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 <u>NOT-OD-18-010</u>: "NIH Plans for Clinical Trial Specific Parent R01 and Parent R21 FOAs"

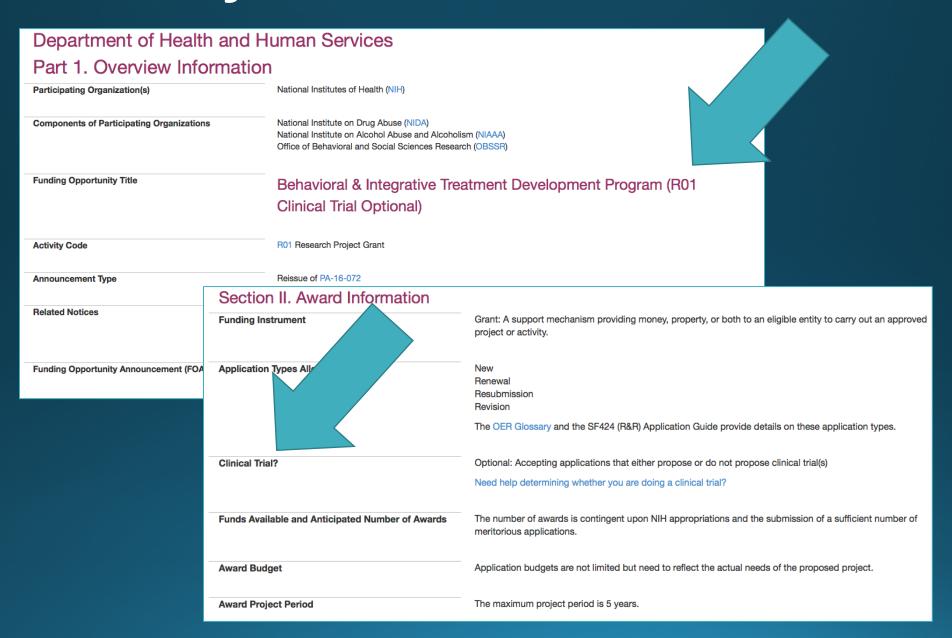
Details on mechanistic exploratory studies that meet the definition of a CT however are not designed to demonstrate clinical improvement

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 <u>8 weeks</u> prior to due date for updates

Does my FOA allow CTs?



Does my FOA allow CTs?

Funding Opportunity Title

NIH Research Project Grant (Parent R01 Clinical Trial Required)

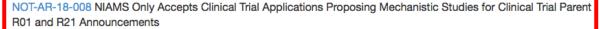
Activity Code

R01 Research Project Grant

Announcement Type

New

Related Notices



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?

 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 <u>ClinicalTrials.gov</u>
 - 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 <u>domestic</u> sites in newly funded <u>multi-site studies</u>

<u>conducting the same protocol</u> to use a single IRB

PHS HS & CT Information Form

PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001

Please complete the human subjects section of the Research & Related Other	r Project Information	form prior to completing this form.
The following items are taken from the Research & Related Other Project Info fields must be made on the Research & Related Other Project Information for		
Are Human Subjects Involved?	Yes	□ No
Is the Project Exempt from Federal regulation	ns? Yes	□ No
Exemption number:	<u> </u>	3
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 rese	arch.
	Add Attachment	Delete Attachment View Attachment
Skip the rest of the PHS Human Subjects and Clinical Trials Information	on Form.	<u>-</u>
If Yes to Human Subjects		
Add a record for each proposed Human Subject Study by selecting 'Add studies are those for which there is no well-defined plan for human subj Studies. For delayed onset studies, you will provide the study name and Other Requested Information	ject involvement at th	e time of submission, per agency policies on Delayed Onset
	Add Attachment	Delete Attachment View Attachment
Click here to extract the Human	Subject Study Rec	ord 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
		Add Attachment Delete Attachment View Attachment

Take a <u>video tour</u> of the new form

PHS HS & CT Information Form

PHS Human Subject	s and Clinic	ai Triais Information
		OMB Number: 0925-0001 Expiration Date: 03/31/2020
Please complete the human subjects section of the Research & Related Oth	er Project Information	form prior to completing this form.
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Exemption number:	<u> </u>	3
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If Yes, provide an explanation of why the application does not involve	human subjects rese	arch.
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		Add Attachment Delete Attachment View Attachment
Delayed Onset Study(ies)		
Study Title	Anticipated Clinical Trial?	Justification
		Add Attachment Delete Attachment View Attachment
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Take a <u>video tour</u> 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:

- Explain how the material was <u>not</u> collected primarily for/by your proposed study
- 2. Clarify the source (repository, purchased commercially)
- 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

