

# Human Samples, Human Subjects, Human Data... OH MY!

Navigating the new NIH Human Subjects and  
Clinical Trials section



**SIU** MEDICINE  
FORWARD. FOR YOU.

# GOALS OF TODAY'S PRESENTATION



- Understand what category your research falls into (Human Subjects, Human Data, Clinical Trials, etc.)
- Understand the nuances of the new 'Human Subjects and Clinical Trial' tab, so you don't underestimate the time that is needed
  - New information, but most was previously required in various components of applications
- NIH online resources



# NIH Human Subjects and Clinical Trials Section

## WHO DOES THIS APPLY TO?



# WHO DOES THIS APPLY TO?



## Everyone!

- Tissue samples
- Blood samples
- Surveys, evaluations, etc.
- Anything that came from a live human being
  
- Doesn't pertain to you? Using animals only?  
You still have to answer 'no'!



# WHAT IF I'M ONLY USING ANIMALS?

- You will still need to answer a few questions to complete your application

Summary R&R Cover Cover Page **Other Project Information** Sites Sr/Key Person Profile R&R Budget Research Plan Human Subjects and Clinical Trials Assignment Request Form

**Research & Related Other Project Information** OMB Num Expiration D

R&R OtherProjectInfo v1.4 ?

Edit \* Requi

1. \* Are Human Subjects Involved  Yes  No

1.a If YES to Human Subjects

Is the project exempt from Federal regulations?  Yes  No

If yes, check the appropriate exemption number.  1  2  3  4  5  6  7  8

If no, is the IRB review Pending?  Yes  No

IRB Approval Date

Human Subjects Assurance Number

2. \* Are Vertebrate Animals Used?  Yes  No

2.a If YES to Vertebrate Animals

Is the IACUC review Pending?  Yes  No

# WHAT IF I'M ONLY USING ANIMALS?



## Application Information

Summary R&R Cover Cover Page Supplement Other Project Information Sites Sr/Key Person Profile R&R Budget Research Plan **Human Subjects and Clinical Trials** 

### PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001 and 0925-0002

Expiration Date: 03/31/2020

### PHS Human Subjects and Clinical Trials Information v1.0

Edit

**View Burden Statement**

\* Required field(s)

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

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

Other Requested

Add Attachment

Delete Attachment

View Attachment

# FILLING OUT YOUR APPLICATION



# OTHER PROJECT INFO TAB



Summary R&R Cover Cover Page Supplement **Other Project Information** Sites Sr/Key Person Profile R&R Budget Research Plan Human Subjects and Clinical Trials Assignment Request Form

**Research & Related Other Project Information** OMB Number: 4040-0001  
R&R OtherProjectInfo v1.4 ? Expiration Date: 10/31/2019

Edit \* Required field(s)

1. \* Are Human Subjects Involved  Yes  No

1.a If YES to Human Subjects  
Is the project exempt from Federal regulations?  Yes  No

If yes, check the appropriate exemption number.  
 1  2  3  4  5  6  7  8

If no, is the IRB review Pending?  Yes  No

IRB Approval Date

Human Subjects Assurance Number

2. \* Are Vertebrate Animals Used?  Yes  No

2.a If YES to Vertebrate Animals  
Is the IACUC review Pending?  Yes  No

IACUC Approval Date

Animal Welfare Assurance Number

3. \* Is proprietary/privileged information included in the application?  Yes  No

4.a. \* Does this project have an actual or potential impact - positive or negative - on the environment?  Yes  No

4.b. If yes, please explain:

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an exemption been authorized or an exemption been authorized (FA)?  Yes  No



# WHAT DOES NIH SAY?



Human subjects research is research involving:

- A living individual
- About whom an investigator (whether professional or student) conducting research obtains:
  - Data through intervention or interaction with the individual, or
  - Identifiable private information

NIH Human Subjects webpage:

<https://humansubjects.nih.gov/>

SCRIHS: 545-7602

Grants and Contracts: 545-8034



# ARE HUMAN SUBJECTS INVOLVED?



- NIH provides a short survey to determine which forms you should fill out
- Only 4 questions!

