

# Children's

Hospital & Regional Medical Center  
Office of the Vice President for Research

## OPERATING PROCEDURES/POLICIES

|                 |                                   |
|-----------------|-----------------------------------|
| Committee:      | <u>Institutional Review Board</u> |
| Policy Number:  | <u>IRB-17</u>                     |
| Effective Date: | <u>June 20, 2005</u>              |

### POLICY TITLE:

### INVESTIGATOR and RESEARCH TEAM MEMBER TRAINING IN THE PROTECTION OF HUMAN SUBJECTS

### POLICY:

All investigators and research team members involved in the design or conduct of any research project involving human subjects that is subject to review and approval by the Children's IRB shall undergo training in the protection of human participants in research.

### DEFINITIONS:

**Principal Investigator.** Individual responsible for directing a research project.

**Research team members.** Individuals who contribute in a substantive way to the research project. These may be team members who are responsible for the scientific development or conduct of a research study, members who interact directly with the participants or their individually identifiable private health information, e.g., obtain consent or assent, conduct research visits, administer research surveys, questionnaires, or review medical records for research purposes. Team members may include but are not limited to: co-investigator(s), post-doctoral fellow(s), graduate student(s), research technician(s), research assistant(s), research coordinator(s) and research technologist(s).

### PROCEDURE:

17.1 The principal investigator and all research team members responsible for the design and conduct of the human subjects part of any research project must be trained prior to project initiation. This policy shall apply to all research

projects regardless of funding source.

- 17.2 Upon receipt of a new application for IRB review, the IRB Coordinator conducting the preliminary review of the application (pre-review) shall review the information provided in the application by the principal investigator regarding human subjects protections training of the PI and research team members. If any research team member has not had the required training, the principal investigator shall be notified that such training is required before the team member can work on the research project. The Principal Investigator shall be responsible for ensuring that all research team members are current in their human subjects protections training.
- 17.3 Children's IRB allows the following training to satisfy this policy for basic human subjects protections training:
- A. Workshops provided by the IRB Chair of Children's. This workshop provides a basic overview covering history, ethics, and the federal regulations pertaining to human subjects protections with a specific emphasis on research involving children.
  - B. Human Subjects Protections Training workshops provided by University of Washington or Fred Hutchinson Cancer Research Center IRB Office.
  - C. Human Subjects Protections Training workshops provided by recognized agencies, e.g., Office for Human Research Protections (OHRP), U. S. Food and Drug Administration (FDA), Association for Applied Research Ethics (ARENA), Public Responsibility in Medicine and Research (PRIM&R).
  - D. Completion of the Investigator 101 CD-rom training produced by the Office for Human Research Protections. Copies of this training CD are available in the IRB office.
  - E. Web-based on-line training, called Collaborative IRB Training Initiative (CITI), available to University of Washington faculty. UW faculty may find information about this site at University's IRB web page at <http://depts.washington.edu/hsd/INFO/train.htm> or at CITI <http://www.miami.edu/citireg/>
  - F. IRB member training provided by the institution of the IRB member.
  - G. Other training tutorials or workshops offered by recognized organizations, upon review and approval by Children's IRB Chair and IRB Manager.
- 17.4 Documentation of training will be required for each research team member listed on the IRB application in which Children's IRB review and approval is required.
- 17.5 All research team members must have human subjects protections training for the IRB to grant final approval to a research project. In the event that all

conditions for final approval have been met, but one or more research team members have not completed human subjects protections training, the principal investigator may choose either to wait for final IRB approval until all research team members have received human subjects protections training and provided the documentation to the IRB or remove the persons as research team members. These persons may be added on as research team members after they have obtained human subjects protections training and provided documentation to the IRB of their training.

Submitting Committee: \_\_\_\_\_ Institutional Review Board

Approved by: Douglas S. Diehema 6/20/05  
Chair Date

Elizabeth Trias 6/20/05  
Manager Date