Protecting Participants: Improving the Quality and Effectiveness of Institutional Review Boards (IRBs) and Human Research Protection Programs (HRPPs)

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Introductions

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What are IRBs and HRPPs?

- Review research proposals
- Uphold ethical standards and regulations
- Develop institutional policies to protect participants

2700+ Registered with OHRP
Researchers and Participants

Focused on scientific rigor and participant protection vs. Participant rights and responsibilities

Regulatory compliance and ethical standards vs. Who can I contact for questions, complaints, and injuries?
Participant protections

❖ Informed Consent
❖ Minimization of risk
❖ Reasonable balance between benefits and risk
❖ Continuous oversight
How can IRBs serve as a trusted source of information about research?
Does the IRB provide information relevant to people considering participation in research?

Does the IRB have resources specifically directed towards research participants?
IRB Websites

Accessible?

Open to the public?
Methods

- Reviewed an **initial list of 15 IRBs** selected across several geographic areas in USA
- **Developed a draft data collection tool**
  - Google Forms and Sheets
- Refined the data collection tool as a full group
- Tested the tool again through a double-coding **exercise** and refined further
- Used IORG # as organizing tool and randomized sample for final research
  - Sample based on 2700+ IRBs
  - **Sample reduced to 400+ IRBs based on # of HHS protocols**
Qualitative and Quantitative Data Analysis

What are we looking for?
- Participant Bill of Rights
- Contact information
- FAQs
- **Community Outreach**
- History
- Information about role of IRB
- Questions to ask when considering enrollment
- Research risks and benefits

How many sites have some or all of these?
About Research Participation

Before joining a research project, we encourage you to learn more about your rights as a research volunteer and the risks and benefits of being in research. The IRB has a brochure available for you. This brochure can be downloaded and printed by participants, investigators, or departments who wish to distribute the pamphlet as an educational resource. If you are a participant and would like the IRB to send you a paper copy of the pamphlet or if you are an investigator or department who would like a supply for use in your office please contact the IRB at 801-581-3655 or irb@hsc.utah.edu.
I'm a Biomedical Researcher or Student

I'm a Social Behavioral Researcher or Student

University of Pennsylvania Human Research Protections Program (HRPP)

Mission:

- To promote the ethical conduct of research and ensure the protection of human research participants’ rights and welfare
- To facilitate excellence in human research by providing timely and high quality review of human research
- To provide professional guidance and support to the research community
Forms & Templates
This page is a Penn researcher resource of IRB forms and document templates commonly utilized in IRB submissions.

LEARN MORE

Education
This page provides information about training required to conduct human research at Penn as well as curated educational sessions offered by the Penn IRB.

LEARN MORE

IRB Member Toolbox
This page provides guidance and resources for Penn IRB Board members.

LEARN MORE

Information for Research Participants
The page provides information for research participants, including how to contact the IRB if you have a complaint.

LEARN MORE
What is Research?

According to the U.S. Department of Health and Human Services (DHHS) definition at §46.102, research is “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Activities and projects that meet this definition are considered to be research.

People participate in research for a variety of reasons such as helping others or contributing to scientific progress in improving a health or societal condition. If approached to participate in a research study, you should think carefully about your decision. Click below for an educational video on informed consent and what information will help you decide whether to participate.

Types of Research Conducted by Penn Researchers

Penn researchers conduct both biomedical and social behavioral research. Click below to view educational videos that explain these different types of research.
Next Steps

❖ Finished coding
❖ Qualitative analysis
❖ Writing
❖ Ethical analysis
Research Team

Dr. Tanya Matthews  Monique Tadeo  Daniel Ashat  Dr. Holly Taylor  Dr. Elisa Hurley
What I have learned...

★ Research assistants have some of the most important work on a research project
★ Great teams make research easy
  ○ Communication
  ○ Encouragement/confidence
Thank you!