

# ClinicalTrials.gov Registration & Results Reporting

## Background

---

[ClinicalTrials.gov](#) is a databank or registry of federally and privately supported clinical trials conducted in the United States and worldwide. It is managed by the National Library of Medicine within the National Institutes of Health (NIH). ClinicalTrials.gov is the result of a federal law requiring that clinical trials be registered to [improve public access to information about clinical research](#), promote public trust in research, and inform future research (Public Law 110-85). In some cases, registration is required for journal publication. This guidance document provides information about clinical trial registration requirements set forth by the Food and Drug Administration, the National Institutes of Health, and the International Committee of Medical Journal Editors.

## Applicability

---

### Food and Drug Administration (FDA) Registration Requirements

Registration at ClinicalTrials.gov is required for all [applicable clinical trials](#) (ACTs) that were initiated after 9/27/2007, or were initiated before 9/27/2007, but were ongoing as of 12/26/2007. Applicable drug and device clinical trials are defined as follows:

**Drugs and Biologics:** A controlled clinical investigation, other than a Phase 1 clinical investigation, of a drug or biologic product subject to FDA regulation.

**Medical Devices:** A prospective clinical study of health outcomes comparing an intervention with a medical device against a control, or pediatric postmarket surveillance required by the FDA.

Registration is *not* required for small trials to determine the feasibility of a device or to test prototype devices where the primary outcome measure relates to feasibility, and not to health outcomes. For more information, see:

[Identifying an “Applicable Clinical Trial” under FDAAA](#)

[Checklist for Evaluating Whether a Clinical Trial or Study is an Applicable Clinical Trial](#)

### National Institutes of Health (NIH) Registration Requirements

Clinical trials funded wholly or partially by NIH [must be registered](#) at ClinicalTrials.gov. 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. For more information, see:

[Clinical Trials Definition](#)

[Clinical Trials Registration and Results Reporting](#)

[NIH Decision Tool](#)

## ICMJE Registration Requirements

Member publications of the [International Committee of Medical Journal Editors \(ICMJE\)](#), require registry as a condition of publication. Thus, researchers who plan to publish in an ICMJE member journal must meet [ICMJE guidelines](#) for clinical trial registration.

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.*

## Frequently Asked Questions

---

### Who is responsible for registration and reporting results?

Responsibility for registration falls to the individual designated to be the [Responsible Party](#). At Iowa State, **the lead principal investigator for the project is the Responsible Party**, unless other requirements apply. For example:

For research involving an IND (Investigational New Drug Application) or IDE (Investigational Device Exemption Application) with the FDA, the holder of the IND or IDE is the responsible party unless responsibility has been delegated to the principal investigator.

In some cases, the sponsor (funder) of the project may be the responsible party—this is most common for industry-funded research.

It is very important for research teams to identify the Responsible Party and ensure their responsibilities are clearly articulated prior to starting a clinical trial. Substantial penalties (i.e., [monetary fines](#), withholding federal funds, denial of publication in an ICMJE journal, etc.) can be levied against Responsible Parties for failure to meet these requirements.

A Responsible Party may designate an individual to complete registration and results reporting in ClinicalTrials.gov. However, the Responsible Party is ultimately obligated to ensure that registration occurs and the information provided is accurate and current.

## How are clinical trials registered?

Clinical trials are registered via a web-based protocol registration system (PRS). Instructions for completing registration can be found [here](#).

Iowa State researchers who need an account may contact the PRS Account Administrator in the Office of Research Ethics at [cltrlgov@iastate.edu](mailto:cltrlgov@iastate.edu). Please be aware that setting up an account with the ClinicalTrials.gov federal office can take time, so plenty of advanced notice is advised.

***Important: The PRS Account Administrator's role is to help establish an account for the Responsible Party. The PRS Account Administrator is not responsible for registering a study, ensuring a study is registered or results are entered in accordance with required timelines, or verifying the accuracy of information entered by the responsible party.***

## How is registration handled for research projects conducted at multiple institutions?

A research project should be registered only once on ClinicalTrials.gov. Generally, the lead principal investigator should assume the role of Responsible Party register the project.

