

Investigator Education: Training for Accountability in Human Research Programs

Barry Bercu, M.D.
Chair, USF Biomedical IRB
Professor of Pediatrics,
Biochemistry and Molecular Biology,
Pharmacology and Therapeutics
USF College of Medicine

John Arnaldi, Ph.D.
Coordinator of Education
USF Research Compliance

April 21 – 23, 2004
Baltimore, Maryland



Overview

- **Elements of Institutional Policy**
- **Typical Course Content**
- **Formats for Education**
- **Outcome Measures**
- **Tracking and Enforcement**
- **Pearls for Developing a Successful Program**

Elements of Policy

- **Target Groups**

Education is required for all faculty, staff, and students directly involved in research with human subjects, including anyone who:

- **Collects data from or about human subjects**
- **Conducts study procedures or interventions with human subjects**
- **Uses or has access to private data that can be linked to identifiable persons**

Elements of Policy (cont.)

- Requirements – Basic & CE
- Approved Courses – Previously Identified
- Renewal Period – Annual by 12-31
- Submission Procedures – Because of Demands on IRB Staff Time, Try to Transfer More Responsibility for Documentation from IRB Staff to PIs

Elements of Policy (cont.)

- **Changes & Transition from Previous Policy – Updates and Mechanisms to Publicize Policy Changes via:**
 - **Newsletter**
 - **Web Site**
 - **E-Mail Blasts**
- **Failure to Comply – Need Consistent and Fair Policy; Final Decision Referred to Full Board**

Typical Course Content

- **Definitions of Research and Human Subjects**
- **Background History of Human Subject Protections as Basis for IRB of 2004**
- **Ethical Foundations - Belmont Report**
- **Legislative Mandates for Oversight**
- **Types of IRB Review**
- **Criteria for IRB Approval**

Course Content (cont.)

- **Informed Consent**
- **Recruitment & Selection of Subjects**
- **Vulnerable Populations**
- **Specific Institutional Policies & Procedures**
- **Adverse Events**
- **Conflict of Interest**
- **Special Topics – e.g., Current Hot Topics**

Formats for Educational Programs

- **Seminars & Workshops –Keep to 1 Hour**
- **On-Line (Web-Based) & Computer-Based (CD)**
- **Conferences (National, Regional, Local)**
- **Videos & Audio/Video Conferences**
- **Workbook with Test**
- **Brown-Bag Lunches & Networking Meetings**
- **Web Site**
- **Newsletters and E-Mail News**

Outcome Measures

- **Quizzes/Tests – After Each Module**
- **Attendance Sign-In Sheets**
- **Certificates of Completion**
- **Signature to Certify Completion of Reading Material**

Tracking & Enforcement

- **Develop Database**
- **Issue Certificates of Completion**
- **Maintain Database & Investigator Files**
- **Send Renewal Notices**
- **Generate Non-Compliance Reports**
- **Send Non-Compliance Letters**
- **Refer Non-Compliant Investigators to IRB**

Pearls

- **Include stakeholders in policy development**
- **Keep policy simple & consistent – no exceptions**
- **Publicize constantly – educate about education**
- **Schedule courses for a variety of times & locations**

Pearls

- **Require Online RSVP to make it easy for IRB staff to give out pre-printed CME certificates (thereby avoid having to mail certificates)**
- **Balance collegiality with accountability**
- **Keep database up to date**
- **Transfer responsibility for documentation from IRB Staff to PIs, as much as possible**
- **Yet remain user friendly**

Summary

- **Elements for Successful Program Reviewed**
- **Emphasis on Partnership Among Investigators, Coordinators, IRB Staff, and IRB Chair**
- **Need for Dedicated Individual as Educator/Trainer, Dependent on Size of Program**

Contacts



Division of Research Compliance

Web site: <http://www.research.usf.edu/cs/>

Phone: (813) 974-5638

Mail: USF Division of Research Compliance
12901 Bruce B. Downs Blvd., MDC 035
Tampa, FL 33612-4799

Contacts (cont.)



Division of Research Compliance

Barry Bercu, M.D.

Chair, USF Biomedical IRB

Professor of Pediatrics,

Biochemistry and Molecular Biology,

Pharmacology and Therapeutics

USF College of Medicine

(813) 974-5638

bbercu@research.usf.edu

John Arnaldi, Ph.D.

Coordinator of Education

USF Research Compliance

(813) 974-7363

jarnaldi@research.usf.edu