TIGER TIPS
RESOURCES FOR AUBURN RESEARCHERS

Does Your Human Subjects Research Study Meet the NIH Definition of a Clinical Trial?

The NIH definition of a clinical trial is very broad. Some investigators conducting human subjects research may not be aware that NIH considers their study to be a clinical trial.

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***.

The term "***prospectively assigned***" refers to a pre-defined process (e.g., randomization) specified in an approved protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control) of a clinical trial.

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.

A "***health-related biomedical or behavioral outcome***" is defined as the pre-specified goal(s) or condition(s) that reflect the effect of one or more interventions on human subjects' biomedical or behavioral status or quality of life. Examples include: positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression); positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and /or information retention); positive or negative changes to disease processes; positive or negative changes to health-related behaviors; and, positive or negative changes to quality of life.

NIH has provided a tool to help determine if your research meets the NIH definition of a clinical trial via response to five (5) targeted questions:

1. Does this study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?
5. Are you considering applying for an NIH fellowship or career development award?

In order to assist with the answers to these questions, NIH has also provided a number of case studies and Frequently Asked Questions (FAQs) to address concerns.

For application due dates on/after January 25, 2018, identifying whether your study is a clinical trial will be important for:

- picking the right NIH **funding opportunity**
- ensuring your application includes all the **information required for peer review**
- complying with the appropriate **policies and regulations**

NIH has updated information on its website regarding this information and the changes that are being rolled out in 2017-2018 at the following link: https://grants.nih.gov/policy/clinical-trials.htm