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)?

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

Application due date on/after January 25, 2018

Use FORMS-E
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 (NIH)
- Components of Participating Organizations:
  - National Institute on Drug Abuse (NIDA)
  - National Institute on Alcohol Abuse and Alcoholism (NIAAA)
  - Office of Behavioral and Social Sciences Research (OBSSR)

Funding Opportunity Title

Behavioral & Integrative Treatment Development Program (R01 Clinical Trial Optional)

Activity Code

R01 Research Project Grant

Announcement Type

Reissue of PA-16-072

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.

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?

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

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.
The following forms 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.

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 subject study information.

Other Requested Information

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

Delayed Onset Study(s)

<table>
<thead>
<tr>
<th>Study Title</th>
<th>Anticipated Clinical Trial?</th>
<th>Justification</th>
</tr>
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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

Stacey Goretzka (Institutional Review Board)
goretzka@musc.edu

Darren McCants (Office of Research & Sponsored Programs)
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 Human Subjects and Clinical Trials Information

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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.

If Yes to Human Subjects

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Other Requested Information

Study Record(s)

Click here to extract the Human Subject Study Record Attachment

Attach human subject study records using unique filenames.

Delayed Onset Study(ies)

Study Title | Anticipated Clinical Trial? | Justification
--- | --- | ---

Take a video tour of the new form.
Section 1 - Basic Information

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 Federal Regulations?

1.3. Exemption Number

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?

1.4.b. Are the participants prospectively assigned to an intervention?

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT07654321) for this trial, if applicable
### Section 3 - Protection and Monitoring Plans

<table>
<thead>
<tr>
<th>Question</th>
<th>Details</th>
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<tbody>
<tr>
<td><strong>3.1. Protection of Human Subjects</strong></td>
<td>Add Attachment</td>
</tr>
<tr>
<td><strong>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?</strong></td>
<td>Yes</td>
</tr>
<tr>
<td>If yes, describe the single IRB plan</td>
<td>Add Attachment</td>
</tr>
<tr>
<td><strong>3.3. Data and Safety Monitoring Plan</strong></td>
<td>Add Attachment</td>
</tr>
<tr>
<td><strong>3.4. Will a Data and Safety Monitoring Board be appointed for this study?</strong></td>
<td>Yes</td>
</tr>
<tr>
<td><strong>3.5. Overall Structure of the Study Team</strong></td>
<td>Add Attachment</td>
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</tbody>
</table>
### 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

<table>
<thead>
<tr>
<th>Intervention Type</th>
<th>Name</th>
<th>Description</th>
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<tr>
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Add New Intervention

#### 4.3. Outcome Measures

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<tr>
<th>Name</th>
<th>Type</th>
<th>Time Frame</th>
<th>Brief Description</th>
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</table>

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

- [ ] completion
- [ ] progress
- [ ] data
- [ ] analysis

#### 4.8. Other Clinical Trials

#### 4.9. References

#### 4.10. Appendices
Section 5 – Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments

Add Attachments  Delete Attachments  View Attachments
Delayed Onset Study

• 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