Changes to NIH Submissions for Human Subjects Research

Get Ready, Get Set, Apply Early.

Information for Research Investigators
Submitting Proposals for Human Subjects Research?

Changing NIH Policies May Impact You!

- Good Clinical Practice
- Single IRB
- Clinical Trial Review Criteria
- Registration & Reporting
- Clinical Trial FOAs
- New Application Forms
Objectives for today

- Reasons for the changes
- Review definition for Clinical Trial
- Review of specific changes
  - Data elements
  - Attachments
  - Tools (Grants.Duke, annotated forms package, instructions)
- Where to go for additional help
Why the changes

- **Efficiency**: Enhance the efficiency of how research studies involving human participants are conducted.
- **Transparency**: Promote a culture of transparency in research in order to advance public health.
- **Accountability**: Ensure that NIH can appropriately identify and report on their clinical trials portfolio to ensure proper stewardship.
- **Timely Reporting**: Decrease the time it takes investigators to publicly report study results.

To prepare for the Common Rule changes; Learn more:
All Research Involving Human Participants

- New forms to collect human subjects information
- Use of a single Institutional Review Board (IRB) for multi-site studies

Research that Meets the NIH Definition of a Clinical Trial

- Training in Good Clinical Practice (GCP)
- Clinical trial-specific Funding Opportunity Announcements (FOAs)
- New review criteria
- Expanded registration and results reporting in ClinicalTrials.gov
How Does NIH Define a Clinical Trial?

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Learn more at https://grants.nih.gov/policy/clinical-trials/definition.htm
Questions to Ask Yourself

Does your study...

✓ Involve one or more human subjects?
✓ Prospectively assign human subject(s) to intervention(s)?
✓ Evaluate the effect of intervention(s) on the human subject(s)?
✓ Have a health-related biomedical or behavioral outcome?

If YES TO ALL of these questions, your study is considered a clinical trial
What is changing and why

• Consolidation of human subjects, inclusion & enrollment, and clinical trial information previously collected across multiple agency forms

• Incorporation of recent Grants.gov changes to the R&R Budget and SBIR/STTR Information forms.

• Expansion & use of discrete fields to collect additional clinical trial info
Walkthrough of changes

- 45 new data elements
  - Range from drop down menus to free text
  - includes a protocol synopsis
  (components up to 10 pages)

- 14 new stand-alone attachments
  - Explained in upcoming slides
Walkthrough of changes

- Detailed guide is available here: https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general-forms-e.pdf

- Fillable forms: https://www.grants.gov/web/grants/forms/r-r-family.html#sortby=1


- Grants.Duke & SPS
Fillable forms – how to find

- Go to website: https://www.grants.gov/web/grants/forms/r-r-family.html#sortby=1
- Select “PHS Human Subjects and Clinical Trials Information”
- Click to “Extract Human Subjects Study Record Attachment”
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.

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

Study Record(s)

Attach human subject study records using unique filenames.
Sections

• 1 – Basic Info
• 2 – Study Population
• 3 – Protection & Monitoring Plans
• 4 – Protocol Synopsis
• 5 - Other Clinical Trials Attachments
Sections

• 1 – Basic Info
• 2 – Study Population
• 3 – Protection & Monitoring Plans
• 4 – Protocol Synopsis
• 5 - Other Clinical Trials Attachments
Section 1 - Changes/elements

• Required for all HS research
• Clinical trial questions as distinct items
• Exemption categories*

*Items marked with * have additional information in Appendix slides.
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

