Major Changes to NIH & AHRQ Submissions
Get Ready, Get Set, Apply Early
In 2016, NIH announced initiatives to enhance and improve:

**Efficiency**
Enhance the efficiency of how human subjects research studies are conducted

**Transparency**
Promote a culture of transparency in research in order to advance public health

**Accountability**
Ensure proper stewardship by identifying and reporting on clinical trials

**Timely Reporting**
Decrease the time it takes investigators to publicly report study results
Reforms and Initiatives

All Research Involving Human Participants

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

Research that Meets NIH Definition of a Clinical Trial

- ALL FOAs being reissued
  - No Clinical Trials Allowed
  - Clinical Trial Optional
  - Clinical Trial Required
- Clinical trial-specific Funding Opportunity Announcements (FOAs)
What is Changing

• Expansion & use of **discrete fields** and **new attachments** to collect additional human subjects and clinical trial info

• **SPS Web** (for fields and data) and **Grants.Duke** (for attachments) will be ready for these changes

The NIH fillable form is the most efficient way to collect the necessary information in the right formats.
How do I know if it is a clinical trial?

Does the 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, it is a clinical trial.

Learn more at: https://grants.nih.gov/policy/clinicaltrials/definition.htm
How Big are these Changes?

As in, please take this seriously.
What should I plan for?

• For **each** study (and there could be **multiple** studies):
  
  – **45 new data elements**
    • Range from **drop-down menus** to **free text** including a protocol synopsis with components that allow for ~10 pages
  
  – **14 new stand-alone attachments**
    • Study Design
    • Recruitment & Retention Plan
    • Study Timeline
    • Structure of Study Team
    • Single IRB
What about sIRB?

• When is sIRB needed?
  – Same protocol conducted at 2+ sites
  – Not for career development, research training/fellowship

• Duke Health IRB can provide Support Letter to serve as sIRB or state that we will rely on another site as the sIRB

• If Duke is NOT going to be the sIRB, IRB of record must be named in the proposal

Contact IRB to verify ability to serve as sIRB
minna.pak@duke.edu
jody.power@duke.edu
## Timing of Rollout

<table>
<thead>
<tr>
<th>If your due date is...</th>
<th>You must use...</th>
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<tbody>
<tr>
<td><strong>On or before January 24, 2018:</strong></td>
<td><strong>FORMS-D</strong> application package</td>
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<tr>
<td>• Applications with due dates <strong>on/before January 24, 2018</strong></td>
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<tr>
<td>• Applications submitted under <a href="https://www.nih.gov">NIH Late Policy</a> <strong>2-week window</strong> of consideration for <strong>intended due dates on/before January 24, 2018</strong></td>
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<tr>
<td>• Applications <strong>submitted by February 7, 2018</strong> under NIH <a href="https://www.nih.gov">Continuous Submission Policy</a> for <strong>January 7, 2018 AIDS intended due date</strong></td>
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<td><strong>On or after January 25, 2018:</strong></td>
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<td>• Applications submitted for due dates <strong>on/after January 25, 2018</strong></td>
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<tr>
<td>• Applications submitted <strong>early for intended due dates on/after January 25, 2018</strong></td>
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<tr>
<td>• <strong>All application types</strong> (New, Resubmission, Renewal, Revision)</td>
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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 – i.e., correct human subjects / clinical trial information and attachments are not included – **the application cannot be submitted**

• Will eventually **feed ClinicalTrials.gov**, making reporting more efficient for faculty
• Forms require **greater level of detail than before**; multiple “studies” per application

• Includes information PIs might be familiar with, but **now required earlier and in very different formats and places**

• **Use NIH fillable form to collect data** / direct development of attachments and text entries
Tips for Success

• If you have a tool for collecting proposal info from your faculty, **be sure to update it to include new requirements**

• Enter information into **SPS Web and Grants.Duke**

• **Plan Early!** There is no last-minute escape hatch.
Resources

• **High-level Summary of Forms-E Changes**

• **9-minute overview video**

• General Information
  ORA or ORS contact

• SPS/Grants.Duke System Questions
  Office of Research Administration (ORA)

• General Inquiries
  Office of Research Initiatives - researchinitiatives@duke.edu

• Complex grants
  Office of Research Development - joanna.downer@duke.edu
What can I do to prepare?

• Use the various resources available

• Communicate with faculty – early and often

• Ask them (now) if they plan to submit proposals (with human subjects) for Jan-Mar deadlines

• Encourage faculty to view recorded information session (available on ORA website)

• Call for help!
What can I do to prepare?

- Attend a training session

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<thead>
<tr>
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<th>Time</th>
<th>Location</th>
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<tbody>
<tr>
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<td>Trent Semans Great Hall</td>
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<tr>
<td>Dec 8</td>
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<td>Dec 11</td>
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Questions?