ClinicalTrials.gov
Fact Sheet

Registration Requirement

The Food and Drug Administration Amendments Act or FDAAA (Public Law 110-85, Title VIII, Section 801) was enacted on September 27, 2007 and mandates the types of trials that need be registered regardless of the study funding source including the data elements submitted and results reported for posting on ClinicalTrials.gov. The International Committee of Medical Journal Editors (ICMJE) also mandates clinical trial registration and updates.

Applicable Trials & Registration Requirements

FDAAA requires registration of all trials for drugs, devices and biologics excluding Phase I drugs studies and small device feasibility studies no later than 21 days after the first participant is enrolled. ICMJE requires registration of all human research projects that prospectively assign human participants to an intervention or comparison group to examine the relationship between a medical intervention and a health outcome before the first participant is enrolled. As of 7/1/2008 this includes Phase I and pharmacokinetic trials. It can take up to five working days for a record to post. To meet FDAAA and ICMJE requirements, UC recommends registering applicable trials at least 30 days prior to study start up.

FDAAA requires registered trial records to be updated at least once every 12 months and changes in recruitment status or study completion within 30 days of occurrence. Results must be registered upon the completion of the primary aim. ICMJE requires information to be updated every six months. Records containing results may take up to 30 days to become available. To meet FDAAA and ICMJE requirements, UC recommends updating records every six months (including date of change) and updating recruitment status and/or study completion within 30 days of the given time point.

Responsibility for Registration

The person or organization responsible (i.e., responsible party) for registering the trial is the sponsor of the trial or the principal investigator as designated by the sponsor, grantee, contractor or awardee.

Failure to Register

Penalties for responsible parties who do not register applicable trials may include notices of noncompliance, monetary sanctions (up to $10,000 per day), withholding or recovery of grant funds for federally funded trials as well as difficulties publishing.

How to Register

The University of Cincinnati maintains an institutional account and individual investigators should not attempt to set up their own account. Investigators should contact the UC Office of Research Integrity for access to an account (researchcompliance@uc.edu).

UC Resources

Guides through initial posting, updating and reporting basic results are available online (link below).
http://researchcompliance.uc.edu/HSR/ClinicalTrials.gov.aspx

Identifying an "Applicable Clinical Trial" under FDAAA

- This flowchart presents basic guidance on determining if a trial is considered an "applicable clinical trial" under FDAAA. It maps out the guidance provided in the "Elaboration of Definitions of Responsible Party and Applicable Clinical Trial", and is also available as an interactive flowchart at: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm
- This flow chart may not address every situation. The grantee's sponsored research office, general counsel, or other similar official should be involved in determining whether or not the grant supports an applicable clinical trial that needs to be registered under FDAAA.