IMPORTANT ClinicalTrials.gov Requirement Announcement

January 18th is the effective date to comply with Clinical Trials Reporting Final Rule. If you are an Investigator doing interventional research at Rutgers University, you may have to register/update your research study on ClinicalTrials.gov (https://clinicaltrials.gov/) per FDAAA(https://clinicaltrials.gov/ct2/manage-recs) or ICMJE guidelines (http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html).
In September 16, 2016, the Department of Health and Human Services (HHS) issued a final rule implementing section 402(j) of the Public Health Service Act (the Final Rule).
The Final Rule, which comes two years after HHS' initial Notice of Proposed Rulemaking, clarifies and expands clinical research sponsor responsibilities for drug and device research information on ClinicalTrials.gov. Most notably, the Final Rule broadens the range of studies that must be registered, requires submission of additional registration and summary results information, and sets forth legal consequences for non-compliance.

Responsible parties will have **90 days to comply.**

Please contact the Rutgers University Human Subjects Protection Program (HSPP) department at 973-972-1149 for assistance.

FAQ

What Happened?
The Federal Government's recently approved Final Rule clarifies and expands clinical research sponsor responsibilities for drug and device research information on ClinicalTrials.gov. Most notably, **the Final Rule also broadens the range of studies that must be registered on ClinicalTrials.gov**, requires submission of additional registration and summary results information, and sets forth legal consequences for non-compliance.

When Is This Effective?
January 18, 2017 with 90 days to comply.

Who Does This Effect?
If you are an Investigator doing interventional research at Rutgers University, you may have to register/update your research study on ClinicalTrials.gov (https://clinicaltrials.gov/) per FDAAA(https://clinicaltrials.gov/ct2/manage-recs) or ICMJE guidelines (http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html).

Determining If Your Study Is A Clinical Trial?
Flow Chart: Identifying an "Applicable Clinical Trial".

How To Register?
You must contact your ClinicalTrials.gov Point Person and register your study on ClinicalTrials.gov. Note some studies are registered by their Sponsors.

Help
Contact the Rutgers University Human Subjects Protection Program (HSPP) Unit for assistance at 973-972-1149.
https://orra.rutgers.edu/clinicaltrialsgov