



The View from the IRB Committee

Sherril B. Gelmon, Dr.P.H.
Portland State University
Co-Chair, PSU Human Subjects
Research Review Committee

Multiple Perspectives



- Institutional authorities
 - Staff who support IRB
 - Faculty chair of IRB
 - Faculty member serving on IRB
 - Community member participating in research
 - Researcher who employs community-based participatory methods
- *** Challenge is to be attentive to all these perspectives and present a coherent proposal

Mandate of the Institutional Review Board



- Ensure protection of rights and welfare of human subjects involved in research
- Review process ensures that all protections are in place
- Researchers may then disseminate findings
- Standardized documentation required by IRB to conduct human subjects reviews
- Most universities manage an IRB, and will conduct reviews for community-based nonprofit organizations
- Other IRBs in teaching hospitals/health systems, community research organizations, Indian Health Boards

Three Categories of Review



- Waived: Procedures involving survey, interviews, publication observation may undergo certification by a member of the IRB
- Expedited: Research activities involving no more than minimal risk, and in which there will be minimal involvement of human subjects carried out through standard methods, may be expedited
- Full: All federally funded proposals (whether funded directly by a government agency or with pass-through funding), and regardless of the type of study, must undergo full review
- No review is required when data will not be published or otherwise disseminated.

Institutional Authorities



- Institution assumes legal responsibility for all research conducted/sponsored by it
- Serves as legal grantee for funds and therefore assumes risk as well as responsibility
- Multiple emphases for compliance:
 - Human subjects, animal care and use, bio-safety, radiation safety, etc.
- Assures independent determinations on methods, risks, benefits and rights
- Responsible for reviewing and approving all relevant projects, conducted by both faculty and students

Staff Who Support IRB



- Responsibility is to ensure smooth and effective functions of committee
- Play gatekeeping role for proposals, determining level of review required
- Provide consultation services to researchers
- Organize training for researchers and IRB members on procedures and protocols
- Manage the entire review process, including follow-up and continuing reviews
- Facilitate access to role model proposals/forms

Faculty Chair of IRB



- Coordinates process in consultation with staff
- Has public responsibility for representation of IRB decisions
- Usually signs all letters and therefore assumes institutional representation and authority on behalf of IRB
- May work with staff to recruit new IRB members
- May assist in trainings and information sessions

Faculty Serving on IRB



- Reviewer of all levels of proposals
- Participate in IRB meetings (at least monthly)
- Engage in decision-making on proposals
- Develop advice and guidance for researchers
- Conduct expedited reviews
- Provide additional reviews to support staff for pre-submission, continuing reviews, proposals requiring additional consultation

Community Research Participants



- May or may not have actual role on IRB depending on local practice
- Most IRBs have community representative, especially for review of community-oriented proposals (e.g. CBPR)
- Play important role for certain vulnerable populations (e.g. children, prisoners)
- Community members seek to protect their members individually and collectively

Researcher (Faculty or Community) Using CBPR



- Prepares proposal for review by IRB
- Follows same procedures for CBPR as for any other research
- Vital to understand rules, procedures, issues
- Responsibility is to document all concerns and issues regarding protection of human subjects
- Invest time in carefully documenting unique and challenging aspects of own research
- Well-prepared proposals will make a clear case and explain any unfamiliar methods

Challenging Situations



- IRB members who do not understand CBPR
- IRB staff who are not familiar with various protections and strategies for CBPR
- Researchers who do not prepare coherent and well-substantiated descriptions in proposals
- Graduate students who do not receive sufficient mentoring from faculty in proposal preparation
- Community members who may not understand responsibilities of IRB and value they can offer

Advice



- Be attentive to all these perspectives and present a coherent proposal
- Learn the rules and regulations in advance of submitting a proposal
- Consult with IRB staff to answer questions
- Review models of exemplary proposals
- Develop informed consent protocols using models on IRB websites -- most common issues
- Be respectful and respond quickly

Resources



- Office for Human Research Protections
 - Valuable resources on compliance, regulations, policy, registration of IRBs, research participation
 - Search for IRBs in your community
 - <http://www.hhs.gov/ohrp>
- Protection of human subjects in research is codified in the Code of Federal Regulations, 45 CFR 46
 - www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
- Review guidelines and procedures at your local university, health system, or community IRB website
- Consult with IRB staff on procedures

For Further Information



Sherril B. Gelmon

Professor of Public Health

Co-chair, Human Subjects Research Review
Committee

Portland State University

Portland, OR, USA

(503) 725-3044

gelmons@pdx.edu