Memorandum

To: University Research Community

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Subj.: NIH Changes for Application Submissions and Impacts on Clinical Trials

Date: January 19, 2018

The NIH has released a series of policy updates that impact the submission of NIH applications due on or after January 25th, 2018. Below is a summary of the relevant changes:

New Application Forms Set "E"
The critical changes with these new forms include:

- New PHS Human Subjects & Clinical Trials Information Form
  - Consolidates human subjects, inclusion enrollment, and clinical trial information into one form.
  - Collects information at the study-level.
  - Uses discrete form fields to capture clinical trial information and provide the level of detail needed for peer review.
  - Presents key information to reviewers and staff in a consistent format.
  - Aligns with ClinicalTrials.gov (where possible) for future data exchange with ClinicalTrials.gov.
  - Includes attachment to comply with NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (see NIH-OD-17-076).
- Clarification that the Research Strategy attachment should be used to discuss the overall strategy, methodology, and analyses of the proposed research, but applicants should not duplicate information collected in the new PHS Human Subjects and Clinical Trials Information form.
- Incorporation of updated appendix policy (see NOT-OD-17-098).
- Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms.
- Discontinue use of supplemental instructions for all competing applications and progress reports
  - All information has been folded into the application guide form instructions and/or is contained in the appropriate policy website (e.g., NIH Grants Policy Statement).

Additional details on these changes are available at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-009.html

New Funding Opportunity Announcements (FOA)
Effective for due dates on or after January 25, 2018 all applications involving one or more clinical trials need to be submitted through a Funding Opportunity Announcement (FOA) specifically designed and designated for clinical trials. For the majority of NIH applications there are two parent announcements– one for projects with Clinical Trials, and one for projects without Clinical Trials. Particular attention should be paid to ensure that the correct FOA is selected in accordance with the proposed project.

Additional details are available at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-106.html

NIH Definition of a Clinical Trial
The NIH defines a clinical trial as "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." Please note that this definition includes Phase 1 clinical trials, and trials that do not involve any FDA-regulated products (such as trials involving only **behavioral** interventions).

In an effort to assist PIs in determining whether their proposed project is an NIH defined clinical trial (which would require submission of their project via a clinical trial specific FOA) the NIH has provided detailed guidance on their website at https://grants.nih.gov/policy/clinical-trials/definition.htm.

The Office of Research and Economic Development recommends that if there are any questions as to whether a PI's proposed project falls under a clinical trial FOA or not that they contact the NIH Program Officer listed on the FOA and confirm with them whether their project is defined by the NIH as a clinical trial.

Additional Resources
In an effort to provide further information and resources related to clinical trials, the Office of Research Integrity has created a website at http://research.fiu.edu/irb/clinical-trials/ which reminds the University Research Community of critical requirements related to clinical trials. Please visit this site for resources on:

- ClinicalTrials.gov registrations
- Good Clinical Practice (GCP) Training
- Submitting protocols (involving drugs, biologics, or medical devices) to Western IRB (WIRB)
- NIH and FDA Guidance on Clinical Trials

If you have any questions about these revisions by the NIH please contact your ORED Pre-Award representative at 305-348-2494 for further assistance.