IRB & Investigator Education

Jeffrey M. Cohen, Ph.D.
Associate Dean,
Responsible Conduct of Research
Weill Medical College of Cornell University

Some material courtesy of Susan Kornetsky, Children's Hospital Boston

Why emphasis on IRB education?

- Lack of knowledge root cause of most problems
  - Part of OHRP's required actions by Johns Hopkins:

    "A satisfactory plan to ensure that all IRB members, all IRB staff, and all research investigators are appropriately educated, on an immediate and ongoing basis, about the regulatory requirements for the protection of human subjects."

Topics

- Who needs education
- Why they need it
- How to do it
- NIH Education Requirement
- OHRP Guidance
- OHRP Education Programs

Who, Why and How

Who needs IRB education?

- Institutional Officials
- IRB members / Chairpersons
- IRB professionals
- Principle Investigators
- Research staff (research nurses, research assistants)
- Others involved in clinical research (pharmacists)

Why educate Institutional Officials?

- “The buck stops here”. Signs the assurance.
- Sets tone for institutional culture of respect for IRB process.
- Acts on behalf of institution
  - understand process
  - resource/staffing needs
  - ramifications of non-compliance
  - contact for OPRR

Why educate IRB members/ Chairpersons?

- Must understand regulations to apply to review process
- Understand role and responsibility
- Has ultimate authority in reviewing, approving, suspending research.
- Need to recognize new concerns, interpretations of regulations, policies

Why educate IRB Professionals?

- Responsible for day to day operation
- Liaison between staff and IRB
- Professional association allows them to keep current
- Eyes and ears of what is happening
- Maintain “history/consistency” of IRB review process
- Provides training/education on an ongoing basis

Why educate Researchers/Support Staff?

- Front line interaction with subjects
- “It is their research”, they hold ultimate responsibility
- Must understand/accept and “buy into” human subject protections
- Cannot expect PIs to receive education elsewhere
- Must differentiate role as clinician/provider and researcher

Considerations for Educating an Institutional Official?

- Do they attend IRB meetings?
- How involved are they in policies/procedures/ recordkeeping?
- Who is responsible for keeping them advised.
- Should attend segments of any training provided by IRB
- Strongly recommended under FWA

Considerations for IRB Professionals/Chairpersons

- Strongly recommended under FWA
- Budget money for travel to national meetings, seminars
- Membership in professional organizations (ARENA newsletter)
- Network, network, network
- Encourage certification

Considerations for PI and Staff

- What time is required and when?
- Who mandates it, makes a difference
- Address pertinent issues
- Use of cases works great !
- Apply concepts, do not just present abstract ideas
- Stress ultimate responsibility of PI

Methods For Education

- Lectures, seminars, courses
- Web based tools
  - NIH tutorial
  - CITI
- Self study with or without test
  - University of Rochester : book and test
  - Required for all PIs performing > minimal risk research
  - CME Credit
- Outsource
  - PRIMRs Program “IRB 101”
  - one day program, history ethics, overview of regulations, case studies
  - 2-4 expert faculty come to institution, some room for individualization

Internal vs External Training

- Internal program:Institution develops their own program
  - Pros : Can individualize for needs and culture of institution
  - Cons: Labor and cost intensive
- External program: Adapt established educational programs
  - Pros: Why reinvent the wheel? May reduce costs
  - Cons: May need to adapt

NIH Education Requirement

NIH Education Requirement

- Took effect 10/1/2000
- Applies to all “key personnel”
- Description of education to be included in cover letter certifying IRB approval in keeping with “Just-In-Time” provisions
- No NIH standards for adequate education

NIH Education Requirement

- Basic Notice
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html
- Frequently Asked Questions
  http://grants.nih.gov/grants/policy/hs_educ_faq.htm
- For Further Information contact Belinda Seto (**bs11e@nih.gov**).

Human Participant Protections Education for Research Teams

ENTER

U.S. Department of Health and Human Services
National Institutes of Health

Returning users can click here to login.

URL: http://cme.nci.nih.gov/

OHRP Guidance on Education Programs

OHRP Federalwide Assurance

- Completion of OHRP Assurance Training Modules
  - The Institutional Signatory Official
  - The Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)
  - IRB Chairperson(s)
- Institutions should establish education programs for IRB members and investigators
  - Completion by investigators should be documented


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Human Subject Assurance Training
Welcome to Assurance Training Online.
Browse
Login
URL: ohrp-ed.nih.gov

Recommended Features

- Ongoing
  - One-time presentations inadequate
- Broad based
  - Institutional Officials
  - IRB members
  - Investigators
  - Staff
- Not voluntary

Content

- Ethical principles of human subject research
- Requirements of the Federal regulations
- Applicable state law
- Provisions of Institutional Assurance
- Institutional policies and procedures for the protection of human subjects

OHRP Education Programs

- Presentations and Training Programs
- Workshops and Town Meetings
  - **Video Town Meetings**
  - For further information on both of the above contact Darlene Ross (dr20a@nih.gov)
- Educational Materials
  - **PRIM&R "Investigator 101" CD**
  - "IRB Guidebook" (1993) http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm
    - **Federal-wide Guidebook (2003)**
  - Videotape Series: "Protecting Human Subjects" (1986) http://ohrp.osophs.dhhs.gov/references/resource.htm