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
Exemptions

• Added exemption numbers 7 and 8 to question 1.3 on the fillable pdf; however, these exemptions will not be used at this time
Access Grants.duke via myRESEARCHhome  https://mrh.duke.edu
### Proposal Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposal ID</td>
<td>167835</td>
</tr>
<tr>
<td>PIF/PDF Name</td>
<td>Stephanie B. Dash (TEST)</td>
</tr>
<tr>
<td>Sponsor</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>Owning Duke Org</td>
<td>0802010420 - Information Technology</td>
</tr>
<tr>
<td>PI/PD/CO Duke Org</td>
<td>0802010420 - Information Technology</td>
</tr>
<tr>
<td>Start Title</td>
<td>Stephanie's First Form E Test Proposal</td>
</tr>
<tr>
<td>Proposal Dates</td>
<td>07/01/2019 - 09/02/2024</td>
</tr>
<tr>
<td>Initiated By</td>
<td>Stephanie B. Dash (TEST)</td>
</tr>
<tr>
<td>Dept. Pre-Award Liaison (PA)</td>
<td></td>
</tr>
<tr>
<td>Human Subjects Used?</td>
<td>Yes</td>
</tr>
<tr>
<td>Vertebrate Animals Used?</td>
<td>No</td>
</tr>
<tr>
<td>Agency Due Date</td>
<td>10/06/2018</td>
</tr>
<tr>
<td>Agency ID</td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td>Clinical Trial</td>
</tr>
<tr>
<td>Submission Date</td>
<td></td>
</tr>
<tr>
<td>Award Date</td>
<td></td>
</tr>
<tr>
<td>Proposal Type</td>
<td>New</td>
</tr>
<tr>
<td>Status</td>
<td>Initialized</td>
</tr>
<tr>
<td>FOA #</td>
<td>PA-EN-F01</td>
</tr>
<tr>
<td>Proprietary Info Indicated?</td>
<td>No</td>
</tr>
<tr>
<td>Multiple PI's Indicated?</td>
<td>No</td>
</tr>
</tbody>
</table>

### Attachments

#### Introduction if applicable

**Research Plan**

- Abstract.pdf
- Project Narrative.pdf
- Bibliography.pdf
- Specific Aims.pdf
- Research Strategy.pdf
- Proposal Report Publication List.pdf

**Other Research Plan**

- Vertebrate Animals
- Select Agent Research
- Multiple PI/PO Leadership Plan
- Consortium/Contractual Arrangements
- Letters of Support
- Resource Sharing Plans
- Authentication of Key Biological/Chemical Resources

**PHS Human Subjects and Clinical Trials Info**

- Other Requested Information.pdf

#### Human Subjects Study 1 - Study 1 Short Title

- Inclusion of Women, Minorities and Children
- Recruitment And Retention Plan
- Study Timeline
- Protection of Human Subjects
- IRB Plan for Multiple Domestic Site Non-Exempt Research
- Data Safety Monitoring Plan
- Study Team Structure
- Statistical Design and Power
- Dissemination Plan
- Other Clinical Trials Attachment 1

#### Human Subjects Study 2 - Study 2 Short Title

- Inclusion of Women, Minorities and Children
- Recruitment And Retention Plan
- Study Timeline
- Protection of Human Subjects
- Study Team Structure
### Proposal Information

<table>
<thead>
<tr>
<th>Proposal ID</th>
<th>107835</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD/PI Name</td>
<td>Stephanie B. Dash (TEST)</td>
</tr>
<tr>
<td>Sponsor</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>Owning Duke Org</td>
<td>6860010403 - Information Technology</td>
</tr>
<tr>
<td>PI/PPD Duke Org</td>
<td>6860010403 - Information Technology</td>
</tr>
<tr>
<td>Short Title</td>
<td>Stephanie’s First Forms E Test Proposal</td>
</tr>
<tr>
<td>Project Dates</td>
<td>07/01/2019 - 06/30/2024</td>
</tr>
<tr>
<td>Initiated By</td>
<td>Stephanie B. Dash (TEST)</td>
</tr>
<tr>
<td>Dept. Pre-Award Liaison (PAL)</td>
<td>Stephanie B. Dash (TEST)</td>
</tr>
</tbody>
</table>

### List of Studies

#### Human Subject Studies

- [Add Human Subject Study](#)

#### Delayed Onset Studies (Study Title only)

- [Add Delayed Onset Study](#)
**Study 1**

### Basic Study Information

**Short Title**

*Full Title*

If the proposed study is exempt from federal regulations governing use of human subjects, please check all applicable exemption categories:

- 1
- 2
- 3
- 4
- 5
- 6

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

#### Clinical Trial Questions

- **Will human participants be involved at any performance site?**
  - Yes
  - No

- **Will any participants be prospectively assigned to an intervention?**
  - Yes
  - No

- **Is any study designed to evaluate the effect of the intervention on any participants?**
  - Yes
  - No

- **Is the effect that will be evaluated a health-related biomedical or behavioral outcome?**
  - Yes
  - No

