

CHILDREN'S HOSPITAL AND REGIONAL MEDICAL CENTER  
Seattle, Washington

OPERATING POLICIES / PROCEDURES

DEPARTMENT: Office of Vice President for Research  
POLICY NUMBER: OVPR-15  
REPLACES: \_\_\_\_\_  
EFFECTIVE DATE: April 20, 2005  
REVISION DATE: \_\_\_\_\_

POLICY TITLE: Clinical Trials Compliance Review Program

POLICY:

**Federal regulations and guidance requires clinical trial monitoring to verify that: (a) the rights and well-being of human subjects are protected, (2) reported trial data are accurate, complete, and verifiable from source documents, and (3) the conduct of trials is in compliance with approved protocol, with Good Clinical Practice (GCP), and with applicable regulatory requirements. To address these requirements, Children's Hospital's Office of Clinical Research shall manage a Clinical Trials Compliance Review Program charged with conducting clinical study reviews and serving as an educational resource.**

PROCEDURE:

- 15.1 The Office of Clinical Research (OCR) shall establish and manage a Clinical Trials Compliance Review Program (CTCRP) charged with: (1) education and (2) conducting clinical study reviews. OCR may establish specific policies under which this program shall operate, provided that any such policies are consistent with OVPR15. The Research Executive Committee shall have oversight responsibility for the CTCRP.
- 15.2 The CTCRP shall conduct clinical study reviews to determine that the rights and safety of research subjects are maintained and the educational and training needs of research professionals are met. Reviews shall ensure compliance with 45 CFR Part 46, 21 CFR Parts 50, 312 and 314, ICH Guidelines as adapted by the FDA, and Children's Hospital policies.
- 15.3 The CTCRP shall conduct the following types of reviews:
  - 15.3.1 Closed Medical Record Review. Conducted on a random basis by to obtain a sampling of the quality of research compliance; not intended as a complete review of the study itself. Identified by querying the IRB database.

- 15.3.2 Random Study Review. Conducted on a random basis by querying the IRB database. A site visit is conducted by a CTCRP monitor to review the regulatory files and documents maintained by the investigator. Following the review, the study monitor will schedule an exit meeting with the principal investigator and prepare a confidential summary report.
- 15.3.3 For-Cause Study Review. Conducted on the basis of known or suspected violations of human subject or GCP regulations. The investigator, Division Chief, Department Head and Medical Director shall be notified by the CTCRP of For-Cause Study Reviews. A site visit is conducted by a CTCRP monitor and will focus on the study in question. Substantiated compliance findings can lead to audits of all active studies conducted by the PI. Following the review, the study monitor will meet with the PI, Division Chief, Department Head and Medical Director to discuss findings. A summary report will be prepared, with notification to the Vice President for Research should finding require reporting to OHRP and/or FDA.
- 15.3.4 Investigator Initiated Review. Investigators may request a review of regulatory files and documents for educational purposes.
- 15.4 Investigators must be given a minimum of two weeks advanced notice for Closed Medical Record Reviews [OVRP15.3.1] and Random Study Reviews [OVRP15.3.2]. This notification should include the name and CV of the medical monitor and a list of materials to be made available to the monitor at the time of the review. Advanced notice requirements are not required for For-Cause Study Reviews [OVRP15.3.3].
- 15.5 Investigators are required to make requested information available to the CTCRP monitor.
- 15.6 For Medical Record Reviews [OVRP15.3.1] and Random Study Reviews [OVRP15.3.2] Investigators may request a change in medical monitor if they feel a conflict of interest exists. Such request must be made in writing to the Vice President for Research within 7 days of the advanced notice date and include compelling evidence of a potential conflict of interest. The Vice President for Research shall rule on the request within 2 days. The date of the review shall not be changed even if the Vice President for Research agrees to the assignment of a new monitor.
- 15.7 In the course of conducting any of the reviews outlined in OVRP15.3, should a reportable incident of non-compliance be found, the medical monitor shall report this immediately to the PI, Division Chief, Department Head and Research Executive Committee.
- 15.8 The CTCRP shall report de-identified summary findings of its monitoring activities to the Clinical Research Steering Committee on a quarterly basis. The Clinical Research Steering Committee shall be responsible for recommending educational programs designed to familiarize investigators with Federal and local regulations/policies.

15.9 Monitors shall be appointed by the OCR Director and shall be appropriately trained with the scientific and/or clinical knowledge needed to adequately monitor a trial. Monitors must be thoroughly familiar with the investigational product, the protocol, the written informed consent and assent forms, and any other information provided to subjects in advance of a site visit. If in the opinion of the OCR Director, a study to be monitored requires qualifications that cannot be met by Children's employed staff, an outside monitor may be contracted.

15.10 Pharmaceutical sponsored clinical trials that are monitored by the Sponsor or Contract Research Organization are not exempt from this policy.

Submitting Office: Vice President for Research

Approved by:

 7/28/05  
Vice President for Research Date

 7-28-05  
Chair, ROC Date