NIH Questionnaire:

<https://humansubjects.nih.gov/questionnaire>



# HUMAN SUBJECTS AND CLINICAL TRIALS



Summary R&R Cover Cover Page Supplement Other Project Information Sites Sr/Key Person Profile R&R Budget Research Plan **Human Subjects and Clinical Trials** Assessment Form

### PHS Human Subjects and Clinical Trials Information

PHS Human Subjects and Clinical Trials Information v1.0 ?

OMB Number: 0925-0001 and 0925-0002  
Expiration Date: 03/31/2020

Edit View Burden Statement \* Required field(s)

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

**If Yes to Human Subjects**  
Add a record for each proposed Human Subject Study by selecting 'Add New Study'.  
In some cases a study cannot have defined plans for human subject involvement per agency policies on Delayed Onset Studies. In these cases, select 'Add New Delayed Onset Study' to provide the study name and justification for omission of human subjects study information.

Other Requested Information  Add Attachment Delete Attachment View Attachment

**Study Record(s)**  
Attach human subject study records using unique filenames.

Add New Study Download Study Upload Study

Entry #	Study Title	Clinical Trial?	Action
Nothing found to display.			

# PROJECT EXEMPT VS. STUDY RECORD EXEMPT



- 1 non-exempt study record will make the entire project non-exempt
- The project is only exempt if all study records are exempt



# STUDY RECORDS



# STUDY RECORDS



Think of Study Records as..

- Specific Aims, or
- The “mini” projects within your grant, or
- The different processes by which you are obtaining data



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# **Section 1: Basic Information**

# SECTION 1: BASIC INFORMATION



Summary R&R Cover Cover Page Supplement Other Project Information Sites Sr/Key Person Profile R&R Budget Research Plan **Human Subjects and Clinical Trials** Assessment

Human Subjects Summary > Study Record: 1

### PHS Human Subjects and Clinical Trials Information - Study Record 1

PHS Human Subjects and Clinical Trials Information v1.0 ?

Edit  Ex

#### 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., NCT87654321) for this trial, if applicable  
Click the Populate button to retrieve data from ClinicalTrials.gov registration once Identifier is entered.





# EXEMPTIONS

- Exempt human subjects research meets the definition of human subjects research but meets the criteria of one of the following six exempt study designs.
- Friendly Reminder: Investigators involved in research considered exempt must still meet the Human Subjects education requirement (CITI Training)

# EXEMPTIONS 1-6



- **Exemption 1** - Research conducted in an educational setting involving normal educational practice.
- **Exemption 2** - Research using educational tests, survey procedures; interviews; or observations of public behavior, unless subjects are identifiable and disclosure could place them at risk. This exemption for parts involving educational tests is applicable to children. However, this exemption for parts involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.
- **Exemption 3** - Research using educational tests, survey procedures; interviews; or observations of public behavior, if the subjects are public officials or candidates for public office or federal law requires that confidentiality be maintained. **Not typically used in NIH research projects.**
- **Exemption 4** - Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens; if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified. Since 2008 guidance from OHRP, E4 is seldom applicable; most research with existing data or specimens is either non-exempt human subjects research (code 30) or not human subjects research (code 10).
- **Exemption 5** - Research and demonstration projects that evaluate public benefit or service programs. **Not typically applicable to NIH research projects.**
- **Exemption 6** - Research that evaluates taste and food quality; or consumer acceptance of foods. **Not typically applicable to NIH research projects.**



# RELEVANT EXEMPTIONS TO HUMAN SUBJECTS RESEARCH (NIH GRANTS)

- Exemption 1
  - Research conducted in an educational setting involving normal educational practice
- Exemption 2
  - Research involving observation of public behavior when the investigator(s) do not participate in the activities being observed
- Exemption 4
  - Human subjects and samples that cannot be identified

# 1.4: CLINICAL TRIAL QUESTIONNAIRE

Asks basic information to determine whether or not you have a clinical trial

Summary R&R Cover Cover Page Supplement Other Project Information Sites Sr/Key Person Profile R&R Budget Research Plan **Human Subjects and Clinical Trials** Assignment Request Form

Human Subjects Summary > Study Record: 1

**PHS Human Subjects and Clinical Trials Information - Study Record 1** OMB Number: 0925-0001 a Expiration Date

PHS Human Subjects and Clinical Trials Information v1.0 ?

