UCLA OHRPP
Office of the Human Research Protection Program

Guidelines for Registering in the ClinicalTrials.gov Registry (last updated April 21, 2016)

What Is ClinicalTrials.gov?

ClinicalTrials.gov is a publicly available registry and results database of federally and privately supported clinical trials conducted in the United States and around the world. The purpose of ClinicalTrials.gov is to disclose to the public key information about clinical trials that are currently available or that have been conducted. ClinicalTrials.gov captures significant summary protocol information before and during the trial as well as and summary results and adverse event information of a completed trial. Federal laws and regulations as well as editors of prominent medical journals require registration of a clinical trial, as described below.

Do I Need to Register My Clinical Trial?

Yes, if, as described below, your clinical trial

- meets the definition of clinical trial and
- you meet the requirements of the responsible person for registering the trial.

What Is the Definition of a Clinical Trial for Registration Purposes?

Three similar definitions of a "clinical trial" are provided below. If your study meets any one of these definitions, the trial should be registered.

The FDA (Food and Drug Administration) requires registration for "applicable clinical trials" defined as follows:

- For any trials of drugs and biologics: controlled clinical investigations, other than Phase I investigations, of a product subject to FDA regulation.
- For trials of biomedical devices: controlled trials with heath outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance.

The ICMJE (International Committee of Medical Journal Editors) definition of a clinical trial includes:

- 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.

The NIH defines a clinical trial as

- A prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices).

Who is Responsible for Registering the Trial?

By law, the "responsible party" must register a clinical trial. The responsible party is defined as:

- The ***sponsor*** of the clinical trial

OR

- The principal investigator (PI) of the clinical trial if so designated by a sponsor, grantee, contractor, or awardee. The PI should contact the sponsor for to confirm that they are the responsible party and responsible for registration of the trial.

- For those studies that involve an application for ***an Investigational New Drug (IND) or Investigational Device Exemption (IDE)***, the responsible party may be someone other than the PI. If the PI receives NIH or other government funding for a trial, particularly those that do not include an IND or IDE application, the PI is the responsible party. To ensure that any extramurally funded trial is properly registered, the PI should contact the sponsor for clarification.

- For ***clinical trials that are being performed at multiple institutions,*** the lead sponsor should take responsibility for registering the trial. If the PI is not the lead sponsor, he or she should work with the other investigators and sponsors to ensure that the trial is registered only once for the entire project.

- For ***investigator-initiated clinical trials***, whether or not there is industry funding or, in fact, if there is no funding, the PI is considered the sponsor and is responsible for registering the clinical trial.

For cancer-related trials, the Jonsson Comprehensive Cancer Center provides assistance in the registration process. Please contact the JCCC PRS Administrator, Mark Glover (mglover@mednet.ucla.edu) for more details.

When and How Does a UCLA PI Register a Trial?

When do I register my clinical trial?

Register a trial before any subjects are enrolled. The FDA requires you to register no later than 21 days after the first subject is enrolled; however, the ICMJE requires registration before the first subject is enrolled. To avoid publication restrictions imposed by the ICMJE, register your trial before enrolling the first subject. You may expect each registration to take approximately 1 to 2 hours.

What are the Steps for Registering?

Clinical trials are registered on ClinicalTrials.gov via a web-based data entry system called the Protocol Registration System (PRS). As a PRS user you are responsible for ensuring that the information you provide on your trial is correct, complete, readily understood by the public, and updated in a timely manner.

1. **Obtain a User Account:** To obtain a new PRS user account, contact the UCLA PRS Administrator, Elaine Cooperstein (ecooperstein@mednet.ucla.edu). The UCLA PI is the responsible official for initial registration and for keeping the listing updated. You will receive an e-mail confirmation within two business days when the user account has been created.

   To register a cancer related study, please contact the Jonsson Comprehensive Cancer Center PRS Administrator, Mark Glover (mglover@mednet.ucla.edu).

2. **Login to PRS:** Once your account has been created go to https://register.clinicaltrials.gov/. Complete the three fields on the Login screen. See example below:
   - Organization: UCaliforniaLA
   - Username: JDoe
   - Password:

3. **Create a Protocol Record:** A trial is registered in the system by creating a "protocol record." Click on the ***Create*** link under ***Protocol Records*** on the Main Menu and fill in a series of data entry screens. Clicking on the various fields will allow you to access instructions for that field. If you still have questions, mailto:register@clinicaltrials.gov

IMPORTANT NOTE: Using an electronic version of your protocol, you can copy and paste information into the requested data fields.

