

# **Town Hall on NIH Human Subjects Policy**

**Sponsored by:**  
MUSC Office of Research Development

December 5, 2017

1. **Overview: Revised HHS Regulations & New NIH Policies**  
– *Alexis Nagel, Ph.D.*

2. **NIH sIRB Mandate and the IRB**  
– *Stacey Goretzka, C.I.P.*

3. **Q&A:**  
*Alexis Nagel (ORD)*  
*Stacey Goretzka (IRB)*  
*Darren McCants (ORSP)*

# **Overview: Revised HHS Regulations & New NIH Policies**

# Does my study involve Human Subjects (HS)?

Application due date  
on/after **January 25, 2018**

**Use FORMS-E**

**All research involving Human Subjects:**

- ✓ New form: **PHS Human Subjects and Clinical Trials Information**
- ✓ Use of a single IRB for domestic, multi-site studies

# Is my study a Clinical Trial (CT)?

Application due date  
on/after **January 25, 2018**

**Use FORMS-E**

Research that meets the NIH definition of a Clinical Trial:

- ✓ Clinical trial-specific FOAs
  - ✓ New review criteria
- ✓ Training in Good Clinical Practice (GCP)
- ✓ Expanded reporting in ClinicalTrials.gov

# Is my study a Clinical Trial (CT)?

## Does your study...

1. Involve one or more human participants?
2. Involve one or more interventions?
3. Prospectively assign human participant(s) to intervention(s)?
4. Have a health-related biomedical or behavioral outcome?

# Is my study a Clinical Trial (CT)?

## Does your study...

1. Involve one or more human participants?
2. Involve one or more interventions?
3. Prospectively assign human participant(s) to intervention(s)?
4. Have a health-related biomedical or behavioral outcome?

If “YES” to all four, your study is defined as a clinical trial

# Mechanistic Clinical Trials

- Please read **NOT-OD-18-010**: “NIH Plans for Clinical Trial Specific Parent R01 and Parent R21 FOAs”

*Details on mechanistic exploratory studies that meet the definition of a CT however are not designed to demonstrate clinical improvement*

- Also, **Clinical Trial case studies** posted through the NIH Office of Extramural Research (evolving)



# Does my FOA allow CTs?

- After **January 25, 2018**, all FOAs will be designated:
  1. “Clinical Trials Not Allowed”
  2. “Clinical Trials Optional”
  3. “Clinical Trials Required”
- Check the FOA online **8 weeks** prior to due date for updates

# Does my FOA allow CTs?

## Department of Health and Human Services

### Part 1. Overview Information

Participating Organization(s)	National Institutes of Health ( <a href="#">NIH</a> )
Components of Participating Organizations	National Institute on Drug Abuse ( <a href="#">NIDA</a> ) National Institute on Alcohol Abuse and Alcoholism ( <a href="#">NIAAA</a> ) Office of Behavioral and Social Sciences Research ( <a href="#">OBSSR</a> )
Funding Opportunity Title	Behavioral & Integrative Treatment Development Program (R01 Clinical Trial Optional)
Activity Code	<a href="#">R01</a> Research Project Grant
Announcement Type	Reissue of <a href="#">PA-16-072</a>

#### Related Notices

Funding Opportunity Announcement (FOA)

### Section II. Award Information

#### Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

#### Application Types Allowed

New  
Renewal  
Resubmission  
Revision

The [OER Glossary](#) and the SF424 (R&R) Application Guide provide details on these application types.

#### Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s)

[Need help determining whether you are doing a clinical trial?](#)

#### Funds Available and Anticipated Number of Awards

The number of awards is contingent upon NIH appropriations and the submission of a sufficient number of meritorious applications.

#### Award Budget

Application budgets are not limited but need to reflect the actual needs of the proposed project.

#### Award Project Period

The maximum project period is 5 years.

# Does my FOA allow CTs?

Funding Opportunity Title	NIH Research Project Grant (Parent R01 Clinical Trial Required)
Activity Code	R01 Research Project Grant
Announcement Type	New
Related Notices	<div><div>NOT-AR-18-008 NIAMS Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements</div><div>NOT-HL-17-546 NHLBI Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for the NIH Parent R01 Clinical Trial Required Announcement</div><div>NOT-AT-18-001 NCCIH Policy for Submission of Parent R01 Applications Proposing Clinical Trials</div><div>NOT-NS-18-001 Notice of NINDS Participation and Policy for Submission of Applications to PA-18-345 "NIH Research Project Grant (Parent R01) - Clinical Trial Required". NINDS only accepts Clinical Trial Applications Proposing Mechanistic Studies</div><div>NOT-MH-18-004 NIMH Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements</div><div>NOT-MH-18-006 Notice of NIMH Participation in (PA-18-345) NIH Research Project Grant (Parent R01 Clinical Trial Required)</div></div>
Funding Opportunity Announcement (FOA) Number	PA-18-345

# **New Review Criteria for Research Project Applications Involving Clinical Trials**

## **(NOT-OD-17-118)**

1. For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?
2. Are the study populations, proposed interventions, and duration of the trial appropriate and well-justified?
3. Amended/Revised Significance, Investigator, Innovation, Approach, Environment, and Study Timeline...

