IRB Considerations for Conducting Research with Students and Community Members as Respondents

with
David Delmonico, Ph.D.
Duquesne IRB Chairperson
(412) 780-1459 (cell)
irb@duq.edu

Co-sponsored by the Center for Community-Engaged Teaching and Research and the Institutional Review Board
Agenda

• IRB Basics (Refresher)
  • Levels of Review

• Research Involving Duquesne Students as Subjects

• Community Based (Participatory) Research

• Panel Discussion
  • Dr. Jeryl Benson (Rangos School of Health Sciences)
  • Dr. Darius Prier (School of Education)
Important Websites

www.duq.edu/mentor

www.duq.edu/citi

www.duq.edu/irb

www.duq.edu/research
IRB Basics

• Levels of Review
  • Excluded
  • Quality Improvement
  • Exempt
  • Expedited
  • Full Board

• Pre Protocol Questionnaire

• OHRP Decision Charts
§46.102 Definitions.

*Research* is a systematic investigation...designed to develop or contribute to generalizable knowledge.

*Human subject* is a living individual about whom an investigator conducting research obtains either:

(a) Data through intervention or interaction with the individual

(b) Identifiable private information.
Excluded

• Does not require a review by the IRB
• Does not meet regulatory definition of research
• Does not involve human subjects
• Public dataset with no identifiers (large datasets)
• Results in a determination letter issued by the IRB Chair
• Researchers cannot make the decision about the exclusion on their own
Quality Improvement (QI)

• Focused on the improvement of a process or practice within a specific institution or system
• Data collected is limited to the efficacy of an improvement to an existing process
• Focus of the benefit is on a group of individuals
• Participants will benefit in some way from the QI
• Dissemination of data is primarily back to the institution
• Results are not used to generalize to other institutions or systems
Exempt

• Minimal risk studies
• Exemptions must be VERIFIED by the IRB
• Exempt from IRB oversight once verified
• Exempt from annual reviews / terminations
• De-identified datasets or records (not public)
• Standard Educational Practices*
• Anonymous surveys, tests, interviews, observations
• Local university policies and procedures apply (e.g., consent forms)
Standard Educational Practices

Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
Expedited

- Minimal / Slightly More than Minimal Risk
- All Federal Regulations Apply
- Must be APPROVED and reviewed annually
- Confidential data (not de-identified)
- Recorded Interviews (voice is an identifier)
- Higher risk studies
- Clear guidelines for protecting human subjects and their respective data
- Informed Consent is critical (use most current templates)
Full Board

• High Risk Studies
• Protected Populations
  • Children under the age of 18
  • Prisoners / Parolees
  • High Risk + a vulnerable groups = Full Board Review
    (e.g., elderly, pregnant women, different abilities, TBI, etc.)
• Must follow specific deadlines
• Reviewed by multiple reviewers in multiple disciplines
• There is no appeal to an IRB Decision
Important Documents

- Duquesne University IRB Policy & Procedures Manual
- Mentor IRB User Guidelines
Mentor Login

Please use the "Single Sign-On" button above to login to Mentor using your Duquesne credentials.
The Duquesne University Institutional Review Board (IRB) is charged by the Federal Government with protecting human subjects involved in research. The IRB performs prospective and continuing review of protocols, the informed consent process, and the procedures used to enroll subjects in order to ensure that the human subject research is conducted ethically and in compliance with the Belmont Report, and with applicable federal, state, local and institutional requirements.

**Submitting a Protocol**

- Complete the CITI Online Training Program
  - YouTube Video on how to complete CITI
  - YouTube Video on how to upload your completed CITI Certificate

- Read the IRB Policies and Procedures

- Read the Mentor User Guide

- Determine your Level of Review with the IRB Diagnostic Survey or the OHRP Decision Charts

- Use the Protocol Summary Form

- Use the Templates and Samples

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<th>Size</th>
<th>Dated</th>
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<tbody>
<tr>
<td>Assent Form_Adolescents</td>
<td>24 K</td>
<td>05/29/2017</td>
</tr>
<tr>
<td>Assent Form_Young Children</td>
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<td>Consent Form Template</td>
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<td>Consent Form_Online Version</td>
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<td>Parental Permission Form</td>
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<tr>
<td>Protocol Summary Form</td>
<td>31 K</td>
<td>01/26/2017</td>
</tr>
<tr>
<td>Quality Improvement Request Template</td>
<td>18 K</td>
<td>01/17/2017</td>
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**IRB Calendar**

If your protocol requires Full Board Review, you can find the 2017-2018 Meeting Schedule

**Amendments/Modifications**

Use the Amendment Submission Form.doc to submit additions and/or changes to your protocol after it has already been approved.

