	Required	
4.1 Brief Summary	Required	
4.2 Study Design		
4.2.a. Narrative Study Description	Required	
4.2.b. Primary Purpose	Required	
4.2.c Interventions	Required	→ Up to 20 interventions
4.2.d Study Phase	Required	→ Select Y/N NIH Phase III
4.2.e. Intervention Model	Required	
4.2.f. Masking	Required	→ aka Blinding, if YES select type(s)
4.2.g. Allocation	Required	
4.3 Outcome Measures	Required	→ At least 1 required; up to 50
4.4 Statistical Design and Power	Required	
4.5 Subject Participation Duration	Required	
4.6 Will the study use FDA-regulated intervention?	Required	→ If YES, provide attachment
4.7 Dissemination Plan	Required	→ File name must be unique to the proposal if more than one study record is included
Section 5 Other Clinical Trial-related Attachments	**Only include per FOA**	

↓

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

These guidelines are generally applicable to NIH R-series proposals. Please refer to the FOA for specific instructions.
Please refer to the NIH Application Guide Section G.500 for details and content requirements:
https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/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: 03/31/2020

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

Answer required and system enforced when human subjects is No.

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.

Required if Yes to human specimens/data question.

Add Attachment | Delete Attachment | View Attachment

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

When human subjects is No, applicants answer a single question, provide associated attachment (as applicable), and are done with the form unless instructed in announcement to include Other Requested Information attachment.

If Yes to Human Subjects

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 the study name and a justification for omission of human subjects study information.

Other Requested Information

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

Add Attachment | Delete Attachment | View Attachment

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: 03/31/2020

* 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. Exemptions 7 and 8 can be used for due dates on/after January 25, 2019.

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. 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 study is exemption 4. Up to 20 conditions at 255 characters each.

2.2. Eligibility Criteria

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

Age limits are required and system enforced unless study is exemption 4 or otherwise noted in opportunity.

2.3. Age Limits **Minimum Age** Dropdown: Years, Months **Maximum Age** Dropdown: Years, Months, Weeks, Days, Hours, Minutes, N/A (No limit)

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

2.4. Inclusion of Women, Minorities, and Children Required and system enforced unless study is exemption 4.

2.5. Recruitment and Retention Plan Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

2.6. Recruitment Status Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity. Dropdown: Not yet recruiting, Recruiting, Enrolling by invitation, Active, not recruiting, Completed, Suspended, Terminated (Halted Prematurely), Withdrawn (No Participants Enrolled)

2.7. Study Timeline Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

2.8. Enrollment of First Subject Date: MM/DD/YYYY. Dropdown: Anticipated, Actual

Required and system enforced unless study is exemption 4, 1.4.a=No, or otherwise noted in opportunity.

Inclusion Enrollment Report(s)

Inclusion Enrollment Reports required and system enforced unless study is exemption 4 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. * Using an Existing Dataset or Resource ☐ Yes ☐ No — Answer required and system enforced.

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

3. Enrollment Country(ies)

Multi-select from list of countries.

4. Enrollment Location(s)

5. 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 for fellowship, and career development applications OR if study is exempt from federal regulations (i.e., Question 1.2a is Yes).

If yes, describe the single IRB plan — Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies. 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. Brief Summary

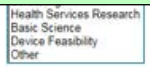
Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

4.2. Study Design — All Study Design fields (4.2.a thru 4.2.g) are required and system enforced for CT studies unless otherwise noted in opportunity.

4.2.a. Narrative Study Description

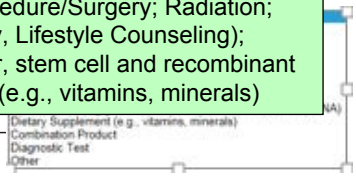
Up to 32,000 characters.

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

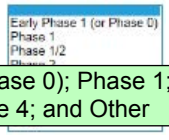


4.2.c. Interventions — Up to 20 Interventions allowed.

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



4.2.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 Other



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

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

4.2.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.

4.2.g. Allocation

Dropdown list: N/A; Randomized; and Non-randomized

N/A
Randomized
Non-randomized

4.3. 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	Primary / Secondary / Other — Dropdown list: Primary; Secondary; and Other
Time Frame	Up to 255 characters.
Brief Description	Up to 999 characters.

4.4. Statistical Design and Power

Required and system enforced for CT study unless otherwise noted in opportunity.

dd Attachment | Delete Attachment | View Attachment

4.5. Subject Participation Duration

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

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

Answer required and system enforced for CT study unless otherwise noted in opportunity.

4.6.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

4.7. 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.

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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.