Provide the ClinicalTrials.gov Identifier (e.g. NCT87654321) for this trial, if applicable:
Sections

• 1 – Basic Info
• 2 – Study Population
• 3 – Protection & Monitoring Plans
• 4 – Protocol Synopsis
• 5 - Other Clinical Trials Attachments
Section 2 - Changes/elements

• Required for all HS research
• Many data elements aligned with ClinicalTrials.gov reporting
• New data elements, including date of planned enrollment
• New Attachment: Recruitment & Retention Plan*
• New Attachment: Study Timeline*
Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Add New Condition

2.2. Eligibility Criteria

2.3. Age Limits

Minimum Age

Maximum Age

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

2.7. Study Timeline

Add Attachment
Delete Attachment
View Attachment

2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report
Inclusion Enrollment Report

1. * Using an Existing Dataset or Resource
   [ ] Yes  [ ] No

2. * Enrollment Location Type
   [ ] Domestic  [ ] Foreign

3. Enrollment Country(ies)
   [ ]
   Add New Country

4. Enrollment Location(s)
   [ ]

5. Comments
   [ ]
Enrollment Report 1

* Using Existing Dataset or Resource?  ○ Yes  ○ No

* Location Type

Country(ies)

Location(s)

Comments

* Enrollment Type  ○ Planned  ○ Cumulative (actual)  ○ Both
### Planned Enrollment

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>More than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Total**

### Cumulative (Actual) Enrollment

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Unknown/Not Reported Ethnicity</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>Male</td>
<td>Unknown</td>
<td>Female</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>More than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Total**
Recruitment & Retention Plan

• Required unless either/both apply:
  – Selected only Exemption 4
  – Answered “No” to “Does the study involve human participants?” question

• Address:
  – planned recruitment activities
  – proposed engagement strategies for retention

Help from:
Recruitment Innovation Center
studyrecruitment@duke.edu
Study Timeline

• Provide a description or diagram describing the study timeline
• General (e.g., "one year after notice of award"), and should not include specific dates
• Beyond this, NIH not dictating format/categories
Sections

• 1 – Basic Info
• 2 – Study Population
• 3 – Protection & Monitoring Plans
• 4 – Protocol Synopsis
• 5 - Other Clinical Trials Attachments
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 3 – Changes/elements

- Protection of Human Subjects
  - Required for all HS research but NO changes from Forms D
  - Required elements
    - Risks to Human Subjects
    - Adequacy of Protection Against Risks
    - Potential Benefits
    - Importance of Knowledge to be Gained
Section 3 – sIRB Requirement

- Multi-site study to conduct non-exempt human subjects research involving domestic sites
  - If not applicable
    - Exempt from Federal Regulations
    - Career development, training or fellowship applicant
  - If yes, describe single IRB (sIRB) plan*
sIRB Plan Attachment – Required Elements


• Name of IRB that will serve as the sIRB of record

• All identified participating sites have agreed to rely on the proposed sIRB How communication between sites and the sIRB will be handled

• All sites will sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites

• Which institution or entity will maintain records of agreements/plans
Duke Health IRB as sIRB

- Contact IRB to verify ability to serve as sIRB
- Duke Health IRB can provide Support Letter to serve as sIRB or state that we will rely on another site as the sIRB
- Use of SMARTIRB reliance agreement: https://smartirb.org/

Help from:
IRB team
Minna.pak@duke.edu
Jody.power@duke.edu
Section 3 – DSMP

- Required for all clinical trials
- May be provided for HS studies that are not trials but involve sensitive information or involve risk to subjects
- Required elements*
DSMP Attachment – Required elements

• Framework for safety monitoring and what info will be monitored
• The frequency of monitoring, plans for interim analysis, stopping rules
• The process by which AEs, SAEs, and Unanticipated problems will be managed and reported
• The individual(s) or group responsible for monitoring & advising the appointing entity. A number of options for monitoring are possible, including, but not limited to monitoring by:
  – PI
  – Independent safety monitor/designated medical monitor
  – Independent Monitoring Committee or Safety Monitoring Committee
Section 3 – DSMB

- Required to answer the question
- DSMB may be required for Clinical Trial, optional if HS only
- Required for multi-site trials involving potential risk
- The composition of the Board without naming specific individuals should be included in the DSMP
Section 3 – Changes/elements

