To: The HSC Community

From: Richard Larson, MD, PhD. Executive Vice Chancellor, Vice Chancellor for Research, UNM CTSC PI

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RE: Changing Policies Impact NIH-Funded Involving Human Subjects

The National Institutes of Health (NIH) is implementing substantial changes to NIH-funded grants and contracts involving human research beginning with applications submitted to due dates on or after January 25, 2018. These important changes will have far-reaching impact on what activities qualify as clinical trials, the regulatory and reporting requirements, and the staff and faculty training related to Good Clinical Practice that is required by the NIH.

Please note the definition of "clinical trial" is greatly explicit.

For the past year, the CTSA has kept the HSC Community apprised of forthcoming NIH changes, and fortunately, in anticipation of these impending changes our CTSC offers regular Good Clinical Practice (GCP) training for anyone impacted. The CTSC - NIH Good Clinical Practice (GCP) training is designed to promote investigator and staff compliance with NIH regulations. For more information about the course, the CTSC training calendar can be found here: CTSC GCP Training Calendar

If you are conducting NIH-funded research or considering applying to NIH, you will need to be aware of all the following information regarding new policies and procedures as detailed in the attached *Overview of Clinical Trial Changes*:

1. **NIH policy changes related to enhancing stewardship of clinical trials –** NIH has made a number of policy changes to improve the stewardship of clinical trials throughout the life cycle of the trial.
    a. Requirement to apply to an FOA that specifically allows for the submission of clinical trial applications for due dates beginning January 25, 2018.
    b. Good Clinical Practice training expectations for NIH staff, grantees, and contractors that went into effect January 2017.
    c. Updated peer review criteria that will be included in FOAs for clinical trial applications and solicitations for due dates on/after January 25, 2018.
    d. 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.
    e. Use of a single IRB for non-exempt, multi-site clinical trials for application due dates on/after January 25, 2018.
    f. 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:
    a. respects our ethical obligation to participants to maximize the use of the knowledge from the trials in which they participate
    b. facilitates design of clinical trials while reducing unnecessary duplication

c. promotes broad, timely, and responsible dissemination of research information and results
d. fosters responsible stewardship of the public's investment in biomedical research

2. **New PHS Human Subject and Clinical Trial Information form**
   For application due dates of January 25, 2017 and thereafter, a new application form package (FORMS-E) will be required. The form package includes the "new human subject and clinical trial form". Information about the new form is attached and can also be found at: grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm

3. **Determine if your study is a clinical trial or is it a clinical study. Answer these four questions about your current or proposed research:**
   a. Does the study involve human participants?
   b. Are the participants prospectively assigned to an intervention? Many activities now qualify as interventions.
   c. Is the study designed to evaluate the effect of the intervention on the participants?
   d. 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. The new definition can be found at: grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html

   Both the *NIH Notice of Revised HIH Definition of "Clinical Trial"* as well as a *decision tree* are attached to this email.

The NIH has developed a new web page (grants.nih.gov/policy/clinical-trials.htm) 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. An overview of "clinical trial" changes is also attached to this email.

The NIH and the CTSC will be releasing a series of reminder policy notices, training opportunities, and other resources in the NIH Guide to grants and contracts in the coming weeks.

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. The NIH and the CTSC are most grateful to you for your help and support.