Registration for Clinical Research Trials

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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 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.

- 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). 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, 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:

- UCLA Guidance on ClinicalTrial.Gov Registration and Reporting Requirements - Updated Guidance on ClinicalTrial.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)**
- Steps to Compliance for NIH Awardees
- 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.

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