Establishing an IRB: Current and Emerging Legal Issues

Medical Research Summit

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IRB Registration

- intended to facilitate HHS's effort to establish effective communications with IRBs
- Required - for IRBs (and IECs) designated under an OHRP Federalwide Assurance
- Voluntary - for all other IRBs and IECs
  - IRB Registration is not currently required by FDA
- unique IRB Number

Assurances

- Each institution "engaged" in Federally-supported HSR must file an Assurance of protection for human subjects.
  - Assurance formalizes the institution’s commitment to protect human subjects
  - "awardee" and collaborating "performance site" institutions must each file
- MPAs, SPAs, CPAs

The Federalwide Assurance

- Released December 3, 2000
- Any institution may file an FWA with OHRP
- Each legally separate entity must file its own FWA
- Existing MPAs and CPAs effective until expiration or December 31, 2003
  - OHRP will no longer process MPA or CPA amendments or modifications
- Implementation - initially, March 1, 2001
  - OHRP will accept SPAs & CPAs until further notice

The Federalwide Assurance - Education Requirements

- OHRP's Assurance Education Module is on-line at http://ohrp-ed.od.nih.gov/
- explains the responsibilities involved in an institutional program of human subject protection
- Required for:
  - Institutional Signatory Official
  - Human Protections Administrator
  - IRB Chairperson
- Three modules:
  - Federal Regulations & Institutional Responsibilities
  - Investigator Responsibilities & Informed Consent
  - Human Protections Program Administration & IRB Responsibilities

Other Educational Requirements

- OIG Report - April 2000 (OEI-01-97-00197)
- Shalala's May 23, 2000 Statement
- NIH Requirement - effective Oct. 2000
  - for all investigators submitting NIH applications for grants or proposals for contracts for HSR
    - NIH - education for Researchers http://ohsr.od.nih.gov/cbt/
    - NIH - Education for Research Teams http://cme.nci.nih.gov/
- Continuing educational programs for IRB members and staff (suggested)

Conflicts-of-Interest and Financial Disclosures

- Required disclosure of financial conflicts-of-interests by investigators
  - Common Rule
  - PHS Regulations & NSF Policy
  - FDA Regulations
- IRB members and institutions
- Non-financial conflicts-of-interest

IRB Members

- Limitations on liability
  - insurance
  - federal law protecting volunteers
  - state laws
- Compensation

Maintaining and Updating Policies

- Designated IRB administrator

- Pregnant Women, Fetuses, and In Vitro Fertilization
  - Published January 17, 2001
  - Effective March 19, 2001
  - Examples
    - Research involving pregnant women or fetuses prior to delivery
    - Research involving fetuses after delivery
    - Research involving, after delivery, the placenta, the dead fetus, or fetal material

More Changes to Come…

- National Human Research Protections Advisory Committee (NHRPAC)
- National Bioethics Advisory Commission (NBAC)
- Institute of Medicine
  - Committee on Assessing the System for Protecting Human Research Subjects
- Accreditation
  - Public Responsibility in Medicine and Research (PRIM&R)
  - NCQA
  - FDA

Likely Developments

- accreditation standards
- conflicts-of-interest disclosures and policies
- educational requirements for all involved in research
- different requirements for medical and non-medical research
- more oversight

Web Sites

- NHRPAC
  - http://ohrp.osophs.dhhs.gov/nhrpac/nhrpac.htm
- OHRP Home Page
  - http://ohrp.osophs.dhhs.gov/index.htm
    - OHRP-L LISTSERV
- Others
  - http://www.iom.edu/hrrp
  - http://ohsr.od.nih.gov/
  - http://bioethics.gov
  - http://www.fda.gov/oc/oha/default.htm#clinical

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