



Proposal Submission

Award and Account Establishment

After Research Commences

Closeout

What is ClinicalTrials.gov?

- ClinicalTrials.gov is a databank or registry of federally funded, privately supported, and unfunded clinical trials involving human subjects.

What types of clinical trials must be registered at clinicaltrials.gov?

- All clinical trials initiated after September 27, 2007 that relate to FDA-regulated drug, biological, and device product trials.
- All clinical trials supported by the NIH with a primary completion date on or after January 18, 2017, regardless of whether the trial is FDA-regulated or not.
http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm.
- All clinical trials giving rise to manuscripts that are submitted for publication to the International Committee of Medical Journal Editors (ICMJE) journal.

When do I have to register my clinical trial?

- You must register a clinical trial no later than 21 days after the first subject enrollment.
- For trials that may later be reported in a journal that adheres to ICMJE standards, registration must occur prior to the enrollment of any subjects.
- The Clinical Trials Office (CTO) at USC requires confirmation of registration prior to approving any Research Order Form (ROF) for the trial.

How do I register a clinical trial in ClinicalTrials.gov?

- Follow the registration steps found on the Department of Contracts and Grants [website](#) to obtain an account in the ClinicalTrials.gov Protocol Registration system (PRS).
- Provide all requested information related to your clinical trial at the time of registration.

References

- [USC Human Subjects Protection Program \(HRPP\) Policies and Procedures](#) (See Chapter 16, Section 12)
- [USC Guide to Research](#)
- Clinicaltrials.gov [registration checklist](#) for evaluating whether a clinical trial is an applicable clinical trial requiring registration.