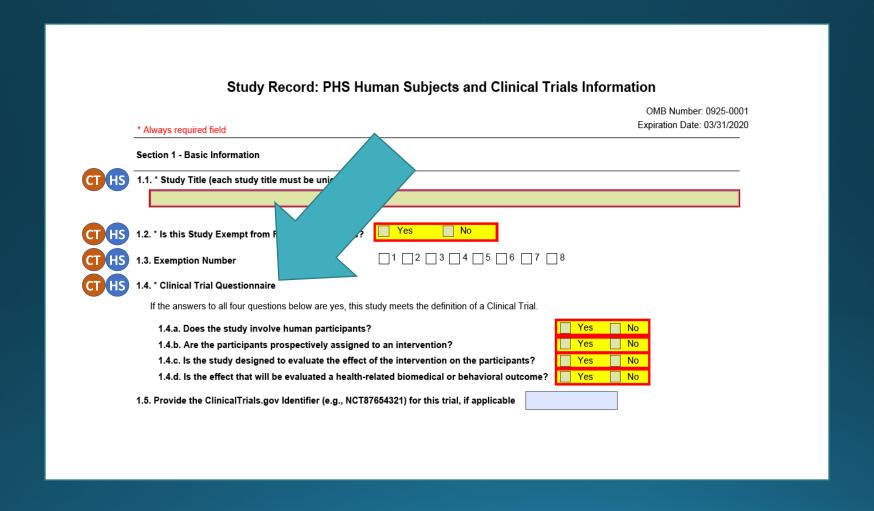
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Take a <u>video tour</u> of the new form



Section 1 - Basic Information





Section 2 - Study Population Characteristics

Section 2 - Study Population Characteristics		
2.1. Conditions or Focus of Study		
Add New Condition		
CT HS 2.2. Eligibility Criteria		
CT HS 2.3. Age Limits Minimum Age	▼ Maxim	num 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		V
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				
HS 3.1. Prot	ection of Human Subjects		Add Attachm	ent Delete Attachment	View Attachment
HS 3.2. Is th	is a multi-site study that will use the	e same protocol to conduct no	on-exempt human subjects res	earch at more than on	e domestic site?
	Yes No N/A				
If ye	s, describe the single IRB plan		Add Attachme	ent Delete Attachment	View Attachment
3.3. Data	and Safety Monitoring Plan		Add Attachm	ent Delete Attachment	View Attachment
3.4. Will	a Data and Safety Monitoring Board	be appointed for this study?			
	Yes No				

Required for Human Subjects studies

Required for Clinical Trial studies

Section 4 - Protocol Synopsis

				-				
	ection 4 - Protocol Synopsis 1. Brief Summary			4.3. Outco	me Measures Name			
				- X	Type			·
СТ	,				Time Frame			
					Brief Description			
CT	2. Study Design				Add New Outcome			
	4.2.a. Narrative Study Description			4.4. Statis	tical Design and Power		Add Attachment Delete Attachment View Attach	ment
СТ				G				_
				4.5. Subje	ct Participation Duration			
СТ	4.2.c. Interventions				_			
СТ				4.6. Will the study use an FDA-regulated intervention?				
	x Intervention Type		•	CT 4.6.a. Devic	If yes, describe the availability of e Exemption (IDE) status	Investigational Product (IP) and Investigation	al New Drug (IND)/Investigational	
	Name						Add Attachment Delete Attachment View Attach	ment
	Description			CT 4.7. Disse	mination Plan		Add Attachment Delete Attachment View Attach	ment
	Add New Intervention							
	4.2.d. Study Phase							
СТ		<u> </u>	_					
	is this an i	NIH-defined Phase III clinical trial? Yes	□ No					
СТ	4.2.e. Intervention Model	▼						
_	nzioi interventari ineger	<u> </u>						
СТ	4.2.f. Masking Yes	No						
	Particip	pant Care Provider Investigator	Outcomes Assessor					
СТ	4.2.g. Allocation	V						
<u>u</u>	4.2.g. Anocution	ш						

Required for Human Subjects studies
Required for Clinical Trial studies

Section 5 – Other Clinical Trial-related 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? Is the Project Exempt from Federal regulations? __1 __2 __3 __4 __5 __6 __7 __8 Exemption number: If No to Human Subjects Does the proposed research involve human specimens and/or data? If Yes, provide an explanation of why the application does not involve human subjects research. 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 Click here to extract the Human Subject Study Record Attachment Study Record(s) Attach human subject study records using unique filenames. Delayed Onset Study(ies) Anticipated Study Title Clinical Justification Trial?

- HS anticipated but specific plans can't be described at time of application
- Must provide JUSTIFICATION why delayed onset. Include:
 - 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