ClinicalTrials.Gov Registration & Reporting Requirements

PURPOSE:

ClinicalTrials.gov is an online database maintained by the National Library of Medicine (NLM) that documents information and results about clinical research studies. This information is available to researchers, health care professionals, and the general public to aid in finding potential clinical studies for patients to join or support new research. Database details may include diseases or health problems studied, information about who can join, and outcome results of the research.

What research studies must be registered with ClinicalTrials.gov?

1. **Applicable Clinical Trials that involve drugs, devices, or biologics that are regulated by the Food and Drug Administration (FDA).**
2. **Research that is federally funded and meets the definition of a clinical trial regardless of whether the trial involves an FDA regulated product.**
3. **Research that includes a plan to publish results in a medical journal AND the study meets the International Committee Journal Editors (ICMJE) definition of a clinical trial.**

Applicability:

Food and Drug Administration Requirements:

FDAAA801

Section 801 of the Food and Drug Administration Act (FDAAA801) defines registration and results reporting for clinical trials. Since 2017, these requirements have been most recently known as the Final Rule update to FDAAA801. A checklist-based tool to assist responsible parties in evaluating whether a study is an Applicable Clinical Trial based on 42 CFR 11.22(b) is now available here. **NOTE: Studies must be registered no later than 21 days after the first participant is enrolled.**

National Institute of Health Requirements:

All clinical trials funded or conducted by NIH in which human subject(s) are prospectively assigned to one or more interventions to evaluate the effects on biomedical or behavioral outcomes must be registered on ClinicalTrials.gov. The NIH definition of a clinical trial is

broader than the federal definition. **NOTE: Studies must be registered no later than 21 days after the first participant is enrolled.**

NIH DECISION TOOL

> This tool will allow you to respond to a set of questions and assist you with making a decision about the need to register the trial on ClinicalTrials.gov.

DECISION TOOL
Does your human subjects study may meet the NIH definition of a clinical trial.
FIND OUT HERE

International Committee of Medical Journal Editors:

The ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public registry at or before the time of first patient enrollment as a condition of consideration for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the relationship between a health-related intervention *and* a health outcome. **NOTE: Studies must be registered at time of or before the first patient is enrolled.**

Link to ICMJE Clinical Trials Registration Guidance:
https://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html

Penalties if Non-Compliant with these Regulations:

It is extremely important to comply with the regulations in place for clinical trial registration. Penalties can include inability to publish in medical journals, loss of federal funding, fines to the investigator and the institution as a result of criminal proceedings and civil penalty ordered.

ClinicalTrials.gov Registration and Reporting Requirements Summary Guide

For more information and guidance about submission requirements, timelines, and penalties, please refer to this guide with links included.

ClinicalTrials.gov Registration and Reporting Requirements Summary Guide

	FDAAA 801	NIH	ICMJE
Definition and Scope of "Clinical Trial"	Interventional studies (with one or more arms) of FDA-regulated drugs, biological products, or devices. • Applicable Clinical Trial (ACT) is the term used to designate the scope of trials that may be subject to the registration and reporting requirements in FDAAA. • See for FDAAA Definition (page 4) and Decision Tools here and here.	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. • See for NIH Definition and Decision Tool.	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. • See for ICMJE Definition.
Studies Requiring Registration	Applicable Clinical Trials (ACT) **regulated by the US FDA** • Drugs & Biologics: controlled clinical investigations of products subject to FDA regulation • Devices: 1. controlled trials with health outcomes of devices subject to FDA regulation 2. pediatric postmarket surveillance of a device as required by FDA	Clinical trials that are partially or fully *funded by the NIH*, **regardless of whether the trial involves an FDA regulated product**	Applies to clinical trials where the intention is to publish in an ICMJE member journal. • See here for journals stating that they follow the ICMJE policy.
Studies Not Requiring Registration	• Phase 1 drug and small feasibility device trials • Behavioral interventional trials (*unless funded by NIH*) • Observational studies • Registries • Retrospective chart reviews	• Observational studies • Registries • Retrospective chart reviews	• Observational studies • Registries • Retrospective chart reviews
Registration Time	No later than **21 days** after enrollment of the first participant – see here.	No later than **21 days** after enrollment of the first participant - see here.	**At or before** the first patient is enrolled in the study – see here.
Results Reporting Time	No later than **12 months** from the study's primary completion date – see here.	No later than **12 months** after the study's primary completion date – see here.	Results reporting is not required
Penalties	• Criminal proceedings and civil penalties (over $14,000/day until noncompliance is resolved • Loss of HHS funding	Loss of current or future NIH funding	Refusal to publish in ICMJE journals

Additional Resources:

To request an account on clinicaltrials.gov for trial registration, please email **orc_clinicaltrials@stonybrook.edu** with the individuals full name, institution email, and institution phone number.

ClinicalTrials.gov Taskforce:

If you are working at Stony Brook University with a professional role that includes registration and results reporting for clinicaltrials.gov you may be eligible to join the Clinical Trials Registration and Results Reporting Taskforce.

https://ctrrtaskforce.org/

Benefits of joining the Taskforce include:

- Up to date information about applicable regulations and guidance from a variety of relevant stakeholders.
- Monthly Taskforce calls
- Access to group e-mail distribution lists where questions can be posted and answered from all taskforce members **(GREAT FOR TROUBLESHOOTING)** and the opportunity to learn from collective knowledge.
- Access to tools and Templates created by the Taskforce

To request membership in this Taskforce, please complete the request here:

Clinical Trials Taskforce Membership Request