From: "NIH-Alert (NIH/OD)" <nih_alert@OD.NIH.GOV>
Date: August 11, 2017 at 1:49:10 PM CDT
To: <NIH-ALERT@LIST.NIH.GOV>
Subject: Changing policies impact NIH-funded studies involving human subjects
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EXTERNAL EMAIL: EVALUATE
Message to NIH grant applicants/awardees, contractors, researchers and research administrators:

If you are conducting NIH-funded research that involves human subjects, or are considering applying to NIH for support of such research, we want to call your attention to important changes that may affect how you:

- select the right NIH funding opportunity announcement
- write the research strategy and human subjects sections of your application
- comply with appropriate policies and regulations

First, familiarize yourself with the new PHS Human Subject and Clinical Trial Information form. For application due dates of January 25, 2018, and beyond, you will be required to use an updated application forms package (FORMS-E), which includes the new human subject and clinical trial form. This form requests human subject and clinical trials information at the study level using discrete form fields, which is a change from current practice. Contract proposals will also require this information. Learn about the new form here.

Second, take a moment to answer these four questions about your current or proposed research:

1) Does the 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?

If the answer to all four questions is yes, then your proposed research meets the NIH definition of a clinical trial. Clarified and broadened in 2014, the definition encompasses a wide range of trial types: mechanistic, exploratory/developmental, pilot/feasibility, behavioral, and more. NIH expanded the clinical trial definition in response to widespread calls from diverse stakeholders for improved reporting of research milestones and outcomes, and for assuring maximal transparency.

Need help determining whether your study would be considered by NIH to be a clinical trial? See our webpage on the definition that includes case studies, FAQs and other resources that can help. Still unsure? Contact your NIH program official or the scientific point of contact listed on the funding opportunity announcement to which you are applying.

Third, familiarize yourself with NIH policy changes related to enhancing stewardship of clinical trials.

NIH made a number of policy changes to improve the stewardship of clinical trials across the life cycle of the trial. We encourage you to familiarize yourself with all that is changing, including:

- the requirement to apply to an FOA that specifically allows for the submission of clinical trial applications for due dates beginning January 25, 2018.
- Good Clinical Practice training expectations for NIH staff, grantees, and contractors that went into effect January 2017.
- updated peer review criteria that will be included in FOAs for clinical trial applications and solicitations for due dates on/after January 25, 2018.
- new Human Subject Information form requirements for clinical trials that will be included in updated application forms (FORMS-E) for due dates on/after January 25, 2018, and contract solicitations published as of January 25, 2018.
- use of a single IRB for non-exempt, multi-site clinical trials for application due dates on/after January 25, 2018.
- expanded ClinicalTrials.gov registration and reporting to include **all** NIH supported clinical trials.

Improving the design, efficiency, and transparency of clinical trials is important because it:

- respects our ethical obligation to participants to maximize the use of the knowledge from the trials in which they participate
- facilitates design of clinical trials while reducing unnecessary duplication
- promotes broad, timely, and responsible dissemination of research information and results
- fosters responsible stewardship of the public's investment in biomedical research

We have developed a new Clinical Trial Requirements for NIH Grantees and Contractors web page to bring together all the information you need to know. Please review this information carefully. Your attention to detail will be critical to ensuring successful funding of your clinical trial awards.

We will be putting out a series of reminder policy notices, training opportunities, and other resources in the NIH Guide to Grants and Contracts, in the NIH Extramural Nexus, and on my blog.

The success of clinical trials relies on the public trust in scientific rigor and ethical oversight. We all play a critical role in this process. We are most grateful to you for your help and support.