



Changes to NIH and ClinicalTrials.gov reporting requirements may affect you.

The [NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information](#) requires submission of results to ClinicalTrials.gov for studies not previously required to submit under the FDA Final Rule. Please see the table below for a summary of these changes and the associated reporting requirements. Changes are noted in **RED**.

Element	FDA Final Rule	New NIH Policy
Scope	<ul style="list-style-type: none"> Applies to all <i>FDA regulated clinical trials</i> (drug, biological, device products, and pediatric post market device surveillance studies under FD&C Act). <i>Does not</i> include Phase 1 studies 	<ul style="list-style-type: none"> Applies to all studies that meet the NIH's expanded definition of a <i>clinical trial</i>: grants.nih.gov/policy/clinical-trials/definition.htm Applies to all "clinical trials" funded wholly or in part by NIH <i>Includes</i> Phase 1 studies
Registration	<ul style="list-style-type: none"> Must occur within 21 days of enrollment of 1st participant 	<ul style="list-style-type: none"> Must occur within 21 days of enrollment of 1st participant
Results Reporting	<ul style="list-style-type: none"> Submission of results information must occur no later than 1 year after the completion date (referred to as the "<u>primary completion date</u>" of the clinical trial, which is defined as <i>the date of final data collection for the primary outcome measure</i>). 	<ul style="list-style-type: none"> Submission of results information must occur no later than 1 year after the completion date (referred to as the "<u>primary completion date</u>" of the clinical trial, which is defined as <i>the date of final data collection for the primary outcome measure</i>).
Potential Consequences of Non-Compliance	<ul style="list-style-type: none"> If Federally funded, grant funding can be withheld Civil monetary penalties of up to \$12,000 per day Record in ClinicalTrials.gov will be marked as non-compliant 	<ul style="list-style-type: none"> May lead to suspension or termination of grant or contract Can affect future funding decisions Record in ClinicalTrials.gov will be marked as non-compliant
Effective Date	<ul style="list-style-type: none"> January 18, 2017 Compliance date is 90 days from the effective date. 	<ul style="list-style-type: none"> Effective for all competing application and contract proposals submitted on or after January 18, 2017
Questions?	<ul style="list-style-type: none"> For more information, contact Michelle Jenkerson, Associate Director of the Center for Clinical Studies, at Jenkerson_m@wustl.edu or 314-362-5626. 	

Steps to Compliance for NIH Awardees: grants.nih.gov/policy/clinical-trials/reporting/steps.htm

Is my Study considered a Clinical Trial according to the NIH? grants.nih.gov/ct-decision/index.htm