



March 22, 2017

### **NIH Policy on Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149)**

The National Institutes of Health (NIH) issued a policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH (regardless of study phase, type of intervention, or whether they are subject to the statute and to the rule) will ensure that these trials are registered at [ClinicalTrials.gov](http://ClinicalTrials.gov), and that results information of these trials is submitted to ClinicalTrials.gov.

It clarifies that the policy is an expectation that applicants are required to submit a plan, outlining how they will meet the policy's expectations, and, that upon receipt of an award, an awardee will be obligated to adhere to their plan through the terms and conditions of the award. The required plan can be a brief statement explaining whether the applicant intends to register and submit results information to ClinicalTrials.gov as outlined in the policy or to meet the expectations in another manner. It is important to remember that an NIH-funded clinical trial that meets the definition of an applicable clinical trial is subject to the regulation and, therefore, register and submission of results information to ClinicalTrials.gov is a requirement. Below is the NIH Definition of a Clinical Trial.

**NIH Definition of Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more intervention (which may include a placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavior outcomes.**

The [Clinical Trial Decision Tree](#) maybe helpful in determining if your study is a clinical trial.

If you need guidance on a specific plan, please contact Yolanda Davis ([Y.P.Davis@med.miami.edu](mailto:Y.P.Davis@med.miami.edu)), Clinical Trial Disclosure Manager in the Office of Research Compliance and Quality Assurance.

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