# Training in Good Clinical Practice (GCP) – CITI MIAMI

1. Training in Good Clinical Practice (GCP) for key personnel must be renewed every 3 years
2. “Good Clinical Practice and ICH” – [CITI Training](#) (it’s free!)
  - A. Log in to CITI MIAMI
  - B. “Main Menu/My Courses”
  - C. “Medical University of South Carolina Courses” → “Add a Course”
  - D. “Human Subjects” → “**Basic course**” → “Good Clinical Practice and ICH”

# Additional NIH CT Requirements

- Register all NIH funded trials and report results in [ClinicalTrials.gov](https://clinicaltrials.gov)
  - All phases
  - All interventions (FDA regulated, behavioral, other)
  - All mechanisms (grant, coop, agreement, contract)
- Registration: no later than 21 days after enrollment of first subject
- Reporting: no later than 1 year after trial's primary completion date

# Single IRB (sIRB) – New and re-competing HS research applications

Starting January 25, 2018!

NIH will require all domestic sites in newly funded multi-site studies  
conducting the same protocol to use a single IRB

# PHS HS & CT Information 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

### 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](#)

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

### 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

[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.

[Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

### Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		<input type="checkbox"/>	<input type="text"/> <a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>

Take a video tour of the new form



# PHS HS & CT Information 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

### 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](#)

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

### 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

[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.

[Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

#### Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		<input type="checkbox"/>	<input type="text"/> <a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>

Take a video tour of the new form

# If “No” To Human Subjects... provide justification for human materials/data, if applicable

If research involves use of human materials only, justify the claim of “No” to HS:

1. Explain how the material was not collected primarily for/by your proposed study
2. Clarify the source (repository, purchased commercially)
3. No investigator can access the ID for coded data (including code key)

# Advice from the NIH

1. Work with POs
2. Be detailed
3. Apply Early!

## MUSC Contacts:

**Alexis Nagel, Ph.D. (Office of Research Development)**

[nage@musc.edu](mailto:nage@musc.edu)

**Stacey Goretzka (Institutional Review Board)**

[goretzka@musc.edu](mailto:goretzka@musc.edu)

**Darren McCants (Office of Research & Sponsored Programs)**

[mccantsd@musc.edu](mailto:mccantsd@musc.edu)

# Resources (linked)

1. [High Level Summary of Forms-E Changes](#)
2. [Forms- E Instructions](#) and [video](#)
3. [NIH OER Human Subjects Website: Infographics, Flow charts, Policy Updates](#)
4. [NIH Definition of Clinical Trial](#)
5. [Single IRB Policy](#)
6. [NIH Data and Safety Monitoring](#)
7. [SF 424 & Electronic Submission Page](#)
8. [NIH Grants How to Apply Application Guide](#)

# PHS HS & CT Information 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

### 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](#)

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

### 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

[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.

[Add Attachment](#) [Delete Attachment](#) [View Attachment](#)



### Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		<input type="checkbox"/>	<input type="text"/> <a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>

Take a video tour of the new form

# Section 1 -

# Basic Information

-  Required for Human Subjects studies  
 Required for Clinical Trial studies

## 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)



1.2. \* Is this Study Exempt from PHS Review?

☐ 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



Required for Human Subjects studies  
Required for Clinical Trial studies

# Section 2 - Study Population Characteristics

## Section 2 - Study Population Characteristics

### CT HS 2.1. Conditions or Focus of Study

X

Add New Condition

### CT HS 2.2. Eligibility Criteria

### CT HS 2.3. Age Limits

Minimum Age

Maximum Age

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

Add Attachment

Delete Attachment

View Attachment

### CT HS 2.5. Recruitment and Retention Plan

Add Attachment

Delete Attachment

View Attachment

### CT HS 2.6. Recruitment Status

### CT HS 2.7. Study Timeline

Add Attachment

Delete Attachment

View Attachment

### CT HS 2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report



Required for Human Subjects studies



Required for Clinical Trial studies

# 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



- HS** Required for Human Subjects studies  
**CT** Required for Clinical Trial studies

# Section 4 - Protocol Synopsis

## Section 4 - Protocol Synopsis

### 4.1. Brief Summary

### 4.2. Study Design

#### 4.2.a. Narrative Study Description

4.2.b. Primary Purpose

#### 4.2.c. Interventions

<input type="text"/>	Intervention Type	<input type="text"/>
	Name	<input type="text"/>
	Description	<input type="text"/>

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

### 4.3. Outcome Measures

<input type="text"/>	Name	<input type="text"/>
	Type	<input type="text"/>
	Time Frame	<input type="text"/>
	Brief Description	<input type="text"/>

Add New Outcome

### 4.4. Statistical Design and Power

### 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

### 4.7. Dissemination Plan



Required for Human Subjects studies  
Required for Clinical Trial studies

# Section 5 – Other Clinical Trial- related Attachments

---

## Section 5 - Other Clinical Trial-related Attachments

---

### 5.1. Other Clinical Trial-related Attachments

[Add Attachments](#)[Delete Attachments](#)[View Attachments](#)

# Delayed Onset Study

## 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

### 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](#)

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

### 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

[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.

[Add Attachment](#) [Delete Attachment](#) [View Attachment](#)

### Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
		<input type="checkbox"/>	<input type="text"/> <a href="#">Add Attachment</a> <a href="#">Delete Attachment</a> <a href="#">View Attachment</a>

- HS anticipated but specific plans can't be described at time of application
- Must provide JUSTIFICATION why delayed onset. Include:
  1. Assurance that you will follow NIH policy for submission of appropriate information before involving HS
  2. Will provide sIRB info prior to start of HS study