4. **Review the Protocol Record:** After filing in the last data entry screen, the ***Edit Protocol*** screen will appear. Review the information for accuracy and completely and address any ERRORS, ALERTS, WARNINGS, or NOTES in the protocol record. If you fail to do so, you cannot complete the registration process.

5. **Mark the Protocol Record as Complete**: If you fail to mark your record as complete, it will not be approved and released for publication and your trial will not be properly registered.

6. **Keep your Protocol Record Up-To-Date:** An affirmative verification or update of the data in the protocol records that have not been closed or terminated is required every six months. Failing to login to the PRS and confirm or update your record(s) every six months, regardless of whether there has been a change to the trial or not, may result in a loss of funding and/or the inability to publish the results of a trial in an ICMJE associated journal.

IMPORTANT NOTE: You will receive a reminder e-mail notification from clinicaltrials.gov once every six months to update your study information.

Suggestions for Completing Certain Items:

- **Pertinent Source Information:** It will be helpful to have the protocol, the informed consent document, the IRB application and the IRB approval letter on hand.
- **Unique protocol ID:** Use a combination of letters and numbers
- **IND/IDE Number:** If an IND or IDE is involved, you will need to enter the serial number. Refer to the IND/IDE letter from the FDA

- **Review Board Approval Number:** Include the IRB number assigned to the study
- **Board Name***:* Enter information for UCLA-IRB
- **Board Affiliation:** UCLA, Office of The Human Research Protection Program
  Institutional Review Board
  11000 Kinross Avenue, Suite 211
  Los Angeles, California 90095-1694
- **Oversight Authority:** Country: United States: Institutional Review Board
- **Record Verification Date:** The date of the most recent IRB approval. This date alerts the public as to whether the information is being kept current, particularly with reference to recruiting status and contact information.
- **Study Start Date:** Use date enrollment began--not date of IRB approval.
- **Last Follow-up Date:** Actual date that the last subject was examined or treated or anticipated date when expected last follow-up will occur.

Do Adverse Events Need to be Posted?

As of September 27, 2009 posting of adverse events is mandatory. Adverse Event posting is required for trials of FDA-approved drugs and biologics. The following *must* be reported:

- Serious adverse events and
- Other (non-serious) adverse events that exceed a frequency threshold of five percent in any arm of the trial

IMPORTANT NOTE: These reporting requirements are different from the UCLA – IRB reporting requirements. See UCLA Post-Approval Reporting Requirements Summary Sheet for details.

Do Basic Trial Results Need to be Posted?

- As of September 2008, posting basic study results is mandatory.
- Basic results posting is required for trials of FDA-approved drugs and devices.
- Submission of results is required within twelve months after primary endpoint completion date.

What are the Consequences of *Not* Registering a Trial?

There are penalties for responsible parties who fail to register clinical trials, keep the information up to date, or submit false or misleading information.

- Civil monetary penalties are allowed under FDA regulations.
- For federally-funded trials, the penalties could include withholding or recovery of grant funds.
- The inability to publish the results of a trial in an ICMJE associated journal.

What is the Specific Wording Required in the UCLA Consent Form?

In the UCLA IRB consent form in the section "WHO CAN I CALL IF I HAVE QUESTIONS ABOUT THIS STUDY," include the following wording:

Public Information about this Study:
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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Whom Do I Contact with Questions?

Contact the Office of Investigator Services (OIS)
310-794-CTSI (2874)
E-mail ois@ctsi.ucla.edu

References and Regulations

Clinical Trials.gov
- ClinialTrials.gov registry
- Clinical Trials.gov Protocol Registration System
- Clinical Trials.gov Fact Sheet

Food and Drug Administration
- Food and Drug Administration Amendments Act (FDAAA) of 2007
- Food and Drug Administration Modernization Act (FDAMA) of 1997

ICMJE Initiative

National Institutes of Health
- NIH Guide Notice NOT-OD-08-014
- NIH Guide Notice NOT-OD-10-007

Public Law 110-85, Title Vlll, Section 801

UCLA Memorandums
- UCLA Office of the VCR Memo: Mandated Clinical Trials Registration, April, 2008
- UCLA Office of the VCR Memo: Updated Guidance on Clinical Trial Registration Requirement (9/08)
- UCLA Office of the VCR Memo: Adverse Event Reporting in ClinicalTrials.gov registry (1/10)