Human Subjects Research at Johns Hopkins Medicine

Introduction to Clinical Research - 2012
Human Subject Protection and IRBs

Government Regulations Followed by the IRBs and JHM Administration
- Department of Health and Human Services regulations - requires submission of a Federal Wide Assurance
- Food and Drug Administration regulations
- Both groups require that JHU constitute an Institutional Review Board
- State of Maryland statutes
- AAHRPP (Association for the Accreditation of Human Research Protection Programs)

Ellen Roche: Colleague and Research Subject Volunteer
Institutional Review Board - IRB

- IRB is located within the School of Medicine Office Of Human Subjects Research
- An IRB can approve, approve with required modifications, or disapprove an application
- Review and completion of the approval process is required before a project may begin. Written approval document should be in hand.

Administrative Actions

- Research approved by an IRB may be subject to further review by officials of the institution
- Institutional officials may decide that an IRB approved study may not be done
- Institutional officials may not approve the research if the IRB has disapproved it
IRB must determine

- Risks to participant are minimized, no better alternative
- Risks are reasonable in relation to anticipated benefits and the importance of the knowledge that is expected to result
- Selection of participants is equitable
- Informed consent will be sought from participants or their legally authorized representatives
- Confidentiality is adequately maintained

Who is responsible

- Faculty and research team have the responsibility to understand policies and procedures and comply with them
- IRBs and institutions have responsibility to comply with state laws and federal regulations

Who may obtain consent from potential research subjects?

- Principal investigator
- Co-investigators listed on the application
- Consent designees:
  - Only if: trained by PI & approved by IRB
What are human subjects?
- Living individuals about whom an investigator obtains either “data through intervention or interaction with the individual or “identifiable private information.”

Private information
- Information that a person can reasonably expect is not being observed or recorded
- Information that has been provided for specific purposes and that “the individual can reasonably expect will not be made public (a medical record)”

What is the definition of research?
- DHHS and FDA regulations contain different definitions:
  - DHHS: The systematic collection of data designed to contribute to generalizable knowledge
  - FDA: Clinical investigation: Any experiment that involves a test article and one or more human subjects must be submitted to the FDA.
What isn’t research?
- Clinical practice activities
- QA/QI activities
- Research materials/information from only deceased persons - HIPAA issue
- Purchased, de-identified biospecimens from a national repository
- A single case study (up to 3 cases)

Types of Review
- Exempt
- Expedited
- Convened

Who can be the principal investigator?
- SOM and SON faculty
- Senior staff - JHH Nursing, APL
- Senior staff - Howard County General Hospital
- Physicians on the medical staff at one of the Johns Hopkins Hospitals
- Fellows CANNOT be principal investigator
What must be submitted for IRB review?

- Research
  - Regardless of funding or lack of funding
  - Regardless of site where conducted
- Examples are:
  - Clinical trials
  - Retrospective chart reviews
  - Lab research with existing specimens
  - Prospective collection of specimens

How to handle case studies?

- A single case study does not meet the definition of research
- IRB will not review and approve
  - IRB will acknowledge and provide letter to the journal
  - IRB policy posted on the web site at [http://irb.jhmi.edu](http://irb.jhmi.edu)

JHM IRBs that review new research proposals

- Broadway campus: JHM IRB Committees 1, 2, 3, 6 & X (for expedited protocols)
- Bayview campus - JHM IRB 5
Assignment of Applications to IRB X

- IRB X reviews the majority of projects that qualify for an expedited review process and requests for exemption, regardless of topic or department of origin.
- IRB X does not review projects submitted by their members or projects submitted from KKI.

General Assignment of Applications

- Applications may be assigned to any JHM IRB.
- May be transferred to another JHM IRB after original assignment at the request of the IRB or the Vice Dean for Clinical Investigation.
- Convened versus expedited review.

How to start the IRB review process - E-IRB

- Obtain training in e-IRB procedures - call 5-3008 to schedule.
- Online submission required as of 9/1/2005 for new applications.
What are the presubmission requirements for JHM IRBs

- Completion of JHUSOM on-line human subjects training course at https://secure.lwservers.net (revised July 2005)
- Department chair signatures, when applicable
- Cancer treatment trials
  - Review by the Oncology Center Clinical Research Office - regardless of Department of origin
- Review by the Kennedy Krieger Institute (KKI) when subjects are recruited from the KKI, KKI facilities used

How to obtain answers to IRB process questions

- Generic questions may be sent to the office e-mail site at ohsceb@jhmi.edu
- Contact the Director of the Office of Human Subjects Research - Judith Carrithers (5-3008)
- Contact the IRB Associate Managers via e-mail or phone (5-3008)
- IRB Chairs/Co-Chairs may be contacted with specific questions about issues raised in the review process - membership lists are on the IRB website
- Consent specialists
- Guidance documents available on the IRB website at http://irb.jhmi.edu

Answers to HIPAA Questions

- Research related questions - OHSR regulatory specialists and Assistant Dean for Human Subjects Research Compliance (5-3008)
- General questions - HIPAA Privacy Officer - Carol Richardson (410-735-6509)
Answers to Ethical Questions

- Consult with the ICTR Clinical Research Ethics consultation service
- They consult to research team and not the IRB or Vice Dean’s office

Who is in the middle?

Impact of Non-compliance

- Institutional
- Protocol
- Investigator – warning letters published on FDA Website
Responsibilities of PI

- Human subjects protection is more than creating an acceptable consent form
- Train and manage the study team
- Treat each research participant with respect
- Report adverse events in a timely manner
- Ask for help if you have questions
- Think beyond the regulations

New Initiatives IRB

- Data Safety Monitoring Boards
- Policy on Incidental Findings
- Bringing Science of Safety to Research