On January 25, 2018, new policies regarding NIH Clinical Grants and Research will take effect.

- Clinical trial-specific Funding Opportunity Announcements (FOA) will utilize the broadened NIH definition of a Clinical Trial (see below).
- Investigators must apply to a FOA specifically designed for clinical trials (do not submit a clinical trial grant proposal through a parent announcement, i.e. Parent R01).
- New FORMS-E includes a *Human Subject and Clinical Trial Information* Form.
- Good Clinical Practice Training is required of Awardees involved in NIH-funded Clinical Trials.
- Proposals must include a plan for using a single IRB (sIRB) for multi-site research.
- New appendix policy only allows:
    1. Blank data collection forms, survey forms, questionnaire forms
    2. Simple lists of interview questions
    3. Blank informed consent/assent forms
    4. Other items ONLY if specified in FOA

- Registration and results reporting on clinicaltrials.gov.

The stated goal of the changes are 1) more oversight of trials; 2) improved transparency; 3) enhanced efficiency; and 4) maximize public's trust and investment in research.

NIH Definition of 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. An intervention is defined as a manipulation of the subject or subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies.

Is your human subjects research a clinical trial?

1. Does the study involve **human participants**?
2. Are the participants prospectively assigned to an **intervention**?
3. Does the study **evaluate the effect of the intervention** on the participants?
4. Does it have a **health-related biomedical or behavioral outcome**?

If YES to all 4, then NIH considers your study a clinical trial!

The following are **NOT** considered a clinical trial:

- Observational studies
- Secondary research with biospecimens or health information
- Studies that involve a comparison of methods and that do not evaluate the effect of the interventions on the participant
- Studies using correlational designs to prospectively associate biomedical or behavioral parameters with other health-related measures, but do not involve an intervention
- Studies designed to compare the functionality of devices, and not the effect of the devices on the participant

- Studies designed to investigate whether a technique can be used to measure a response in research participants

Reminders for all Investigators:

- Make sure you select the appropriate FOA for your proposal.
- Complete the new *Human Subjects and Clinical Trials Information* form.
- Describe sIRB and plan for communication, if applicable.
- Retain documentation of Good Clinical Practice training.
- Verify appendix materials comply with the new policy.

Please know that the Office of Research Administration is here to assist Investigators and staff as they navigate these changes.

For complete NIH Clinical Grants and Research policy information please go to:
https://grants.nih.gov/policy/clinical-trials.htm

If you have any questions, please do not hesitate to contact your department's assigned Sponsored Programs Administrator within the Office of Research Administration (http://research.ouhsc.edu/SPA.aspx). Thank you