• New Attachment: Overall Structure of the Study Team
  – Required for Clinical Trials; optional for Human subjects only
  – Overview of organizational structure of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers.
  – Do not include study team members’ individual professional experiences (i.e., biosketch information).
Sections

• 1 – Basic Info
• 2 – Study Population
• 3 – Protection & Monitoring Plans
• 4 – Protocol Synopsis
• 5 - Other Clinical Trials Attachments
Section 4 – Changes/elements

• Required for Clinical Trials only
• New Element: Protocol Synopsis - Brief Summary
  – Description of objectives, including the primary & secondary endpoints
  – Limited to 5,000 characters
Section 4 – Changes/elements

• New Element: Study Design*
  – Narrative study description (up to 32,000 characters)*
  – Primary Purpose (drop down/enter)
  – Interventions*
  – Study Phase (drop down)
  – Intervention Model (drop down)
  – Masking (drop down)
  – Allocation (drop down)
Study Design

• Narrative Study Description
  – Describe plans for assignment of participants and delivery of interventions
  – Show that methods for sample size and data analysis are appropriate
  – Additional info at Research Methods Resources webpage
  – Limited to 32,000 characters

• Interventions field for each intervention (up to 20)
  – Intervention type
  – Intervention name
  – Intervention description (up to 1,000 characters)
Section 4 – Changes/elements

• New Element: Outcome Measures*
  – For each primary, secondary, other measure
  – Description, up to 999 characters
• New Attachment: Statistical Design and Power
• New Element: Subject Participation and Duration (describe, 255 characters)
• New Attachment: Study use an FDA-regulated intervention?*
• New Attachment: Dissemination Plan*
Study Phase

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

Intervention Model

Will the study use masking?  Yes  No

Allocation Type

Outcome Measures

* Name
* Type
* Timeframe
* Description

Add Outcome Measure

Subject Participation Duration

Will the study use an FDA-regulated intervention?  Yes  No
Outcome Measures

• Complete “Outcome Measures” fields for each primary, secondary, and other important measures

• May have >1 primary outcome measure

• Add up to 50 outcome measures.

• Enter:
  – Name
  – Type (dropdown – Primary, Secondary, Other)
  – Timeframe (e.g., baseline, post-treatment)
  – Description
    • Describe metric if not already included in outcome measure name.
    • 999 character limit
FDA-regulated intervention?

- Describe availability of IP, and IND/IDE status
- Describe interactions with the FDA
- Add as attachment
- 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

Help from:
ORAQ team
ORAQ@duke.edu
Dissemination Plan

• One for each study within application
• Explain plan, ensure that:
  – Trial is registered and results reported in ClinicalTrials.gov
  – Consent documents include statement of ClinicalTrials.gov
  – Recipient institution has policy to ensure reporting is in compliance
• If delayed onset, include dissemination plan in “Delayed onset study justification”

Help from:
DOCR ct.gov team
docr-ctgov@dm.duke.edu
Sections

• 1 – Basic Info
• 2 – Study Population
• 3 – Protection & Monitoring Plans
• 4 – Protocol Synopsis
• 5 - Other Clinical Trials Attachments

Section 5 - Other Clinical Trial-related Attachments

5.1. Other Clinical Trial-related Attachments
Section 5 – Changes/elements

• Required for Clinical Trials *if requested by FOA only*
  
• Do NOT include for others or it will cause errors

• Special considerations for Career Development and Fellowships
  – For each primary, secondary, other measure
  – Description, up to 999 characters