Once completed, the form should be uploaded under the amendment tab at the bottom of your protocol page.
Research Involving Duquesne Students
Scholarship of Teaching and Learning

- “A **systematic** reflection on teaching and learning made public.” (Illinois State University)

- The formulation of an assessment plan to determine the impact of pedagogy on student learning….and disseminating the outcomes of the assessment in various venues (Bowen, 2010).
Why Special Considerations?

• Captive audience
• Easy access
• Implicit coercion built into the system
• Hierarchical relationships
• Evaluative nature of relationships
Solutions?

- Place people or procedures between you and the students
- Have an ‘honest broker’ de-identify your data
- Be clear that task (or use of data) does not affect grades
- Protect students beyond grades or class – include progress in program
- Review “Standard Educational Practices”
- Does the project even meet the regulatory definitions?
Other Considerations

• Tasks that would be part of the class regardless of research
• Seeking IRB approval after the class is over
• Extra credit for participation
• Clear withdraw procedures
• Having students conduct research for class
Community Based (Participatory) Research
Community Engaged Research

• A framework, orientation or research approach, not a method itself.

• Tends to focus on partnerships and relationships between the communities and academic researchers.

• Requires cooperation and negotiation, iterative research orientation, thinking outside traditional parameters.

• A continuum: Varies in the relative proportion of partnership depending on research objectives, participants and scientists, and community context, including history.

Nancy Schoenberg
(University of Kentucky)
Community Based Participatory Research

“A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community and has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities. “

– WK Kellogg Foundation
<table>
<thead>
<tr>
<th></th>
<th>Traditional</th>
<th>Community engaged</th>
<th>CBPR</th>
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</thead>
<tbody>
<tr>
<td>Research objective</td>
<td>Based on epidemiologic data &amp; funding priorities</td>
<td>Community input in identifying locally relevant issues</td>
<td>Full participation of community in identifying most important issues</td>
</tr>
<tr>
<td>Study design</td>
<td>Based entirely on scientific rigor and feasibility</td>
<td>Researchers work with community to ensure culturally acceptable</td>
<td>Community intimately involved with study design</td>
</tr>
<tr>
<td>Recruitment &amp; retention</td>
<td>Based on scientific issues &amp; “best guesses” on how to reach community members</td>
<td>Researchers consult with community reps on recruitment &amp; retention strategies</td>
<td>Community reps provide guidance &amp; aid on recruitment &amp; retention strategies</td>
</tr>
<tr>
<td>Instrument design</td>
<td>Instruments adopted/adapted from other studies. Tested chiefly w/psychometric analytic methods</td>
<td>Adopted from other studies &amp; tested/adapted to fit local populations</td>
<td>Developed with community input &amp; tested in similar populations</td>
</tr>
<tr>
<td>Data collection</td>
<td>Conducted by academic researchers or individuals w/ no connection to community</td>
<td>Community members involved in some aspects of data collection</td>
<td>Conducted by community members to extent possible, based on skill set. Focus on capacity building</td>
</tr>
<tr>
<td>Analysis &amp; interpretation</td>
<td>Academics own data, conduct analysis, &amp; interpret findings</td>
<td>Academics share results w/community for comments, interpretation</td>
<td>Data shared w/community &amp; collaboration on results</td>
</tr>
<tr>
<td>Dissemination</td>
<td>Peer reviewed academic journals</td>
<td>Peer reviewed academic journals</td>
<td>Community venues plus peer reviewed academic journals</td>
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Source: Mary Anne McDonald, Duke Center for Community Research, Duke University School of Medicine, 2007
Regulatory Challenges

• Who are the researchers vs. participants?
• Who needs to consent and how?
• Who needs CITI training?
• How to deal with the iterative and constantly changing process? (amendments?)
• When does the “research” begin?
• What information will be returned to the community? ...and how will individuals be protected in the feedback loop?
Solutions?

• Work closely with IRB reps in your school and the IRB Chair if necessary
• Error on the side of getting consent from community members, keeping in mind...
  • Consent process can be waived, modified, and documentation of consent can be waived
• Key personnel community members may need ethics training, but there may be alternatives to CITI
• Write protocol broadly enough that it can accommodate some changes as the process moves forward (amend when necessary)
• Clearly articulate the who, what, when, why, and how of returning data to the community
Key Personnel

“Key Personnel” for a research study are individuals who contribute to the scientific development or execution of a project in a substantive or measurable way. This includes, individuals involved in conducting the research through an interacting with or intervening for human subjects in a way that would impact outcomes/data. This also includes anyone participating in the consent process by either leading it or contributing to it; and those who are directly involved with recording or processing identifiable private information, including protected health information, related to those subjects for the purpose of conducting the research study.
Remember....

CeR / CBPR cannot circumvent the regulatory process, but....
It may require creative ways to think about the project.

It is your responsibility to clearly articulate your project, but...
It is IRBs responsibility to help you accomplish your goals.

The IRB is not set up to be your adversary, but...
We also have a charge and responsibility to fulfill.

Let’s work together and make this process better.