Edit  Expand All \* Require

**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., NCT87654321) for this trial, if applicable  
Click the Populate button to retrieve data from ClinicalTrials.gov registration once Identifier is entered.



# IS THIS CONSIDERED A CLINICAL TRIAL?



1. Does the study involve human participants? Yes/No
2. Are the participants prospectively assigned to an intervention? Yes/No
3. Is the study designed to evaluate the effect of the intervention on the participant? Yes/No
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Yes/No



# IS THIS CONSIDERED A CLINICAL TRIAL?



If you answered **YES to ALL** of the previous questions, this study would meet the definition of a **clinical trial**.

Form Section	If you answered YES to ANY of the previous questions:
Section 2-Study Population Characteristics	Required
Section 3-Protection and Monitoring Plans	Required
Section 4-Protocol Synopsis	Required
Section 5-Other Clinical Trial-related Attachments	Required if specified in FOA



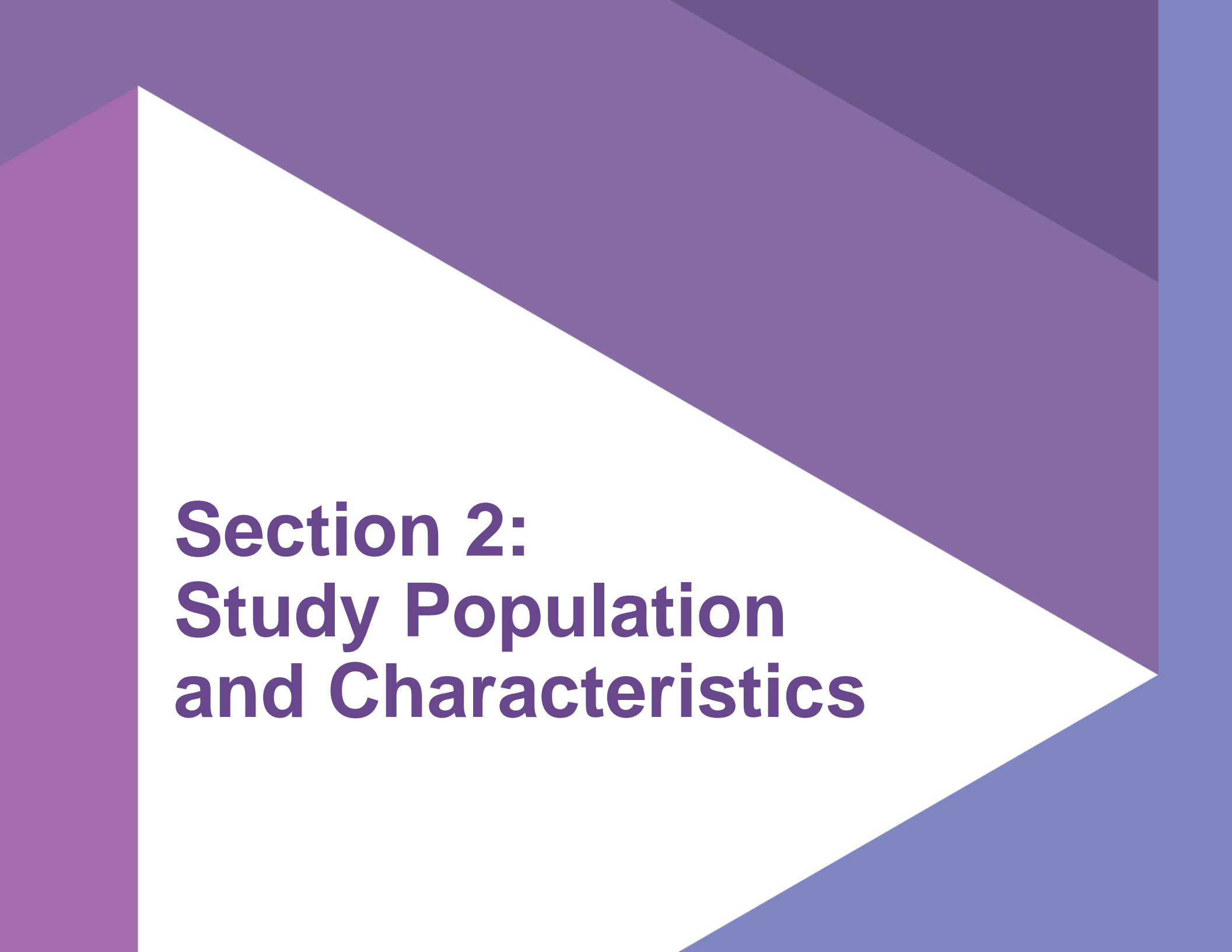
# IS THIS CONSIDERED A CLINICAL TRIAL?



