Children's Hospital and Health System, Inc.
Administrative Policy and Procedure

SUBJECT: Required Research Training

POLICY

It is the policy of Children's Hospital and Health System (CHHS) that all investigators and related staff conducting clinical research at CHHS meet current regulatory requirements and core research competencies.

The purpose of this training is to assure responsible conduct in research, scientific integrity, and demonstrate a public duty to our research volunteers, community and sponsors and to comply with Federal regulations. The Children's Research Institute has established training standards for clinical research in the following areas: Human research protection, biomedical ethics, and shipping of hazardous materials.

Clinical Research: To comply with the terms of our Federal wide Assurance, any person participating in research on human subjects must have training in the Protection of Human Subjects. This policy applies to all "Clinical Researchers", defined as investigators, research or study coordinators/assistants, research nurses, or any employee or member of the research team who has contact with human subjects specifically for research purposes.

Examples of research purposes (including but not limited to):

1. Subject recruitment
2. Consent/Assent Process or HIPAA Authorization
3. Administration of study medications
4. Use of study devices
5. Administration of study surveys, tests, questionnaires.
6. Recording/Obtaining subject data in a manner that is different from or exceeds standard hospital practice.
7. Access to identified human data for research data collection.

This policy does not apply to hospital staff interacting with study subjects only to provide non-experimental support care or procedures for a subject participating in research.

Examples (Including but not limited to):

1. Staff performing a CT scan as part of a research protocol.
2. Staff collecting blood samples in the CHW Laboratory.
3. Nursing staff providing standard care for a patient enrolled in a study.

Protection of Human Subjects: The approved training program is the Collaborative Institutional Training Initiative (CITI) in Human Research (www.CITIprogram.org). CRI and the Children's Hospital of Wisconsin IRB require completion of this program for all "Clinical Researchers" as defined above. Biomedical, Social Behavioral, and Community partner tracks are all available to accommodate the best fit for training depending on the research focus. Once initial certification is obtained, the CITI Refresher Course must be completed every two years.

Research Ethics: All new research personnel handling, recording, generating, analyzing, or publishing scientific data must complete one time training in research ethics. The approved training for Research ethics is the Responsible Conduct of Research (RCR) module developed by CITI (www.CITIprogram.org). This module focuses on data integrity, authorship, publication rights, mentoring, conflicts of interest and other ethical issues. Thereafter, all research personnel are required to reaffirm their understanding of these ethical standards every 2 years by reading and signing the CRI Code of Ethics. Researchers who have previously completed a CRI code of ethics, are not required to complete the RCR module.

Shipment of Hazardous Materials: Federal law requires specific training for any person shipping or supervising the process of shipping, or causing the shipment of biological or hazardous materials. Online training for shipment of non-infectious diagnostic samples is available through Children's University. If researchers are shipping known infectious materials, additional training is required. The preferred training option for shipping known infectious materials is available commercially from Saf-T-Pak (www.saf-t-pak.com). Trainees must sign their certificates and forward the certificate to the CRI for Institutional signature. Training is not valid without Institutional signature. This training is only required for those who ship hazardous materials. Researchers not shipping diagnostic or known hazardous materials are not required to complete this training.

Variances:

- "Exempt" human subjects research protocols: Protocols submitted to the CHW Human Research Review Board which qualify for Exempt status require only Investigator level researchers to complete these training requirements.

- Off-site collaborators: Researchers collaborating with Investigators at CHW, but working off campus may substitute local training materials in place of CITI and RCR if the training occurred within the prior 2 years. If no such comparable training has been completed, the researcher will be asked to complete CRI required CITI training and the CRI Code of Ethics.

- Non-scientist, community research team members are exempt from RCR Ethics training, and instead should simply submit a complete CRI Code of Ethics form.

- Unusual circumstances: In certain cases there may be unusual events that complicate compliance with these training standards. Such cases will be subject to ad hoc review, and all decisions will be documented within the HRRB office.

Procedure for tracking Training:

1) All HRRB submissions require a complete list of all Clinical Researchers as defined above, who will be participating in conduct of a human research project. Any investigators or staff added to the study after IRB approval must also meet the training requirements.
2) For the protection of our staff and research subjects, no study will be approved by the CHW HRRB until verification of Human Protections and Research Ethics training. Training for Shipment of hazardous goods is study specific and will not affect study approval by the HRRB office.
3) CRI Administration will maintain a training records database for investigators and research staff. CRI will send e-mail reminders to researchers on file to notify them when retraining is due.
4) It is ultimately the PI's responsibility to ensure that all research team members meet training requirements. It is recommended that all Investigators keep a copy of training records for their study personnel in order to confirm compliance in the event of a question.
5) CITI training for the protection of human subjects and the Responsible Conduct of Research (Ethics may be found at www.citiprogram.org, or be accessed through the CRI website). Users must register for an account and sign up for the desired trainings available through CITI. More details are available on the CRI website.

Approved and signed 02/2009 by

Peggy Troy, President CHHS
(Signed copy on file)