Guidelines for Clinicaltrials.gov Registration of Clinical Trials

This guidance offers support to researchers who must register and report clinical research trials to ClinicalTrials.gov, a database of clinical research trials conducted in the United States and around the world.

Why Should You Register Your Clinical Trial?

Non-reporting of applicable clinical trials may result in the following:

- Potential monetary penalties
- Withholding or recovery of grants
- Unregistered trials will not be considered for publication in journals that adhere to the ICMJE standards.

How Do I Register a Trial At Clinicaltrials.gov?

IRB approval required prior to registry.

You will need a user account in order to access the Protocol Registration System (PRS). Send an e-mail to the appropriate Clinicaltrials.gov Administrator:

Non-cancer studies: **Julie Johnson**; johnsjul@email.arizona.edu; Office: (520) 626-7114
Cancer studies: **Carol Margolis;** margolis@email.arizona.edu; Office: (520) 626-3189

- Once the PI and/or the PI's designee receives their user account and logs onto the ClinicalTrials.gov Registration System, they will be guided to enter specific information about the study.
    - Note: Under FDAAA, an applicable trial must be registered **no later than 21 days** after the enrollment of the first subject.
    - There may be a 2 to 5 day waiting period before the study is published on clinicaltrials.gov.

What Trials Should Be Registered?

A Principal Investigator (PI) can be designated by the sponsor (IND/IDE holder or Institution) as the "responsible party" for registering a clinical trial when:

- The trial is investigator-initiated
- The investigator has access to and control over the data from the clinical trial
- The investigator has the right to publish the results of the clinical trial

The FDA Amendments Act of 2007 (FDAAA or U.S. Public Law 110-85) requires a "responsible party" to register "**applicable clinical trials**" involving drugs, biologics, or devices that are subject to FDA regulations. In addition, investigators or sponsors must register clinical trials in the Protocol Registration System (PRS) of ClinicalTrials.gov to comply with the International Committee of Medical Journal Editors

(ICMJE) Initiative, which requires prior entry of clinical trials in a public registry as a condition for publication.

Who Is Responsible for Registering the Trial?

The "responsible party" is responsible for registering the trial on clinicaltrials.gov.

Clinicaltrials.gov defines the "responsible party" as:

- The holder of the IND or IDE
- For studies not conducted under an IND or IDE, the sponsor is the "initiator" of the trial (e.g. NIH Grantee or Institution

What Are My Reporting Responsibilities?

- The Principal Investigator of the study is responsible for maintaining the accuracy of the information on the registered trial by updating:
  - o Every **six months** if there are no changes
  - o Within **30 days** of study changes (i.e. recruitment updates)
  - o Within **30 days** when trial is completed (i.e. concluded or terminated prior to conclusion)

What Happens When the Study Is Completed?

- The sponsor/investigator of a clinical trial is responsible for posting basic study results at the conclusion of the study. The following items must be posted on the clinicaltrials.gov site:
  - o Demographic and Baseline characteristics of patient sample
  - o Adverse Events/Serious Adverse Events
  - o Primary and Secondary Outcomes results measures
  - o Point of Contact

Who Do I Contact with Questions Related to Clinicaltrials.gov?

Non-cancer studies contact:
Julie Johnson; johnsjul@email.arizona.edu; Office: (520) 626-7114
Cancer studies contact:
Carol Margolis; margolis@email.arizona.edu; Office: (520) 626-3189

Additional Information

- Protocol Registration System Information Page
- NIH Fact Sheet - Registering at ClinicalTrials.gov
- NIH Guidance on Registration Requirements
- NIH Office of Extramural Research - Clinical Trials and FDAAA
- Reporting "Basic Results" in ClinicalTrials.gov