If you answered **NO to ANY** of the previous questions, this study would **NOT** meet the definition of **a clinical trial**.

Form Section	If you answered NO to ANY of the previous questions:
Section 2-Study Population Characteristics	Required
Section 3-Protection and Monitoring Plans	Required
Section 4-Protocol Synopsis	Do not complete
Section 5-Other Clinical Trial-related Attachments	Do not complete



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# **Section 2: Study Population and Characteristics**



# SECTION 2: STUDY POPULATION CHARACTERISTICS



## SECTION 2 - STUDY POPULATION CHARACTERISTICS

### 2.1. Conditions or Focus of Study

Action

Breast Neoplasms

Delete

Add New Condition

### 2.2. Eligibility Criteria

List the study's inclusion and exclusion criteria. Your text is limited to 15, 000 characters. For more information about formatting text entry fields, see NIH's Rules for Text Fields page.

Characters Remaining: 14811

### 2.3. Age Limits

Minimum Age

18

Years

Maximum Age

N/A (No limit)

### 2.4. Inclusion of Women, Minorities, and Children

Add Attachment

Delete Attachment

View Attachment

### 2.5. Recruitment and Retention Plan

Add Attachment

Delete Attachment

View Attachment

### 2.6. Recruitment Status

Not yet recruiting

### 2.7. Study Timeline

Add Attachment

Delete Attachment

View Attachment

### 2.8. Enrollment of First Subject

08/01/2018



Anticipated

## 2.1: CONDITIONS OR FOCUS OF STUDY

- Identify the name(s) of the disease(s)/condition(s) that you are studying
- Use NLM's Medical Subject Headings (MeSH)
  - <https://meshb.nlm.nih.gov/search>

2.1. Conditions or Focus of Study	Action
Breast Neoplasms	Delete
<a href="#">Add New Condition</a>	

## 2.2-2.3: STUDY POPULATION CHARACTERISTICS

### 2.2. Eligibility Criteria

- Use the text box to list the study's inclusion and exclusion criteria

2.2. Eligibility Criteria

List the study's inclusion and exclusion criteria. Your text is limited to 15,000 characters. For more information about formatting text entry fields, see NIH's Rules for Text Fields page.

Characters Remaining: 14811

### 2.3 Age Limits

- Enter the numerical value for the minimum and maximum age
- Provide the relevant units of time

2.3. Age Limits

Minimum Age

Maximum Age

Characters Remaining: 14811

## 2.4: INCLUSION OF WOMEN, MINORITIES, AND CHILDREN



- Women and Minority Requirements
  - Distribution of subjects by sex/gender, race, ethnicity
  - The rationale for selection
  - Proposed outreach programs for recruitment
  - Provide a reason for any inclusion or exclusion of any group



## 2.4: INCLUSION OF WOMEN, MINORITIES, AND CHILDREN



- Children
  - Rationale for inclusion or exclusion of children
  - Expertise of the investigative team to work with children
  - The facilities to accommodate children
  - How children can contribute to a meaningful analysis relative to the purpose of the study



## 2.5: RECRUITMENT AND RETENTION PLAN



- Describe how you will recruit and retain participants
- Address planned recruitment strategies
- Address proposed engagement strategies for retention
  - NIH Policy and Guidelines on the Inclusion of Children



# CCR RECRUITMENT STRATEGIES

- Press Release
- All School Email
- Clinic Room Flyer
- Staff Areas
- Presentations
- Brochures/Posters
- Letter to Current Patients
- Letter to EHR List
- SIU Community Outreach
- Health Fair
- Lunch and Learns
- Recruitment Events

