On October 25, 2017, NIH and AHRQ will begin making available new FOAs for due dates on or after January 25, 2018, that significantly change the information required for applications proposing clinical trials and/or work with human subjects. Fortunately, these new requirements will be reflected in SPS and grants.duke, allowing seamless submission to grants.gov.

However, the new requirements affect how and where information is presented regarding human subjects, enrollment, and clinical trial information, and demand close attention. Information on human subjects and clinical trials will now be collected at the “study” level, and an individual Project could include multiple “studies”. While study data will be entered into SPS and attachments uploaded into grants.duke, we recommend using the NIH fillable forms to collect the required information and to identify attachments that will be needed. The NIH form:

- Leads applicants through the human subject and clinical trial information collection requirements;
- Uses data fields – both “drop down” and text entry – to capture clinical trial information that might previously have been included in a protocol attachment or not presented in the application;
- Requires separate attachments for some information that might previously have been included in the Research Strategy or other sections; and
- May require input from several different people (Principal Investigator, statistician, study coordinator, et al.) in order to complete.

The following resources will help with this significant change.

- [Walkthrough 9-minute video – highly recommended](#)
- [More information about the new Forms](#)
- [Revised General Instructions for NIH and other PHIS Agencies: Forms Version E Series, updated 9/25/2017](#)
- [Annotated Forms Set](#)
- [Master list of CRU leadership](#)

Faculty should be directed to attend or listen to a recording of one of the following faculty town hall sessions:

**Faculty Session Slides “Changes to NIH Submissions for Human Subjects Research”**

- 11/16 Duke North 2003 7:30AM [Livestream link & recording](#)
- 11/17 Perkins 217 9:00AM [Livestream link & recording](#)
- 11/20 Duke North 2003 4:30PM [Livestream link & recording](#)

Research administrators should attend one of the following training sessions

- 12/6/17 12:30-4:00 Location: Great Hall
- 12/8/17 12:30-4:00 Location: Great Hall
- 12/11/17 8:30-12:00 Location: Perkins Library 217 (geared to campus admins)
- 12/12/17 8:30-12:00 Location: Great Hall

Questions? Email [researchinitiatives@duke.edu](mailto:researchinitiatives@duke.edu)