Special Considerations for BPR Proposals: Data Management Plans, Institutional Review Board (IRB) Approval, and Dissemination of Findings

QEM NETWORK: Proposal Development Workshop on Broadening Participation Research in STEM Education

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Institutional Review Board
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- The singular purpose of the IRB, as mandated by Federal Law, is to protect the rights and welfare of human research participants recruited to participate in research activities conducted under the auspices of a particular entity.

- This purpose can not be outweighed by any other consideration (i.e. time, money, research publications, graduation, etc.)
In General

- Applies to funded and unfunded research Submission of a protocol and approval by the IRB is mandatory for any faculty, staff or student who will interact with a human being for purposes of conducting research
- Research may not begin before approval from the IRB is given!
Why is IRB Necessary?

- Tuskegee Syphilis Study (Alabama, 1932-1972)
- Nazi Experiments (1930s-1940s)
- Stanley Milgram's experiment. "Obedience and Individual Responsibility" (Yale, 1961-1963)
- Willowbrook Study (New York, 1963-1966)
- Tearoom sex (Washington Univ., 1960s)
- Research conducted with prisoners, children and other vulnerable populations
More Recent Violations

In a totally unprecedented flurry of enforcement activity, the National Institutes of Health (NIH) Office for Protection from Research Risks (OPRR) stopped research at Rush-Presbyterian-St. Luke's Medical Center (AP 1998), the West Los Angeles Veterans Affairs Medical Center (Monmaney 1999; Hilts 1999a), Duke University (Stout 1999; Weiss 1999), the University of Illinois at Chicago (Guerrero and Herguth 1999; Grahnke and Ritter 1999), the University of Colorado (Hubler 1999), Virginia Commonwealth University (Mathews 2000), and most recently, the University of Alabama at Birmingham (Hansen and Spencer 2000; Hilts 2000).

While there have been some substantive concerns relating to subject enrollment and informed consent, most of these sanctions have been levied because of sloppy and inadequate operation of institutional review boards (IRBs) and slow or inadequate response to OPRR's concerns.
In 1979, the federal government developed regulations of ethical principals underlying the current regulations and standards that are contained in the Belmont Report.

It was the capstone of the National Commission for the Protection of Human participants of Biomedical and Behavioral Research. It outlines the ethical principals upon which the ethics of a research study are evaluated in the United States.

The Belmont Report embodies the moral consensus upon which stand our present US Federal regulations governing the ethics of human participants research conduct with Federal funds from the majority of Federal agencies.

Our present regulations formalize The Belmont Report's requirements for informed consent and establish another Commission recommendation that formalized and extended the existing peer review system of that time, which has matured into the Institutional Review Board (IRB) system that we have today.
Common Rule

- The Common Rule is a federal policy regarding Human Subjects Protection that applies to 17 Federal agencies and offices. It does not apply to federal agencies that have not signed the agreement (e.g., Department of Labor, etc.) The main elements of the Common Rule include: Requirements for assuring compliance by research institutions

Requirements for researchers' obtaining and documenting informed consent

Requirements for Institutional Review Board (IRB) membership, function, operations, review of research, and record keeping.
The Common Rule includes additional protections for certain vulnerable research subjects. Subpart B provides additional protections for pregnant women, in vitro fertilization, and fetuses.

Subpart C contains additional protections for prisoners.

Subpart D does the same for children.


FDA Regulations are detailed in 21 CFR, Part 50, and 21 CFR, Part 56. You can review these at [http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=199945](http://www.access.gpo.gov/cgi-bin/cfrassemble.cgi?title=199945)
Required Training for Researchers

Online Training Sites

National Institutes of Health (NIH)
(http://phrp.nihtraining.com/users/login.php)

Collaborative Institutional Training Initiative (CITI)
(https://www.citiprogram.org/).
What type of research requires review?

- Research which involves the administration of drugs or other substances to participants
- Research involving pregnant women and/or fetuses in utero
- Research involving participants with life-threatening physical conditions
- Research involving physically intrusive procedures
- Research which previous experience (by the particular investigator or other investigators) has shown to create a potential of risk to participants
- Research which potentially could put the participant at risk for legal or civil liability or invade a participant's privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use).
What about survey research or questionnaires?