## When must clinical trials be registered?

FDA Applicable Clinical Trials and NIH-funded clinical trials must be registered no later than 21 days after enrollment of the first participant.

ICMJE requires registration *prior to* enrollment of any subjects, and member journals may decline publication articles from studies that were not registered in accordance with this requirement.

## When must results from clinical trials be reported to ClinicalTrials.gov?

Results from clinical trials must be reported to ClinicalTrials.gov no later than 12 months after the *primary completion date*. The *primary completion date* is defined as the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. See [this FAQ](#) for more information.

## What information must be provided to ClinicalTrials.gov?

Detailed information on the data elements required by FDA and the NIH for registration and results reporting can be found on the ClinicalTrials.gov PRS (Protocol Registration System) Information web site:

[Data elements for protocol registration](#)

[Data elements for results reporting](#)

## How often must data on ClinicalTrials.gov be updated?

For clinical trials initiated on or after January 18, 2017, information submitted to ClinicalTrials.gov must be updated at least once every 12 months. However, regulations require more frequent updates of certain information. See [this FAQ](#) for details.

## How does registration of clinical trials relate to IRB review and approval?

IRB review is a completely separate process from clinical trial registration. IRB approval is not required prior to *initial* registration at ClinicalTrials.gov, nor does the IRB review any information submitted for registration. However, IRB approval is needed before research activity with human subjects is initiated (including recruitment of subjects).

The Protocol Registration System requires information about IRB approval of Clinical Trials. If your clinical trial was approved by the Iowa State IRB, you may use the following information:

Board Name: Iowa State U IRB #1 (or, for prisoner research, Iowa State U IRB #2)

Board Affiliation: Iowa State University

Board Contact: Email: [IRB@iastate.edu](mailto:IRB@iastate.edu)

Address: Office of Research Ethics  
2420 Lincoln Way, Suite 202  
Ames, IA 50014

## Do I need to inform research participants about ClinicalTrials.gov Registration?

Yes! Research participants *must* be informed of the availability of clinical trial information on ClinicalTrials.gov. Federal regulations require the following language to be included verbatim in informed consent documents:

*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. You can search this website at any time.*

## What are the consequences for failure to properly register a clinical trial?

Under federal law, penalties for failure to register, or for providing incomplete, false, or misleading information (including updates subsequent to initial registration) may include [civil monetary penalties](#) of up to \$10,000 per incident and/or per day, non-compliance notices from the FDA, and, for federally-funded trials, the withholding or recovery of grant funds.

Compliance with ClinicalTrials.gov registration requirements is required by the terms and conditions of NIH awards. NIH grantees are required to [certify their compliance](#) with registration and reporting requirements in grant applications and progress reports. Failure to comply may lead to suspension or termination of funding and publicly identifying the clinical trial record as noncompliant in clinicaltrials.gov. NIH may consider compliance with these requirements in decisions about future funding.

Additionally, unregistered or improperly registered trials risk being declined for consideration by ICMJE member or other journals.

## Resources

---

### Clinical Trials.gov

[www.ClinicalTrials.gov](http://www.ClinicalTrials.gov)

[ClinicalTrials.gov FAQ's](#)

[ClinicalTrials.gov Protocol Registration System](#)

[ClinicalTrials.gov Federal Regulations](#)

### Food and Drug Administration

[Food and Drug Administration Amendments Act \(FDAAA 801\) Information](#)

[Checklist for Evaluating whether a Clinical Trial or Study is an Applicable Clinical Trial \(ACT\)](#)

[FAQ's](#)

### National Institutes of Health

[Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov](#)

[FAQ's](#)

### Document History

<i>Created/Approved:</i>	<i>May 4, 2012</i>
<i>Revised</i>	<i>January 18, 2017</i>
<i>Revised</i>	<i>November 21, 2023</i>