



## Education and Training: Administrative Staff, IRB Members and Others

### Policy

Children's Hospital policy requires all individuals who are involved either in the performance of clinical research or the oversight of clinical research to be trained in human research protection issues. The type and amount of training required is contingent upon the individual's role in the performance and oversight of the research.

### Purpose

Children's Hospital recognizes the importance of having a strong, comprehensive educational program that ensures that any individual involved in the performance of human subject experimentation at the Hospital understands the ethical principles and regulatory requirements related to the protection of human subjects. The Children's Hospital educational program tailors training to the specific needs of those involved in clinical research at multiple levels. The following information describes the current and future activities developed to provide the necessary education.

### Procedure

#### Medical Staff Executive Committee

The Committee on Clinical Investigation (CCI) is a standing committee of the Medical Staff Executive Committee (MSEC). The MSEC is comprised of all of the Chiefs of service, as well as the President and other senior management representatives. The Chair, the Director of Clinical Research Compliance, and the Institutional Official report to the MSEC on a yearly basis and make additional presentations as requested by the CCI. One purpose of the annual report is to inform and educate Medical Staff Executive Committee members about new federal regulations, IRB initiatives, and policy changes that affect the human subject protections program at Children's Hospital. This occurs, at a minimum, on an annual basis and, at the request of the CCI Chair, more frequently if required.

## **Institutional Official**

The Director of Clinical Research Compliance reports directly to the Vice President of Research Administration, who serves as the Institutional Official. The Institutional Official maintains copies of all pertinent federal regulations and institutional policies and procedures. The Director of Clinical Research Compliance meets with the Institutional Official every week as part of the Directors meeting and on an as needed basis. The Institutional Official is kept apprised of new regulations, mandates and changes in federal policy.

## **CCI Members and Chair**

### **Orientation**

Newly appointed CCI members are required to attend an individualized, comprehensive orientation with the Director of Clinical Research Compliance. At this orientation the history of human subject protections, ethical principles, pertinent federal regulations, and specific institutional policies and practices are discussed. Each member is provided with a copy of the Belmont report, 45 CFR 46, Food and Drug Administration regulations, institutional policies and procedures, a list of resources that includes pertinent web sites, and any other material that is deemed necessary at that time. Members are made aware of a human subject library, which is a collection of books and journal articles that pertain to human subject experimentation. The Director of Clinical Research Compliance maintains this library.

### **Observing CCI Meetings**

Each newly selected CCI member is required to attend at least one CCI meeting as an observer before undertaking the review of research protocols. Newly selected members are also encouraged to seek the assistance of other or outgoing members as they begin to review protocols. Members are encouraged to contact the Director of Clinical Research Compliance whenever specific issues or questions arise.

### **Additional Training**

- Each CCI member is provided with a copy of several resource books which include the Amdur IRB member book and the Institute of Medicine report on research Involving Children
- All CCI members must complete the CITI web-based training.

### **Ongoing and Continuing Education**

All CCI members regularly receive relevant articles and materials as part of their ongoing education. Articles and publications are provided with the protocols that are distributed every other week. Bibliographies of articles pertinent to human subject protections are also distributed on a regular basis. A portion of each meeting is dedicated to the discussion of new and relevant training information. When necessary, the CCI seeks outside assistance and expert advice on new procedures that raise unexpected ethical concerns. IRB members are offered the opportunity to attend the PRIMR national meeting as well.

**CCI Administrative Staff**

All staff involved with the CCI report either to the Manger of Clinical Investigation or the Director of Clinical Research Compliance, who is responsible for their education, training, and performance. Each newly hired CCI staff member receives intensive, individualized training from the Manager and Director of Clinical Research Compliance. Each new staff member also receives the materials mentioned above as well as office administrative operating procedures. All new staff members are required to complete the CITI web-based training. All newly hired staff members are required to take the PRIMR IRB 101 course and the Administrator 101 course, and to attend PRIMR/ARENA meetings and other appropriate regional workshops. In addition, the administrative staff of the CCI are urged to take the CCIP (Council for the Certification of IRB Professionals) certification exam once they have had sufficient experience.

**Other Research Administration Staff**

On an as needed basis, individual seminars and "in services" are held by the Director of Clinical Research Compliance for members of the Office of Sponsored Programs and the Technology Transfer Office. The "in services" review the responsibilities of these departments in the institution's human subject protection program, and in assuring compliance with federal regulations. For Sponsored Programs, such issues as what constitutes human subject research, and what types of applications require human subject certification, are discussed. Discussions with the Technology Transfer staff also include what constitutes human subject research, and the potential for conflicts of interest when negotiating patent and license arrangements with industry.

**Document Attributes**

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