Purpose

This SOP outlines the process for registering clinical research studies through the National Cancer Institute’s (NCI) Clinical Trials Registration Program (CTRP) and the NIH website database, www.clinicaltrials.gov.

Scope

This process applies to all cancer-related, investigator-initiated, interventional clinical research studies conducted at OHSU. It does not apply to cooperative group studies, industry sponsored studies, or studies that are initiated by an investigator at another medical institution where OHSU is a participating study site but not the lead investigator, as groups outside of OHSU maintain the responsibility for registering the clinical studies.

Studies that were previously registered in PDQ (Physicians Data Query) or Clinicaltrials.gov do not need to re-register their studies, however, you may be contacted to supply additional information.

Background and References

The International Committee of Medical Journal Editors (ICMJE) recommended that sponsors of interventional clinical trials list their studies with a clinical trial registry that is accessible to the public and free of charge. The ICMJE member journals will require, as a condition of consideration for publication, registration in a public trials registry. The ICMJE does not advocate one particular registry but suggested that sponsors list with clinicaltrials.gov or a similar public registry. For more information on the ICMJE publication requirements go to: http://www.icmje.org/

More recently, the Food and Drug Administration Amendments Act of 2007 (FDAAA or US Public Law 110-85) was passed on September 27, 2007. The law requires mandatory registration and results reporting for certain clinical trials of drugs, biologics, and devices.

For more information about this law and requirements for sponsors and/or investigators, visit the PRS (Protocol Registration System) and U.S. Public Law 110-85 Information Page

The NCI has implemented CTRP, a new registration system that adheres to these expanded requirements

- This SOP applies to all new trials meeting the above scope.
**OHSU IRB approval of the registration text is NOT REQUIRED.** The OHSU IRB Compliance Manager and IRB Co-Chairpersons stated in an email communication with CRM (dated 5/18/05) that submitting a protocol summary to the NCI PDQ database does not require review or prior approval from the OHSU IRB. They stated that submitting basic facts about a study for inclusion in the NCI online database does not require an “advertisement” IRB review.

Investigators wishing to submit an advertisement to another website should follow the OHSU IRB policy for review and prior approval of the text.

OHSU IRB Policies (see Advertisement Policy under Recruitment & Patient Rights)

http://www.ohsu.edu/xd/about/services/integrity/policies/irb-policies-recruitment.cfm

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**Procedures**

**New Study Registration**

1. Study staff member submits the following documents by email to: [ctrp-admin@ohsu.edu](mailto:ctrp-admin@ohsu.edu) with email subject line: New Protocol Registration {your IRB#} – this is an OHSU email box administered by the Knight CTRP Manager.
   - a. The full protocol
   - b. Clinical Research Review Committee (CRRC) approval memo
   - c. IRB Initial Study Approval Memo
   - d. Knight registration checklist

   **Note:** Trials should ideally be registered before the first subject is consented and must be registered with 21 days of first subject enrolled. **-- If you are aware that you’ll need to start enrollment very soon/immediately after IRB approval, and protocol materials are near final, you can start the registration process before IRB approval has been obtained.**

2. Knight CTRP Manager enters study data into CTRP and provides a draft trial summary report (TSR) to the submitter for review

3. Submitter reviews the TSR, noting any changes and then returns to Knight CTRP Manager at [ctrp-admin@ohsu.edu](mailto:ctrp-admin@ohsu.edu)

4. Steps 1-3 continue until posting is accurate and complete

5. Once posting is accurate and complete, the Knight CTRP Manager will finalize the submission of the study registration to NCI CTRP and www.clinicaltrials.gov.
Changes to Existing Postings

If you need to make updates/changes to existing registrations, please notify Knight CTRP Manager (ctrp-admin@ohsu.edu).
SOP: Knight Clinical Trial Registration

☐ New SOP
☐ Revised SOP

Brief summary of changes:

- 5/19/2011 (Nelson Spencer): Updated contact information in the procedure section and added the revised SOP to the current SOP template.

Approvals:

_____________________________ _______________________________ __________________
Print Name                      Signature                        Date
Director of Knight Clinical Trials Office or Designee

_____________________________ _______________________________ __________________
Print Name                      Signature                        Date
Knight Clinical Research Management Leadership Committee

_____________________________ _______________________________ __________________
Print Name                      Signature                        Date
Knight Executive Leadership Committee