

MCW Guidance: Requirement to Register Clinical Trials on ClinicalTrials.gov

A federal law (Public Law 110-85) requires that all “applicable clinical trials” be registered online with ClinicalTrials.gov, a website managed by the National Library of Medicine.

What clinical trials must be registered?

- Phase II, III, or IV controlled clinical trials of drugs or biologics (i.e., even controlled trials of market-approved drugs); and
- Controlled trials of devices associated with health outcomes (other than small feasibility studies); and
- Pediatric post-market device surveillance studies.
- Other types of clinical trials may be registered even though registration is not required.

Who is responsible for registering the trial?

In most cases, the Sponsor of the trial as defined by FDA regulations [21 CFR 50.3.(e)] has the obligation to register the clinical trial with ClinicalTrials.gov.

- For most industry-sponsored clinical trials, the “Sponsor” is the company that initiated the clinical investigation, but does not actually conduct the investigation.
- The Sponsor (or a grantee, contractor, or awardee) may designate a Principal Investigator to be the “responsible party,” so long as this Principal Investigator is responsible for conducting the trial; has access to and control over the data from the trial; has the right to publish the results of the trial; and has the ability to meet all of the requirements for submitting information under the law.
- Multi-site trials and multi-sponsor trials are susceptible to duplicate registration. The Sponsor, for example, should register the entire scope of a 40-site clinical trial; the individual sites should not redundantly register themselves. Thus care must be taken in how trials are registered. For multi-sponsor trials, the lead sponsor should take responsibility for registration. It is critical that investigators and sponsors work together to ensure that a trial is registered once and only once.
- In situations where an investigator is named as the “holder” of an investigational New Drug Application (IND) or Investigational Device Exemption (IDE), that investigator may be the “Sponsor” per FDA regulations and therefore the “responsible party.”
- For NIH extramural trials where there is no IND or IDE holder, the funding recipient (and not NIH) may be the “responsible party.”

Who can help you figure out if you are the responsible party (or -- have been designated as the responsible party)?

If you do clinical trials, it is your responsibility to determine whether you are obligated to register any of your clinical trials. You might want to check with the Sponsor of your trial or look up your trial on the ClinicalTrials.gov website. If you have questions or need guidance, consult with Dr. Amit Gode, Administrative Director Clinical Trials Office, CTSI (805-6999 or via email agode@mcw.edu)

If you are the responsible party, how do you obtain a clinicaltrial.gov account and password?

- MCW faculty should email Dr. Amit Gode, Administrative Director Clinical Trials Office, CTSI at agode@mcw.edu or 805-6999

Penalties for failing to register

The new federal law provides for significant civil monetary penalties, and (for federally-funded trials) the withholding or recovery of grant funds for responsible parties who fail to register, or who provide false or misleading information in connection with applicable clinical trials. Furthermore, most medical journals will not publish your clinical trial results unless the trial was registered before the first subject was enrolled.

About ClinicalTrials.gov

ClinicalTrials.gov is a collaborative project of NIH, FDA, and the U.S. National Library of Medicine. ClinicalTrials.gov facilitates registration of trials in accordance with the International Committee of Medical Journal Editors (ICMJE) initiative requiring prior entry of clinical trials in a public registry as a condition for publication [DeAngelis et al, Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors. *New England Journal of Medicine* 351:1250-1251, 2004] Additional information about the new registration requirements is available on the ClinicalTrials.gov website [<http://prsinfo.clinicaltrials.gov/>]

Does my trial need IRB approval before I enter it into ClinicalTrials.gov?

The MCW/Froedtert IRB routinely asks clinical trial investigators to document clinical trial registration at the time of IRB application, to help investigators address this regulation in a timely fashion.

Until the eBridge SmartForm has been revised, please enter the following information in the open-ended text box at Section 10 (A-Drugs or B-Devices) (even if your study is not a multi-site study):

- *What is the ClinicalTrials.gov registration number for this study?*

You may register your trial in ClinicalTrials.gov prior to getting approval from the IRB. Before the first patient is recruited, however, IRB approval must be obtained and the protocol record updated accordingly.