**Registration for Clinical Research Trials**

Interventional studies with health outcomes must be registered, and may be required to report results, in ClinicalTrials.gov. Those responsible for conducting a clinical trial must make sure that they are in compliance with these requirements for:

**All NIH-funded trials including phase 1 studies and clinical trials of behavioral or non-FDA-regulated interventions (Registration and Results required)**

- The [US National Institutes of Health (NIH) Policy on the Dissemination of NIH-Funded Clinical Trial Information of 2016](https://www.researchgo.ucla.edu/clinicaltrialsgov) establishes the expectation that all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, will register their NIH-funded clinical trial, and submit summary results information to, clinicaltrials.gov for public posting.
  - [Click here to see if your clinical trial meets the NIH definition of a clinical trial](https://www.researchgo.ucla.edu/clinicaltrialsgov).

- Compliance with NIH Policy is a legal requirement and a term and condition of the NIH award, where applications or proposals are received by NIH on or after the policy’s effective date [January 18, 2017].
  - Consequences of noncompliance may include the suspension or termination of Federal awards and other penalties as described in the [Code of Federal Regulations (§ 75.371 Remedies for noncompliance)](https://www.researchgo.ucla.edu/clinicaltrialsgov). All competing applications (new and renewal) and progress reports for NIH grants (including cooperative agreements) supporting clinical trials must certify compliance with registration and results reporting requirements.

- NIH Application Guide, Section 4.7, Dissemination Plan: A link to [this webpage](https://www.researchgo.ucla.edu/clinicaltrialsgov) will suffice in addressing this requirement.

**Clinical trials involving FDA-regulated drug, biologic and device products (Registration and Results required).**
• **Section 801 of the Food and Drug Amendments Act, known as FDAAA 801**, requires registration and results reporting on the government web site called ClinicalTrials.gov for studies that meet the definition of “Applicable Clinical Trial”. [Click here to evaluate whether your study is an Applicable Clinical Trial (ACT) under 42 CFR 11.22(b)].

• Under the statute, responsible parties, including, for example, investigators and grantee institutions, could be held accountable for noncompliance, with the potential for substantial civil monetary penalties (exceeding $10,000/day), the suspension or termination of grant or contract funding from HHS agencies, and public identification of clinical trial record as non-compliant in ClinicalTrials.gov.

**Studies that will bill routine costs to Medicare or any other insurer (Registration required)**

Effective January 1, 2015, Center for Medicare and Medicaid Services (CMS) requires a clinical trial identifier (NCT#) to be reported on all billing claims for items/services related to a qualifying clinical trial(s). If your study will bill routine costs to Medicare or any other insurer, the study must be registered on ClinicalTrials.gov to obtain the NCT#.

**Clinical trials intended for publication in a journal recognized by the ICMJE (Registration required)**

The International Committee of Medical Journal Editors (ICMJE) requires, and recommends that all medical journal editors require, as a condition of consideration for publication, registration of [all] clinical trials in a public trials registry at or before the time of first patient enrollment.

Studies may be required to comply with clinical trial registration policies of other organizations.

**Informed Consent Statement**

Under new 21 CFR 50.25(c), a ClinicalTrials.gov consent statement must be reproduced word-for-word in informed consent documents for clinical trials registered under the requirements of FDAAA 801 or NIH Policy. In the UCLA IRB consent form in the section “WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY,” include the following:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Please see the following links for more information:
Registration for Clinical Research Trials
Published on ResearchGo | UCLA (https://www.researchgo.ucla.edu)

- UCLA Guidance on ClinicalTrials.Gov Registration and Reporting Requirements - Updated Guidance on ClinicalTrials.Gov Registration and Reporting Requirements
- Registering in the ClinicalTrials.gov Registry - Guidance for UCLA Sponsor-Investigators
- UCLA Creating a New Study Record - Tips on how to initiate a new record
- Resolving Problem Records - This guide explains the types of problem and how to resolve
- Summary of HHS/NIH Initiatives to Enhance Availability of Clinical Trial Information (effective January 18, 2017)
- Clinical Trial Registration for NIH Grantees Frequently Asked Questions (FAQs)
- Certifying compliance in NIH Grants and Progress Reports
- Changes from Current Practice Described in the Final Rule (PDF) (December 2016)

If you have questions or need assistance, please contact the CTSI for non-cancer studies and JCCC for cancer studies.

Last updated: 28 Aug 2023

Source URL: https://www.researchgo.ucla.edu/registration-clinical-research-trials

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