Advancing the IRB Agenda at PUIs: Not All Protocols Are Created Equal!

Margarita M. Cardona  
Director, Sponsored Research & Faculty Development  
University of Baltimore  
mcardona@ubalt.edu

Joseph M. Smith  
Manager – Research Compliance Office  
University of Maryland College Park  
jsmith54@umd.edu
The IRB – In Brief

• Ethics/Regulations
• What is research and who are the subjects?
• Involvement of the IRB
• Types of review and the consent process
• Differences among institutions in Maryland
• The “bottom line”
“Doing the right thing”

“Real integrity is doing the right thing, knowing that nobody’s going to know whether you did it or not.”

Oprah Winfrey

Above any existing law or regulation, it is our duty to conduct research in a manner consistent with proper and responsible conduct of individuals expected in the University community.
Ethics – It’s the law

• 45 CFR 46 – Protection of Human Subjects
  – Ensures *minimal* standards for the treatment of human research subjects.
  – Based on the recommendations of The Belmont Report, released April 18, 1979 after the discovery of the Tuskegee experiments.
Ethical Foundations

• **Freedom from harm** - the right not to be exposed to physical, emotional, or psychological dangers without very strong justification, and only after agreeing to participate with fully *informed consent*.

• **Privacy** - the right to determine how information obtained from them is used, and whether it is publicly shared and how.

• **Voluntary participation** - the right to freely choose to participate or not participate in studies, to know what it is they are volunteering to participate in, and even to withdraw their participation in a study after it has begun.
Protections from Risk

• Typical examples of harm in social and behavioral science research:
  – Emotional or psychological harm
  – Social harm
  – Physical harm
  – Financial harm
  – Legal harm
  – Moral harm

• It is our duty to minimize these potential risks
What is research? Who are subjects?

• The law defines research as a systematic investigation that contributes to generalizable knowledge.
  – An investigator is engaged in research if s/he has proposed an intention to explore a particular topic, while interactive with one or more living persons (the subjects), and either publish the results in a journal or present at a conference.

• The subjects are the living individuals about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information.
Why is the IRB involved?

• Compliance with applicable federal regulations and institutional policies
• Ethical review of research
• Ensure participant rights are projected
• Safeguard participants from risk and harm
• To ensure an appropriate risk : benefit ratio
The IRB

- Members of an IRB represent the background, expertise and scope of social and behavioral science required by federal regulations.
- Provides assurance to the federal government that the institution will comply with the regulations
- Provides oversight of the human subjects research activity at the institution
What projects need IRB review?

• Investigations that will be published or presented at conferences, pilot projects, thesis, dissertations and “capstone” projects that include:
  – Questionnaires
  – Interviews (audio or video recordings)
  – Focus groups
  – Participant observation
  – Non-invasive physical measurements (blood pressure, EKG)
  – Review of medical or academic records & other private data

• Approval **must** be obtained **before** the research begins!
Informed Consent

• It is a **process** that uses a **document** and includes:
  – Research statement
  – Purpose
  – Procedures
  – Confidentiality
  – Risks and Benefits
  – Freedom to withdraw from the study at any time
  – Contact information for the investigator and the IRB
  – Space for signature of participant and date
Types of IRB Review

• Exempt – does not require any further regulatory review after approval
  – Commonly accepted educational settings
  – Educational tests and surveys; anonymous
  – Study of existing data; publicly available

• Expedited – no more than minimal risk
  – Requires continuing review on annual basis

• Full-Board
## Review Process in MD (2010)

<table>
<thead>
<tr>
<th>Institution</th>
<th>Exempt</th>
<th>Expedited</th>
<th>Full Board</th>
</tr>
</thead>
<tbody>
<tr>
<td>JHU – Bloomberg</td>
<td>1 Staff &amp; Chair</td>
<td><em>Full Board</em></td>
<td>Majority Vote</td>
</tr>
<tr>
<td>JHU – Homewood</td>
<td>IRB Director</td>
<td>IRB Director &amp; 1 Member</td>
<td>Majority Vote</td>
</tr>
<tr>
<td>JHU – Medical</td>
<td>IRB Staff</td>
<td><em>Full Board</em></td>
<td>Majority Vote</td>
</tr>
<tr>
<td>Loyola U.</td>
<td>1 IRB Staff or Member</td>
<td>2 Board Members</td>
<td>Majority Vote</td>
</tr>
<tr>
<td>UB</td>
<td>2 Board Members</td>
<td>Chair &amp; 1 Member</td>
<td>Majority Vote</td>
</tr>
<tr>
<td>UMBC</td>
<td>Board Chair</td>
<td>1 Board Member</td>
<td>Majority Vote</td>
</tr>
<tr>
<td>UMCP</td>
<td>IRB Manager</td>
<td>Board Co-Chairs</td>
<td>Majority Vote</td>
</tr>
<tr>
<td>Towson U.</td>
<td>1 Board Member</td>
<td>1 Board Member</td>
<td>Majority Vote</td>
</tr>
</tbody>
</table>
What documents should you include?

Required for all IRB requests:
• IRB application and exempt checklist
• Research protocol/survey instrument/recruitment materials/other supporting documents
• Informed consent form
• Requirements may be different depending on institution
• Incomplete applications will be returned without review
• IRB Office Administrative Review will identify modifications to be addressed prior to final review.
What happens after review?

- **Approval** – typically email followed by letter
- **Pending approval** – request changes, usually minor
- **Deferral/Table** – request major changes, requires new review
- **Denial/Disapproval** – research too risky or does not follow ethical guidelines
- Protocols are approved for one year and a Continuing Review must be submitted and approved to continue
- If changes are proposed an Amendment must be submitted and approved for the changes to take effect.
The Bottom Line – The Investigator

• Be trained and fully aware of your responsibility
• Remember: consideration, clarity, consistency, completeness
• Follow IRB conditions and requirements, stated in the official approval letter
• Report back on the progress of your research
• Be aware of your own ethics
• Publish!
The Bottom Line – The IRB

• When in doubt: CONTACT THE IRB OFFICE
• We are here to help facilitate the research process
• IRB approval is a process; keep the dialogue open
• IRBs (should) use “reasonable person” standard to ensure high standards of ethical research
• IRBs are more than enforcers/regulators, they may also offer great advice to the investigator
How can I get help?

• Take advantage of on-line training from CITI at www.citiprogram.org
• Refer to education training resources provided by OHRP at www.hhs.gov/ohrp
• Network with other institutions!