Contact CCR Director for additional assistance:  
Dr. Joe Milbrandt: [jmilbrandt@siumed.edu](mailto:jmilbrandt@siumed.edu)

## 2.6: RECRUITMENT STATUS



Drop down menu options that best describes the proposed study:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Completed
- Suspended
- Terminated (Halted Prematurely)
- Withdrawn (No Participants Enrolled)

2.6. Recruitment Status	Not yet recruiting ▼
----------------------------	----------------------





## 2.7-2.8: TIMELINE AND ENROLLMENT




### 2.7 Study Timeline

- Can be a description or a diagram
- Do not include specific dates
  - Instead list as 1 year after award, month 1, etc.

### 2.8 Enrollment of First Subject

- Specific date
- Choose 'Actual' or 'Anticipated' from drop down

2.8. Enrollment of First Subject	08/01/2018		Anticipated ▼
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# INCLUSION ENROLLMENT REPORTS



The last requirement of Section 2 is the 'Inclusion Enrollment Report'

Inclusion Enrollment Report(s)

[Add New Inclusion Enrollment Report](#)



Entry #	Enrollment Location Type	Enrollment Location	Action
1	Domestic	Indicate the TYPE of location. Example: Clinic, Hospital, etc.	<a href="#">Edit</a> <a href="#">View</a>



# INCLUSION ENROLLMENT REPORTS



## Inclusion Enrollment Report 1

### PHS Human Subjects and Clinical Trials Information ?

Edit

\* 1. Using an Existing Dataset or Resource

Yes  No

\* 2. Enrollment Location Type

Domestic  Foreign

3. Enrollment Country(ies)

UNITED STATES OF AMERICA

4. Enrollment Location(s)

Indicate the TYPE of location.  
Example: Clinic, Hospital, etc.

Characters Remaining: 191

5. Comments

Optional: Information about distinctive subpopulations, if relevant  
If monitoring is conducted on another study or NIH grant