• Research which involves the interviewing of participants requires review by the IRB for several reasons;
  – The IRB must insure the risks do not outweigh the benefits of this research
  – The IRB must review potential questionnaires and items for inappropriate or potentially harmful items
  – Certain populations may be at risk for psychological harm (for example; crime/rape victims, Post traumatic stress disorder (PTSD), etc.
  – The investigator must be qualified to administer these items.
  – Potential risk of disclosure of identity/confidentiality
What types of Research could possibly be exempted?

- Research in which the risks of harm reasonably anticipated are not greater than those ordinarily encountered in daily life or during the performance of routine procedures in education and/or in the practice of psychology and medicine
- Research on the effectiveness of educational, classroom, and/or instructional strategies, provided that these strategies are familiar, and nonintrusive in their implementation
- Research using educational tests (cognitive, diagnostic, aptitude, achievement) if participants' identities are thoroughly protected
- Research using survey procedures or interview procedures where participants' identities are thoroughly protected and their answers do not participant them to criminal and civil liability
- Research involving the collection or study of existing data, documents, records, specimens, or other products, if these sources are publicly available or the information is recorded by the investigator in such a manner that the participants cannot be identified directly or indirectly.
- Remember – The IRB, not the investigator, decides upon the exemption status of a protocol
IRB Review of Research

All research projects are categorized into one of three categories for the IRB review process. Each category is different in the level of scrutiny and submission procedures. The IRB is responsible for making the final decision of which category a research project falls under.

- Full (Reviewed and critiqued by at least 2 reviewers then taken to the full committee meeting)
- Expedited (Committee Chairman)
- Exempt (Committee Review not required)
- Research Not Involving Human Subjects
Types of Reviews for Various Reasons

- Initial
- Continuing Review
- Amendments
- Safety Information or Unanticipated Problems to Subjects or Others
- Noncompliance
Informed Consent

- **Information** – includes research procedure, purpose, risks, benefits, alternatives, etc.
- **Comprehension** – function of intelligence, rationality, maturity and language, presentation of information must be adapted to the subject’s capacity
- **Voluntariness** – requires conditions free of coercion and undue influence
Consent Form

Required Elements

- Statement that the study involves research
- Research is described
- Description of Risks
- Description of Benefits
- Disclosure of Alternatives
- Confidentiality
- If more than minimal risk, compensation and/or medical treatment
- Participation is voluntary
- Whom to Contact
Additional Elements of Informed Consent

- Unforeseeable risks
- Early termination
- Additional costs to participants
- Consequences of a participant’s decision to withdraw from study participation
- Disclosing new findings which may impact a participant's willingness to continue participation
The IRB is a key element in the conduct of human participant research at a University. But, it is the primary responsibility of the IRB to safeguard the rights and safety of human participants. It is not necessarily the role of the IRB to expedite research at the University at the expense of safety and human rights.
Data Management Plan

- NSF requires proposals to have a two-page "Data Management Plan" (DMP) which describes
- How the proposal will conform to NSF policy on the dissemination and sharing of research results.

Elements for the DMP

- Policies for access and sharing including provisions for appropriate protection of privacy, confidentiality, security, intellectual property, or other rights or requirements.
Additional Elements for the DMP

- Policies and provisions for re-use redistribution, and the production of deliverables/artifacts.
- Plans for archiving data, samples and research products, and for preservation of, and access to them.
Dissemination

According to NSF BPR RFP

- Describe detailed plans to communicate the results and outcomes of the project to other professionals in STEM education and research and the higher education community both during and after the project.
- Describe the information to be disseminated, the means of dissemination and the procedures for determining the success of the dissemination efforts.
Dissemination Suggestions

Specify a few journals to which it would be appropriate to submit research manuscripts based on the content of the research and the target audience of the journal.

Provide a list of association annual meetings where the project findings could be presented, and membership exists

Indicate that articles and presentations will be available online.
Additional Dissemination Suggestions

Forge relationships with groups with the ability and willingness to disseminate the results to various stakeholders and constituents.

Plan to develop different products focusing on implications of the results for such groups as policy makers, faculty, teachers or students.

Take advantage of the social media platform (i.e. Twitter, Facebook, a blog, radio, press releases, and a website, etc.)
Questions
Thank you!!

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