ClinicalTrials.gov Overview

Important Update

Effective January 18, 2017 more studies require registration in clinicaltrials.gov and the reporting requirements have increased. Investigators have 90 days to come into compliance. The NIH is mandating that all clinical trials with any NIH funding register. Summary results information must be submitted for more trials, including FDA-regulated products that have not yet been approved, licensed, or cleared by the FDA. Reporting changes include uploading the full IRB protocol and providing more information regarding adverse events. Clinicaltrials.gov reporting takes a substantial time investment, you should consider including effort in your proposal budget. Additionally, many journals require registration before the first research participant is enrolled. Enforcement for noncompliance includes the termination or withholding of grant funding.

Required by Law

Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) requires Responsible Parties (i.e. principal investigators) to register and submit summary results of clinical trials with ClinicalTrials.gov. The law applies to certain clinical trials of drugs (including biological products) and medical devices. For more information, please visit ClinicalTrials.gov.

Required for Journal Publication

The International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition of the publication of research results generated by a clinical trial. ClinicalTrials.gov is a registry where organizations and individuals can provide the World Health Organization (WHO) Trial Registration Data Set required by ICMJE. For more information, please visit the ICMJE website.

In general, the sponsor of the clinical trial is responsible for registering the clinical trial on ClinicalTrials.gov. Regulations allow for the sponsor to delegate this responsibility to the principal investigator. However, the sponsor should be the party to handle registering the trial.

Most of the clinical trials will fall into one of the following two categories:

1. Clinical trials sponsored by industry, a consortium of cooperative group, another institution or organization, where the UC faculty member is conducting the study as a single site or as one of multiple sites. In this situation the UC PI should not be responsible for registering the trials on ClinicalTrials.gov. However, the UC PI should confirm this position with the sponsor.
2. Clinical trials, designed, initiated and/or sponsored by a member of the UC faculty that is conducted at UC or at one or more institutions. In this situation, the UC PI is responsible for registering the trial on ClinicalTrials.gov and needs to notify the PI at each participating site who will be responsible for this registration. This information should be included in the contract or subcontract language.

If your clinical trial does not fall into one of these categories, you should contact the UC Office of Research Integrity for guidance.

The University of Cincinnati maintains an institutional account and individual investigators should not attempt to set up their own account. Investigators must contact the Office of Research Integrity for access to an account. The Office of Research Integrity will provide the investigator with login information and instructions on how to register the trial. The Investigator is responsible for entering the data. The Office of Research Integrity only provides administrative oversight. Once a clinical trial has been registered, the Office of Research Integrity reviews the information and approves it for release, QA review and posting by ClinicalTrials.gov.

Contact the Office of Research Integrity to register your clinical trial:

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