• New Attachment: Other Clinical Trial-Related Attachment
Check page

### Proposal Information

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposal ID</td>
<td>107835</td>
</tr>
<tr>
<td>PD/PI Name</td>
<td>Stephanie B. Dash (TEST)</td>
</tr>
<tr>
<td>Sponsor</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>Owning Duke Org</td>
<td>6860010403 - Information Technology</td>
</tr>
<tr>
<td>PI/PPD Duke Org</td>
<td>6860010403 - Information Technology</td>
</tr>
<tr>
<td>Short Title</td>
<td>Stephanie’s First Forms E Test Proposal</td>
</tr>
<tr>
<td>Initiated By</td>
<td>Stephanie B. Dash (TEST)</td>
</tr>
<tr>
<td>Dept. Pre-Award Liaison (PAL)</td>
<td>Stephanie B. Dash (TEST)</td>
</tr>
<tr>
<td>Human Subjects Used?</td>
<td>Yes</td>
</tr>
<tr>
<td>Vertebrate Animals Used?</td>
<td>No</td>
</tr>
<tr>
<td>Agency Due Date</td>
<td></td>
</tr>
<tr>
<td>Dept. Needs By</td>
<td></td>
</tr>
<tr>
<td>Agency ID</td>
<td></td>
</tr>
<tr>
<td>Activity</td>
<td></td>
</tr>
<tr>
<td>Submission Date</td>
<td></td>
</tr>
<tr>
<td>Award Date</td>
<td></td>
</tr>
<tr>
<td>Proposal Type</td>
<td></td>
</tr>
<tr>
<td>Status</td>
<td></td>
</tr>
<tr>
<td>WBS Element</td>
<td></td>
</tr>
<tr>
<td>FOA #</td>
<td></td>
</tr>
<tr>
<td>Proprietary Info Indicated?</td>
<td></td>
</tr>
<tr>
<td>Multiple PIs Indicated?</td>
<td></td>
</tr>
</tbody>
</table>

### Check

**Errors**
- The proposal has not yet been centrally approved.
- This opportunity does not allow clinical trials, but the following studies have been defined as such: Study 1 Short Title, Delayed Study 1 Short Title.
- The following studies have errors that must be corrected before submission. Click [here](#) to go to SPS Web to edit/view Study information.
  - Study 1 Short Title
    - Clinical Trial Questions: All four questions have been answered Yes, but this opportunity does not allow Clinical Trials.
  - The following studies have missing attachments ([failure to include these attachments will cause an error at NIH](#)):
    - Delayed Study 1 Short Title
      - Delayed Onset Study Justification: Required for all Delayed Onset studies
    - Study 1 Short Title
      - Protection of Human Subjects: Required for all Human Subject studies
      - Dissemination Plan: Required for studies that are Clinical Trials
      - Data Safety Monitoring Plan: Required for studies that are Clinical Trials
      - Statistical Design and Power: Required for studies that are Clinical Trials
      - IRB Plan for Multiple Institutional Site Non-Exempt Research: Required for studies that are multi-site

**Warnings**
External Resources

- 9-minute overview video
- High-level Summary of Form Changes in FORMS-E Application Packages
- Annotated Form Sets
- Update on Clinical Trial Funding Opportunity Announcement Policy
- Common Rule
- Clinical Trial Requirements for Grants and Contracts
Duke Resources

• General questions/triage – researchinitiatives@duke.edu

• Complex grants – Office of Research Development: joanna.downer@duke.edu

• SPS/Grants.Duke – Office of Research Administration and Office of Research Support

• Recruitment & Retention Plan - Recruitment Innovation Center: studyrecruitment@duke.edu

• sIRB - Duke Health IRB: minna.pak@duke.edu; jody.power@duke.edu

• FDA-related intervention - ORAQ: ORAQ@duke.edu

• Dissemination plan and Outcomes - DOCR ClinicalTrials.gov team: DOCR-ctgov@dm.duke.edu
Important Points

• All parent announcements will be reissued

• FORMS-E packages MUST be used for applications for due dates on/after January 25, 2018 and CANNOT be used for earlier due dates

• If correct forms are not used, application will be rejected at the grants.duke stage

• Will eventually feed ClinicalTrials.gov, making reporting more efficient for faculty
If the NIH definition is met, you have a clinical trial

• Even if…
  – You are studying healthy participants
  – Your study does not have a comparison group (e.g., placebo or control)
  – Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
  – Your study is utilizing a behavioral intervention

FAQ re: the Clinical Trials Definition: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm
Tips for success

• Forms require greater level of detail than before; multiple “studies” per application; frees up room in the research proposal

• Includes components you have been used to providing at some point – now just providing earlier

• To prepare components
  – Use NIH fillable forms and share with grant/research admin staff
  – Enter directly into Grants.Duke & SPS/SPS Web
Thank you

Questions?

researchinitiatives@duke.edu