Special requirements for Revision Applications

Characters Remaining: 325



# INCLUSION ENROLLMENT REPORTS

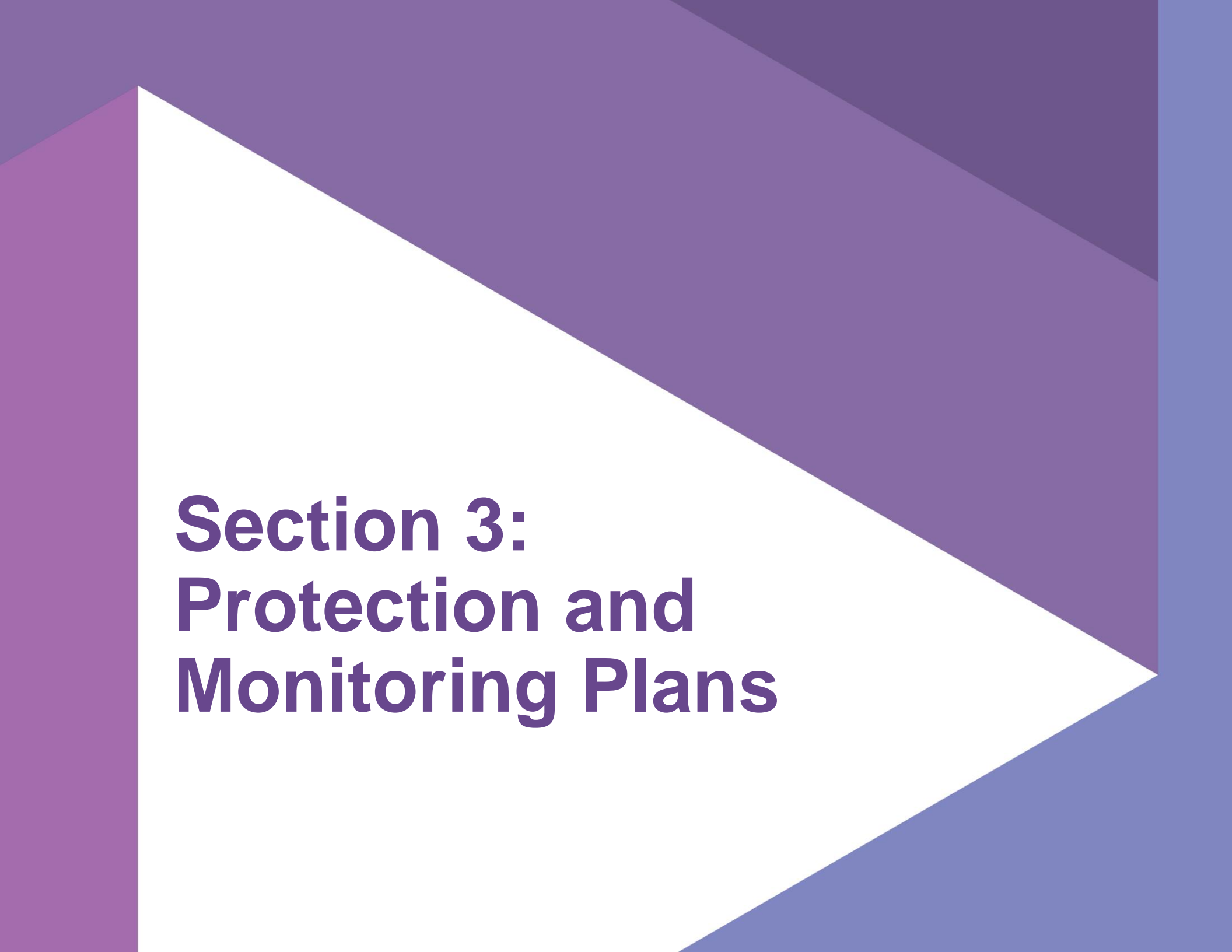


## Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	1	1	0	0	2
Asian	3	3	0	0	6
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	19	19	1	1	40
White	65	65	5	5	140
More than One Race	5	5	1	1	12
<b>Total</b>	<b>93</b>	<b>93</b>	<b>7</b>	<b>7</b>	<b>200</b>

Reports from Electronic Health Record (EHR) can be obtained  
 Contact [grants@siumed.edu](mailto:grants@siumed.edu) for assistance



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# **Section 3: Protection and Monitoring Plans**

# SECTION 3: PROTECTION AND MONITORING PLANS



## SECTION 3 - PROTECTION AND MONITORING PLANS

3.1. Protection of Human Subjects

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

If yes, describe the single IRB plan

Add Attachment

Delete Attachment

View Attachment

3.3. Data and Safety Monitoring Plan

Add Attachment

Delete Attachment

View Attachment

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

Yes  No

3.5. Overall Structure of the Study Team

Add Attachment

Delete Attachment

View Attachment



# 3.1: PROTECTION OF HUMAN SUBJECTS



Everyone must have an attachment

- If any exemption claimed, justification goes in Protection of Human Subjects attachment
- Do not repeat the definitions of the exemptions

SECTION 3 - PROTECTION AND MONITORING PLANS

3.1. Protection of Human Subjects  [Add Attachment](#) [Delete Attachment](#) [View Attachment](#)



# 3.1: PROTECTION OF HUMAN SUBJECTS



Document headings:

- Risks to Human Subjects
  - Human Subjects Involvement, Characteristics, and Design
  - Study Procedures, Materials, and Potential Risks
- Adequacy of Protection Against Risks
  - Informed Consent and Assent
  - Protections Against Risk
  - Vulnerable Subjects, if relevant to your study
- Potential Benefits of the Proposed Research
- Importance of the Knowledge to be Gained

## SECTION 3 - PROTECTION AND MONITORING PLANS

3.1. Protection of Human Subjects

Add Attachment

Delete Attachment

View Attachment





## 3.2 MULTI-SITE STUDY



Multi-site study using same protocol? YES/NO

- If NO, nothing else required
- If YES, attach a description of the single IRB plan
  - Must comply with NIH Policy on the Use of sIRB for Multi-Site Research

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

If yes, describe the single  
IRB plan

Add Attachment

Delete Attachment

View Attachment



## 3.3: DATA AND SAFETY MONITORING PLAN



Optional for non-clinical trials human subjects research,  
mandatory for clinical trials

Describe:

