To: NIH PIs and co-PIs  
Deans  
Research Deans  
Department Chairs

From: Charlie Riordan  
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The Research Office writes to inform the UD Research Community of several reforms and new initiatives the National Institutes of Health (NIH) will be implementing in the upcoming weeks and months with the aim of enhancing clinical trials stewardship. These changes will affect NIH-funded studies as well as applications that involve research considered to be a clinical trial under the NIH definition of clinical trial. That is, any 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.

- **Good clinical practice training**: New NIH policies establish Good Clinical Practice (GCP) training expectations — effective January 1, 2017 — for investigators involved in NIH-supported trials, as well as for staff who design, oversee, manage, or conduct clinical trials. Training should be completed every three years. At UD training must be completed by the CITI Program and selecting the available “CITI Good Clinical Practice – GCP” training course. Investigators are responsible for ensuring their research team members have completed the required GCP training in a timely fashion. The GCP training requirement is in addition to the requirement to complete Human Subjects Protections training.

- **Enhancing clinical trial registration and summary results information**: A new HHS rule specifies requirements for clinical trial registration and summary results information reporting. NIH also issued a policy that complements and expands the federal regulation and sets the same reporting expectations for all NIH-funded clinical trials whether or not they are subject to the regulation (to include, for example, phase 1 studies of FDA regulated products as well as studies of interventions not regulated by FDA, e.g., behavioral interventions.) Read more in a New England Journal of Medicine paper authored by NIH staff. Applicants for NIH funding are required to submit a plan outlining how they will comply with the clinical trial information dissemination expectations of the policy. Consistent with the terms and conditions of their NIH funding, awardees undertaking clinical trials covered by the NIH Policy must ensure the submission and updating of the same type of registration and results information, and in the same timeframes, as responsible parties whose trials are subject to the Final Rule. The policy takes effect on January 18, 2017, and applies to applications and proposals received and intramural clinical trials submitted for Institutional Review Board review on or after that date.
To facilitate compliance with this new requirement the UD Research Office will disseminate further guidance and updated template documents for the submission of research to be reviewed by the UD Institutional Review Board (IRB).

- **Use of a single institutional review board (IRB) for multi-site studies:** This NIH policy, issued in June 2016, is meant to streamline and expedite IRB review of clinical trials conducted across multiple sites. The policy established the expectation that a single IRB will be used for multi-site research as of May 25, 2017. The NIH recently postponed the implementation of the policy until **September 25, 2017**. UD is monitoring the NIH FAQs and guidance on this topic as we develop an implementation plan. In the meantime, we ask that any investigator preparing or collaborating in a future proposal that would be required to use a single IRB to contact the Director for Research Compliance, Dr. Maria Palazuelos, early during the proposal development phase.

- **Changes to clinical trial applications:** Another change to NIH policy requires that the research community submit grant applications requesting support for clinical trials in response to clinical trial-specific funding opportunity announcements (FOAs). This policy applies to applications submitted for due dates on or after **September 27, 2017**. This change will allow NIH to readily identify proposed clinical trials, to ensure that key pieces of trial-specific information are submitted with each application, and to ensure that trial-specific review criteria are uniformly applied. To give NIH institutes and centers flexibility across their different scientific areas, each NIH IC will be developing clinical trial FOAs that address their research funding priorities and strategic goals. There will be commonalities across FOAs, in that all clinical trial applications will need to contain key clinical trial-specific elements, such as protocol information. This change will mean that applications requesting support for a clinical trial on a NIH parent announcement will no longer be possible. Investigators will need to identify an FOA that clearly invites clinical trial applications.