

**Research Integrity Office**

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ClinicalTrials.gov Registration  
Requirements

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**Introduction**

The International Committee of Medical Journal Editors (ICMJE) and the Food and Drug Administration have requirements for clinical trials registration.

In their editorial in the New England Journal of Medicine (NEJM)<sup>1</sup>, the ICMJE has stated that they "will consider a trial for publication only if it has been registered before the enrollment of the first patient." The journal editors specified deadlines for compliance with this policy. Ongoing trials were to be registered by September 13, 2005 and any trials beginning after July 1, 2005, must be registered before the enrollment of the first patient.

In addition to clinical trial registration, in order to publish results of an industry-sponsored clinical trial in the Journal of the American Medical Association (JAMA), JAMA's requirements on data integrity and data analysis must be met. If you anticipate submitting an article on the results of an industry-sponsored clinical trial for publication in JAMA, you should review these requirements in the instructions for authors<sup>2</sup>.

The Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated that a "responsible party" (sponsor or designated PI) register and report results of "applicable clinical trials" at ClinicalTrials.gov.

**What Studies Must Be Registered?**

ICMJE adopted the World Health Organization's (WHO) definition of a clinical trial which has expanded the definitions of the types of trials that must be registered. "A clinical trial is 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. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc."<sup>3</sup> Purely observational studies do not require registration. The new definition went into effect for all trials that begin enrollment on or

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<sup>1</sup> Link to ICMJE NEJM editorial:

<http://gateway.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=fulltext&AN=00006024-200409160-00015&LSLINK=80&D=ovft>

<sup>2</sup> Link to JAMA requirements: [http://jama.ama-assn.org/ifora\\_current.dtl#SEC4](http://jama.ama-assn.org/ifora_current.dtl#SEC4), editorial regarding JAMA requirements: Fontanarosa PB, et. al, *JAMA*. 2005; 294:110-111

<sup>3</sup> Link to World Health Organization International Clinical Trials Registry Platform  
<http://www.who.int/ictrp/en/>

after July 1, 2008. If there is any question whether a study meets the expanded definition, then the investigator should register the trial.

FDA defines applicable clinical trials as

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation;
- Trials of Devices: a prospective clinical study of health outcomes comparing and intervention with a device subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies

### **Where Must Clinical Trials Be Registered?**

Studies that meet FDA's definition of an "applicable clinical trial" or the criteria outlined by ICMJE must be registered at [Clinicaltrials.gov](http://Clinicaltrials.gov). The other database that meets the criteria for oncology trials is the Clinical Trials Registration Program (CTRP) sponsored by the National Cancer Institute (NCI). The OHSU Knight Cancer Institute requires that all principal investigators (PI) conducting cancer-related, investigator initiated, interventional, clinical research studies list their studies through NCI's CTRP and [Clinicaltrials.gov](http://Clinicaltrials.gov). (This requirement does NOT apply to cooperative group studies, industry written studies, or studies that are investigator initiated at another medical institution where OHSU is a study site but not the lead investigator.)

Other registries may become available over time. If you plan to use a different registry to meet ICMJE requirement, verify that the registry collects the WHO Minimal Registration Data Set.<sup>4</sup>

### **Who Must Register Clinical Trials?**

The organization coordinating the trial is responsible for registering the trial:

- **Industry sponsored clinical trials:** For clinical trials being conducted by pharmaceutical and biotech companies, the industry sponsor or sponsor designee is responsible for registering the trial. To assure that the company registers the trial to protect the investigator's subsequent right to publish, OHSU includes language in all clinical trial contracts with industry sponsors to require them to register the trial. Please note that OHSU will not execute the contract until the industry sponsor provides proof of registration or gives OHSU permission for the investigator to register the trial. If an ongoing trial has not been registered by an industry sponsor who holds the IND/IDE, please contact Darlene Kitterman prior to registering the trial yourself. If the OHSU investigator holds the IND or IDE for the trial, then it is the investigator's responsibility to register the trial (see Trials conducted by OHSU investigators below).
- **Trials coordinated by other institutions or cooperative groups:** If a trial is coordinated by another institution or cooperative group, it is the responsibility of that institution or group to register the trial. However, because the study will not be accepted for publication if it has not been registered, the OHSU investigator should check [Clinicaltrials.gov](http://Clinicaltrials.gov) to assure the trial is listed prior to enrolling patients in the trial. If the trial is not listed, the investigator can contact the coordinating organization and ask for proof of registration or may register the trial himself (see how to register trials below).

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<sup>4</sup> Link to WHO Trial Registration Data Set [http://www.who.int/ictrp/data\\_set/en/](http://www.who.int/ictrp/data_set/en/).

- Trials conducted by OHSU investigators: Trials designed and conducted by OHSU investigators must be registered by the OHSU principal investigator in [Clinicaltrials.gov](http://Clinicaltrials.gov). If a trial meets the criteria for registration, but the deadline has been missed, the investigator must register the trial at the earliest opportunity. The ICMJE editors can decide to publish unregistered trials on a case-by-case basis. Authors whose trials are unregistered will need to convince the editor that they had “a sound rationale” when they decided not to register their study (ICMJE, 2004).

**How to Register Clinical Trials in [Clinicaltrials.gov](http://Clinicaltrials.gov) (For cancer studies, see instructions below for NCI CTRP):**

OHSU is not registered with ClinicalTrials.gov Protocol Registration System (PRS); therefore, you will need to apply for your own PRS account.