- Overall framework and frequency of monitoring
- Adverse events and serious adverse events reporting process
- The individual(s) or group responsible for trial monitoring
- DSMB

3.3. Data and Safety  
Monitoring Plan

Add Attachment

Delete Attachment

View Attachment



## 3.4: DATA SAFETY AND MONITORING BOARD (DSMB)

Will a Data and Safety Monitoring Board (DSMB) be appointed for this study? YES/NO

- Optional for non-clinical trials, mandatory for clinical trials
- If NO, nothing further required
- If YES, describe DSMB in Data and Safety Monitoring Plan

3.3. Data and Safety  
Monitoring Plan

Add Attachment

Delete Attachment

View Attachment

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

Yes  No

## 3.5: STUDY TEAM STRUCTURE



Optional for non-clinical trials, mandatory for clinical trials

Describe:

- Organizational structure
- Administrative sites
- Data coordinating sites
- Enrollment/participating sites
- Any separate labs or testing centers

3.5. Overall Structure of the  
Study Team

Add Attachment

Delete Attachment

View Attachment



# **Section 4 and 5: Clinical Trials ONLY**

**Call Grants Office & SCRIHS  
Info posted to website**

# SECTION 4: PROTOCOL SYNOPSIS



## SECTION 4 - PROTOCOL SYNOPSIS

### 4.1. Brief Summary

Enter up to 5000 Characters

Characters Remaining: 5000

### 4.2. Study Design

#### 4.2.a. Narrative Study Description

Enter up to 32000 Characters

Characters Remaining: 32000

#### 4.2.b. Primary Purpose

#### 4.2.c. Interventions

Intervention Type	Name	Description	Action
Nothing found to display			

[Add New Intervention](#)

#### 4.2.d. Study Phase

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

#### 4.2.e. Intervention Model

#### 4.2.f. Masking

Yes  No

Participant  Care Provider  Investigator  Outcomes Assessor

#### 4.2.g. Allocation



# 4.1: BRIEF SUMMARY



- Enter a brief description of objectives of the protocol
- Include the primary and secondary endpoints
- Limited to 5,000 characters

## SECTION 4 - PROTOCOL SYNOPSIS

### 4.1. Brief Summary

Enter up to 5000 Characters

Characters Remaining: 5000



## 4.2: STUDY DESIGN



- Narrative description of the protocol
  - Describe your plans for assignment of participants and delivery of interventions.
  - Explain methods for sample size and data analysis are appropriate given those plans.
  - Limited to 32,000 characters
  - For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the Research Methods Resources webpage
  - <https://researchmethodsresources.nih.gov/>

### 4.2. Study Design

#### 4.2.a. Narrative Study Description

Enter up to 32000 Characters

Characters Remaining: 32000





## 4.2B: PRIMARY PURPOSE



Drop down choices:

- 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.)

4.2.b. Primary Purpose



## 4.2C: INTERVENTION



Include Name, Description, and Action of each Type:

- 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
- Diagnostic Test
- Other

### 4.2.c. Interventions

Intervention Type	Name	Description	Action
Nothing found to display			
<a href="#">Add New Intervention</a>			



## 4.2D: STUDY PHASE



Drop down choices:

- 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

4.2.d. Study Phase

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



## 4.2E: INTERVENTION MODEL



Drop down choices:

- 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.)

4.2.e. Intervention Model



## 4.2F: MASKING (BLINDING)



- YES/NO
- If Yes, select:
  - Participant
  - Care Provider
  - Investigator
  - Outcomes Assessor

4.2.f. Masking

Yes  No

Participant  Care Provider  Investigator  Outcomes Assessor



## 4.2G: ALLOCATION

- N/A
- Randomized
- Non-randomized

4.2.g. Allocation

# SECTION 4: PROTOCOL SYNOPSIS



## 4.3. Outcome Measures

Type	Name	Time Frame	Brief Description	Action
Nothing found to display				

[Add New Outcome](#)

## 4.4. Statistical Design and Power

[Add Attachment](#)

[Delete Attachment](#)

[View Attachment](#)

## 4.5. Subject Participation Duration

## 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

[Add Attachment](#)

[Delete Attachment](#)

[View Attachment](#)

## 4.7. Dissemination Plan

[Add Attachment](#)

