The University of Chicago
Division of the Biological Sciences
and
The University of Chicago Hospitals

Faculty and Staff Training Requirements for the Conduct of Clinical Research

Issued: 11Aug09
Revised:
Reviewed: 15JUN09

Purpose

To ensure that faculty and staff engaged in clinical research are appropriately trained in research conduct, ethics and protocol management with the goals of protecting human subjects, institutional compliance and applicable federal regulations.

Scope of the Policy

This policy applies to all faculty and staff involved in the conduct of clinical research. No individual will be permitted to conduct research activities involving human subjects without meeting the Clinical Research Policy Board's training requirements.

Definitions

Faculty includes principal investigators, co-investigators, and other University of Chicago faculty that are involved in the research process. This includes but is not limited to faculty listed on the grant or contract application; faculty listed on a FDA form 1572/Investigator agreement; faculty who are named as contact persons in the informed consent documents or research recruitment materials; faculty who provide supervision of the persons who are obtaining informed consent to participate in research or faculty that provide any direct patient care to the subjects within the trial.

Research Staff This includes all personnel who assist the PI in the research process including but not limited to research coordinators, research nurses, data managers, regulatory managers, students, volunteers and all other non-faculty who are assigned research duties by the principal investigator on the delegation of authority log and the IRB form B.

Initial Training Requirements Describes the minimum degree of prior training required by research staff before they will be permitted to participate in the conduct, review, or oversight of human subject research.

Continuing Training Maintenance Requirements Describes the minimum amount of mandatory training that must be documented every three years to be permitted to continue to participate in the conduct, review, or oversight of human subject research.

Training Requirements

Faculty and Research Staff - Initial Training Requirements

Prior to participation in any clinical research protocol within ChicagoBioMedicine, faculty and staff will be required to complete the current training expectations as determined by the Clinical Research Policy Board and the Council of the BSD Institutional Review Board.

Continuing Training Maintenance Requirements (On-going Training) for all Faculty and Staff

Faculty and staff will be expected to complete on-going training with acceptable documentation every three years. What is deemed acceptable will be determined by Clinical Research Policy Board and the Council of the BSD Institutional Review Board.

Monitoring of Compliance

Department administration will be responsible for ensuring compliance with this policy and keeping training documentation for all faculty and research staff. The Office of Clinical Research will verify training requirements are met when new protocols are submitted for institutional review and approval. Documentations of any training received through external sources must be provided.

Failure to Comply

Failure to comply with this policy will be reported to the Associate Dean of Clinical Research, Chairman of the Institutional Review Board, the Chief Compliance Officer, and the Chief Medical Officer for determination of corrective action.

Signature/Date: _____ 6-16-09

Dean, Division of the Biological Sciences and the Pritzker School of Medicine and CEO, University of Chicago Medical Center

Date Approved: _____

Oversight Responsibility: This policy is managed by the Medical Center Office of Clinical Research. Revisions to the policy will be made periodically by the Clinical Research Policy Board.

Approved by:
Comments: