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 (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.

Application Types Allied
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?

NIH Research Project Grant (Parent R01 Clinical Trial Required)

Activity Code
R01 Research Project Grant

Announcement Type
New

Related Notices

NOT-AR-18-008 NIAMS Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements

NOT-HL-17-546 NHLBI Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for the NIH Parent R01 Clinical Trial Required Announcement

NOT-AT-18-001 NCCIH Policy for Submission of Parent R01 Applications Proposing Clinical Trials

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

NOT-MH-18-004 NIMH Only Accepts Clinical Trial Applications Proposing Mechanistic Studies for Clinical Trial Parent R01 and R21 Announcements

NOT-MH-18-006 Notice of NIMH Participation in (PA-18-345) NIH Research Project Grant (Parent R01 Clinical Trial Required)

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
  • 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
Take a video tour of the new form
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. [Enter explanation]

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 □

Study Record(s)

Attach human subject study records using unique filenames. [Enter filenames]

Click here to extract the Human Subject Study Record Attachment

Delayed Onset Study(ies)

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

Add Attachment □ Delete Attachment □ View Attachment □
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:**
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Stacey Goretzka (Institutional Review Board)
goretzka@musc.edu

Darren McCants (Office of Research & Sponsored Programs)
mccantsd@musc.edu
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

Take a video tour of the new form
**Study Record: PHS Human Subjects and Clinical Trials Information**

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

**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., NCT0754321) for this trial, if applicable
Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

2.2. Eligibility Criteria

2.3. Age Limits

2.4. Inclusion of Women, Minorities, and Children

2.5. Recruitment and Retention Plan

2.6. Recruitment Status

2.7. Study Timeline

2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report
Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects

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

3.3. Data and Safety Monitoring Plan

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

- Yes
- No

3.5. Overall Structure of the Study Team
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>
</tr>
</thead>
</table>

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

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