[Delete Attachment](#)

[View Attachment](#)



## 4.3: OUTCOME MEASURES



4.3. Outcome Measures

Type	Name	Time Frame	Brief Description	Action
<input type="text" value=""/>	Enter up to 255 Characters	Enter up to 255 Characters	Enter up to 999 Characters	<input type="button" value="Delete"/>

- Type: Primary, Secondary, or Other





## 4.4: STATISTICAL DESIGN

- Number of subjects projected to enroll
- Expected effect size
- Power and Statistical Methods
  - According to Outcome Measures listed in 4.3
- Methods for sample size and data analysis
- Plans for assignment and delivery of interventions
- Randomization
  - <https://researchmethodsresources.nih.gov/>

## 4.5: SUBJECT PARTICIPATION DURATION

- Enter the time for each participant to complete the study (For example, 3 months)
- Unknown or Not Applicable

## 4.6: FDA REGULATIONS



- Will the study use an FDA-regulated intervention?  
YES/NO
- 4.6a: If yes, describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status:
  - Describe the availability of study agents and support for the acquisition and administration of the study agent(s)
  - Indicate the IND/IDE status of the study agent, if applicable
  - Whether or not the investigators have had any interactions with the FDA
  - If the study agent currently has an IND/IDE number
  - **Note:** The awarding component may request consultation with the FDA and the IND/IDE sponsor about the proposed clinical trial after peer review and prior to award



## 4.7: DISSEMINATION PLAN



- 1 per study, can be the same plan for multiple studies
- Registration on [ClinicalTrials.gov](https://clinicaltrials.gov)
- Information is presented in Informed Consent
- Institution has internal policies that adhere to registration and reporting on [ClinicalTrials.gov](https://clinicaltrials.gov)



# SECTION 5: OTHER ATTACHMENTS



- Must answer YES to all 4 Clinical Trial questions for Section 5 to appear

## SECTION 1 - BASIC INFORMATION

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

Human Data Collection- Identifiable

\* 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., NCT87654321) for this trial, if applicable

Click the Populate button to retrieve data from ClinicalTrials.gov registration once Identifier is entered.

Populate



# 5.1 OTHER ATTACHMENTS



- Will be described in the FOA

SECTION 5 - OTHER CLINICAL TRIAL-RELATED ATTACHMENTS

5.1. Other Clinical Trial-related Attachments [Add Attachment](#)

Appendix File Name	Delete on Save	Update Attachment	View Attachment
Nothing found to display.			



# ADD AN ADDITIONAL STUDY RECORD



## Study Record(s)

Attach human subject study records using unique filenames.

[Add New Study](#) [Download Study](#) [Upload Study](#)

Entry #	Study Title	Clinical Trial?	Action
1	Human Data Collection-Not Identifiable	No	<a href="#">Edit</a> <a href="#">View</a>

## Delayed Onset Study(ies)

[Add New Delayed Onset Study](#)

Entry #	Study Title	Anticipated Clinical Trial?	Justification	Delete on Save	Add/Update Attachment	View Attachment
Nothing found to display.						

[Save and Keep Lock](#) [Save and Release Lock](#) [Cancel and Release Lock](#)

# ADDITIONAL RESOURCES



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# ADDITIONAL RESOURCES FOR THIS SECTION



- YouTube video for ASSIST:  
[https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7\\_fDnFZFPEmQK&index=1](https://www.youtube.com/watch?v=nz9NWFhYOG8&list=PLOEUwSnjvqBJeHcb4yai7_fDnFZFPEmQK&index=1)
- YouTube video for Workspace:  
[https://www.youtube.com/watch?v=V9vzcOcx\\_BA](https://www.youtube.com/watch?v=V9vzcOcx_BA)



# DR. TORRY'S SUMMARY



- Start early
- Submit to Grants Office for review early
  - Schedule a meeting with us in advance!
- Work with IRB, if necessary
- Mostly same information
  - New drop downs, YES/NO questions, and attachments





**Questions?**

Grants Office:  
**[grants@siumed.edu](mailto:grants@siumed.edu)**

SCRIHS Office:  
**[emeyer@siumed.edu](mailto:emeyer@siumed.edu)**



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