- If the study is funded by the NIH, you will be prompted to send an email to [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov) including the trial title, grant number and NIH institute or center. You will not need to perform the registration steps outlined below. You will be contacted by your NIH institute with further instructions for fully registering the trial.
- If this is the first trial registered by an investigator and the trial is not NIH funded, the investigator must obtain an individual account at [Getting a PRS Individual Account](#). Note that in answer to Question 6 on the PRS Individual Account Web site, OHSU is not registered with PRS and you will need to apply for your own account.
- When requesting the PRS account, OHSU is listed as the “sponsor.” If the study is funded by a company, list Darlene Kitterman, Program Director, Investigator Support and Integration Services (Oregon Clinical & Translational Research Institute) as the “Official Representative.” If the study is funded by any other mechanism, list Deborah Golden-Eppelein, Director, Research Grants and Contracts as the “Official Representative.” If the investigator holds an IND or IDE for the trial, list the “Regulatory Authority” as the FDA. Otherwise, list the “Regulatory Authority” as the OHSU Institutional Review Board. Please refer to Appendix 1 for more details regarding OHSU-specific PRS account application information.
- After the trial receives IRB approval and you have obtained a PRS account, follow the instructions forwarded to you with your PRS account information to register the trial. Please refer to Appendix 2 for OHSU-specific PRS account registration information. *Keep the Org Name, Username and password in a secure location so you can update your study information as required.*
- Clinical trial registration must be kept up to date should any changes to the protocol take place. Specifically, notice of recruiting status changes must be made immediately, and all submitted data must be reviewed, verified, and updated every six months.

**How to Maintain Your Study Registration:**

You must update your Clinicaltrials.gov registration at least every 6 months and as new information (e.g.: change in IRB status, changes in study design) or results are available.

For FDA “applicable clinical trials, the responsible party is required to submit basic results information no later than 1 year after the final subject as examined or received an intervention for the purposes of data collection for the primary outcome. This requirement must be met whether the trial was

concluded according to the protocol or was terminated. There are allowances for delayed submission of results with certification <http://prsinfo.clinicaltrials.gov/DelayedSubmission.html>.

### **How to Register Clinical Trials in NCI CTRP (Cancer Studies):**

OHSU Knight Cancer Institute centrally registers investigator initiated interventional oncology studies that require both Clinicaltrials.gov and NCI CTRP registration. Please see the [OHSU Knight Cancer Institute Clinical Trials Registration SOP](#) for instructions.

### **Reporting Basic Results in ClinicalTrials.gov**

The NIH published an article with instructions for reporting basic results including baseline characteristics, outcome measures and statistical analysis and adverse events in ClinicalTrials.gov. <http://chestjournal.chestpubs.org/content/136/1/295.full?sid=5bf6541b-d31a-4bc2-9460-35a4a3172186>.

### **Resources Regarding Clinical Trial Registration**

#### ***Links***

- [Clinicaltrials.gov](#) Account Request: <http://prsinfo.clinicaltrials.gov/gettingIndivAccount.html>
- [Clinicaltrials.gov](#): <http://www.clinicaltrials.gov/>
- International Committee of Medical Journal Editors (ICMJE) Statement: [http://www.icmje.org/clin\\_trialup.htm](http://www.icmje.org/clin_trialup.htm)
- NIH Trial Registration: [register@clinicaltrials.gov](mailto:register@clinicaltrials.gov)
- Reporting Basic Results in Clinicaltrials.gov <http://chestjournal.chestpubs.org/content/136/1/295.full?sid=5bf6541b-d31a-4bc2-9460-35a4a3172186>.
- Results Data entry checklist <http://prsinfo.clinicaltrials.gov/pre-submission-checklist.pdf>

#### ***OHSU Resources***

- [Clinicaltrials.gov](#): Bridget Adams, 4-5077
- NCI CTRP: Nelson Spencer & Lara Fournier (email: [ctrp-admin@ohsu.edu](mailto:ctrp-admin@ohsu.edu))

**Appendix 1 – OHSU Specific PRS Account Request Information**

Type of Organization: University

Country: USA

Organization Name: Oregon Health & Science University

Organization Address:  
3181 SW Sam Jackson Park Road  
Portland, OR 97239

Organization Abbreviations and Acronyms:  
OHSU

Parent Organizations, if any:

Regulatory Authority: OHSU Institutional Review Board

Regulatory Authority Address:  
2525 S.W. 1st. Ave., Suite 125  
Mailcode: L106-RI  
Portland, OR 97201

If funded by an industry sponsor:

Official Representative: Darlene Kitterman

Phone: 503-494-6263

Email: kitterma@ohsu.edu

Organization URL (optional): http://w w w .ohsu.edu/

If funded by any other source:

Official Representative: Deborah Golden-Eppelein

Phone: 503-494-4853

Email: goldenep@ohsu.edu

Organization URL (optional): http://w w w .ohsu.edu/

## Appendix 2 – OHSU Specific PRS Trial Registration Information

**Board Name**

OHSU Institutional Review Board

**Board Affiliation**

Oregon Health and Science University

**Board Chair**

Kathryn Schuff, MD

503-494-1685

[schuffk@ohsu.edu](mailto:schuffk@ohsu.edu)

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