Collaboration, Community, and Continuous Improvement

Major Changes to NIH & AHRQ Submissions

Get Ready, Get Set, Apply Early

Purpose of Reforms & Policy Changes

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

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

- 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**

Timing of Rollout

If your due date is…	You must use…
On or before January 24, 2018: • Applications with due dates **on/before January 24, 2018** • Applications submitted under NIH Late Policy **2-week window** of consideration for **intended due dates on/before January 24, 2018** • Applications **submitted by February 7, 2018 under NIH Continuous Submission Policy** for **January 7, 2018 AIDS intended due date**	**FORMS-D** application package
On or after January 25, 2018: • Applications submitted for due dates **on/after January 25, 2018** • Applications submitted **early for intended due dates on/after January 25, 2018** • **All application types** (New, Resubmission, Renewal, Revision)	**FORMS-E** application package

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

Tips for Success

- 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

Date	Time	Location
Dec 6	12:30-4:00	Trent Semans Great Hall
Dec 8	12:30-4:00	Trent Semans Great Hall
Dec 11	8:30-12:00	Perkins Library 217 geared to Campus Administrators
Dec 12	8:30-12:00	Trent Semans Great Hall

Get Ready, Get Set, Apply Early.

Questions?