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New ClinicalTrials.gov Requirements for NIH Proposals

1 message

Alanda R Perry Jones <perryar@vcu.edu> Wed, Feb 1, 2017 at 1:00 PM
Reply-To: Alanda R Perry Jones <perryar@vcu.edu>
To: RES-ADM@lists.vcu.edu

Good afternoon,

In accordance with the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information, NOT-OD-16-149, effective January 18, 2017, all NIH proposals containing a clinical trial funded in whole or in part by NIH are required to address a plan for compliance with registration and results reporting requirements through ClinicalTrials.gov.

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." **This definition includes Phase I studies**.

VCU recommends the following language:

> *Dissemination of study results through ClinicalTrials.gov registration and reporting at a minimum will include the following components:*
>
> - *The Principal Investigator* (PI) *will be responsible for ensuring compliance with ClinicalTrials.gov requirements for this project. The PI or his/her designee will register the trial prior to enrolling the first subject. Once a record is established, s/he will confirm accuracy of record content; resolve problems; and maintain records including content update and modifications. S/he will also be responsible for aggregate results reporting and Adverse Event reporting at the conclusion of the project.*
> - *Add specifics related to this trial*

If the submission contains an Applicable Clinical Trial, the following language should also be included:

" *I certify that this submission contains an Applicable Clinical Trial (ACT) and I will ensure compliance with registration and results reporting submissions to ClinicalTrials.gov as required under the FDA Amendments Act of 2007 (FDAAA) and the Final Rule (42 CFR Part 11*)."

Additional information can be found on the NIH FAQ page: