

NORTHERN ILLINOIS UNIVERSITY
INSTITUTIONAL REVIEW BOARD

POLICY ON REGISTRATION OF CLINICAL TRIALS

[ClinicalTrials.gov](https://clinicaltrials.gov), a service of the National Institutes of Health, was developed by the National Library of Medicine (NLM) in collaboration with the Food and Drug Administration (FDA). Its purpose is to “link patients to medical research” by providing information to the general public on federally and privately supported clinical research for a range of diseases and conditions. Trial registration is therefore established to promote the public good by ensuring that the existence and design of clinically directive trials are publicly available.

I. WHAT RESEARCH MUST BE REGISTERED

Northern Illinois University policy requires that the following new or ongoing clinical trials are registered on ClinicalTrials.gov:

A. Food and Drug Administration The FDA defines a clinical trial as “a clinical investigation or a clinical study in which human subject(s) are prospectively assigned, according to a protocol, to one or more interventions (or no intervention) to evaluate the effect(s) of the intervention(s) on biomedical or health-related outcomes.” The Food and Drug Administration (FDA) Amendments Act of 2007 requires registration of “applicable clinical trials” involving drugs, biologics, or devices that are subject to FDA regulations. These include the following:

- Trials of Drugs/Biologics: Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation
- Trials of devices: Prospective clinical studies of health outcomes comparing an intervention with a device against a control in human subjects (other than small clinical trials to determine the feasibility of a device, or clinical trials to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and pediatric postmarket surveillance studies, as required under the Federal Food, Drug, and Cosmetic Act.

B. National Institutes of Health Clinical trials funded either in whole or in part by National Institutes of Health. NIH defines a clinical trial as “a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.” This definition is broader than the FDA definition and includes Phase 1

clinical trials, and trials that do not involve any FDA-regulated products (such as trials involving only behavioral interventions).

C. International Committee of Medical Journal Editors (ICMJE) Any clinical trials that meet the clinical trial definition of the ICMJE that the investigator may wish to publish must be registered with ClinicalTrials.gov. ICMJE defines a clinical trial as “Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes.) Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration.”

II. INFORMED CONSENT REQUIREMENT

If a research study is a clinical trial that will be registered at ClinicalTrials.gov, the informed consent form must include the following statement: “A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. You can search this website at any time.”

III. WHO MUST SUBMIT THE REGISTRATION

The ClinicalTrials.gov registration must be submitted by the “responsible party (RP)” for the clinical trial. The RP may be an organization (such as a drug or device manufacturer, a university or academic medical center, or a government research organization such as the NIH), or an individual.

For industry-sponsored or multi-site trials, the industry sponsor or lead site generally is the RP. Multisite trials should be coordinated among sites and registered by the “lead sponsor” so that ClinicalTrials.gov does not receive multiple registrations for the same trial. For research studies that involve an Investigational New Drug (IND) or Investigational Device Exemption (IDE), the name of the IND/IDE holder should be entered as the RP.

The PI will be designated as the RP for registering the clinical trial when:

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

If the PI is responsible for the registration, he/she may designate an individual to register the trial(s) and complete the registration information. However, the PI is ultimately responsible for ensuring that the information entered is accurate and for releasing the protocol for the Protocol Registration System (PRS) posting. The clinical trial registration must be kept up to date should any changes to the protocol take place. Specifically, notice of recruiting status changes must be made immediately, and all submitted data must be reviewed, verified, and updated on a periodic basis (typically, every six months.)

IV. TIMING OF REGISTRATION AND RESULTS REPORTING

A. Initial Registration: If an investigator plans to publish, ICMJE requires that the clinical trial registration by the PI or designee occur prior to the enrollment of the first subject. Failure to do so will restrict publications in journals that follow ICMJE recommendations. Both the NIH and the FDA require that the study be registered no later than 21 days after the first subject enrollment.

B. Update of information: All information at ClinicalTrials.gov will be updated so that the record available to the public is continually up-to-date and accurate.

- An initial estimate of the completion date should be made at the time of registration, and updated at least once every 12 months. The completion date should be updated not later than 30 calendar days after the clinical trial reaches the estimated completion date.
- Recruitment status (active, not recruiting; recruiting, completed, etc.) should be entered at the initial registration and updated within 30 days of any change in recruitment status.
- Summary results for the primary outcome measures must be reported no later than one year after the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure.
- Results for secondary outcome measures must be entered one year after the date on which the final research participant is examined or receives intervention for the purpose of final collection for the secondary outcome measures.

- If the study involves an IND or an IDE, changes in the Device or Drug approval status must be reported within 15 calendar days.
- If the RP is notified by ClinicalTrials.gov of any errors, deficiencies, and/or inconsistencies in the registration, these must be updated within 15 calendar days.
- If the RP is notified by ClinicalTrials.gov of any errors, deficiencies, and/or inconsistencies in the results section of the registration, these must be updated within 25 calendar days.
- Throughout the duration of the study, the registration must be updated after one year regardless of whether there are any changes. A study is considered to be ongoing until the final subject has been examined or received an intervention for the purpose of collecting data in the primary outcome.

V. THE REGISTRATION PROCESS

A. Search ClinicalTrials.gov to ensure that the trial is not already listed. NIH-sponsored clinical trials and many industry-sponsored trials have already been registered on this site.

B. If the clinical trial still needs to be registered: Northern Illinois University has an account with ClinicalTrials.gov to allow designated NIU administrators to create a user account for PIs who need to register a clinical trial. The PI may contact the NIU administrator in either Sponsored Programs Administration (ASOSP@niu.edu) or in Office of Research Compliance, Integrity and Safety (ORCIS) (ResearchCompliance@niu.edu) to have a user account created. Once the user account is created, the PI will receive an email from ClinicalTrials.gov Registration with a user name and password. The PI will need to log in and change the password and may then begin the study registration process.

C. The ClinicalTrials.gov website provides information on how to register a study on the website at <https://clinicaltrials.gov/ct2/help/for-manager> The RP may copy and paste information from a grant application or IRB protocol into the data fields to ensure consistency of data entry. Data is saved as each page is filled in, so the registration may be completed in more than a single session.

Note about required training:

Researchers who are conducting a clinical trial that must be registered on ClinicalTrials.gov are required to complete the appropriate Good Clinical Practice (GCP) module in the CITI online training. A link to the CITI training is available on the ORCIS website at

<http://www.research.niu.edu/divresearch/compliance/human/training/index.shtml>

The researcher should make the appropriate selection from the following modules:

- GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)
- GCP for Clinical Investigations of Devices
- GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
- GCP – Social and Behavioral Research Best Practices for Clinical Research