ClinicalTrials.gov Registration Requirements

USC Office of Culture, Ethics and Compliance
Research Compliance Program

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, p.365)

- USC Guide to Research

- Clinicaltrials.gov registration checklist for evaluating whether a clinical trial is an applicable clinical trial requiring registration.

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