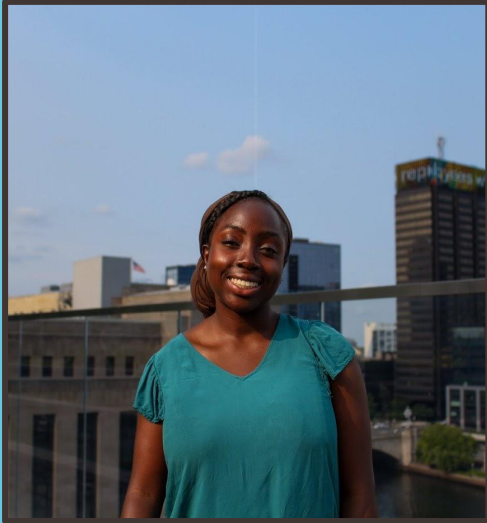


Protecting Participants:
Improving the Quality and
Effectiveness of Institutional
Review Boards (IRBs) and
Human Research
Protection Programs
(HRPPs)

Justin Cayenne SUMR '23
Mentor: Holly Fernandez Lynch, JD, MBe



Introductions



Christine Duah



Holly Fernandez Lynch,
JD, MBe



Justin Cayenne



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

The background is a solid dark blue. On the left side, there is a large, solid teal-colored shape with an irregular, organic edge. On the right side, there is a thin, light blue line that curves from the top right towards the center. At the bottom right, there is a thin white line that forms a partial, rounded shape.

**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 resource
specifically directed towards
research-participants?



Accessible?

IRB Websites



A screenshot of the Institutional Review Board website for The University of Utah. The header includes the university logo and the text 'INSTITUTIONAL REVIEW BOARD'. A navigation menu lists various categories, with 'PARTICIPANTS' circled in red. Below the navigation is a large banner image of a campus with the text 'Institutional Review Board'. The main content area features an illustration of a classical building with a red flag and the letter 'U' on its pediment, titled 'About the IRB'. The text below the illustration states: 'We conduct ethics reviews for research that includes human participants. We strive to protect the rights and welfare of human research participants by ensuring compliance with state and federal laws, as well as the high ethical standards set forth in University policy.' A small upward-pointing arrow icon is visible in the bottom right corner of the screenshot.

Open to the public?



DATA COLLECTION

DATA

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**

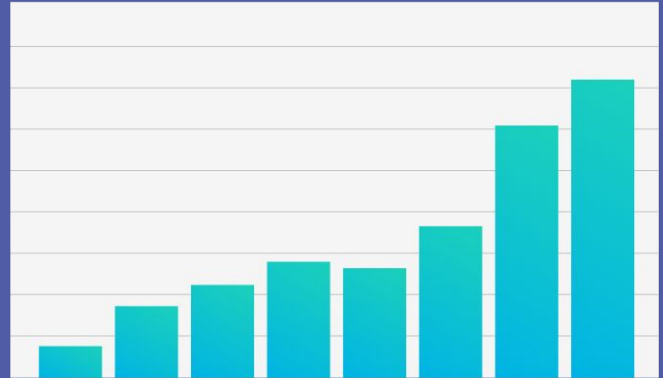


Qualitative and Quantitative Data Analysis

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

Frequently Used Services

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](#)

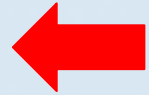
IRB Member Toolbox



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.

[INFORMED CONSENT](#)

[QUESTIONS TO ASK](#)

[COMMON TERMS](#)

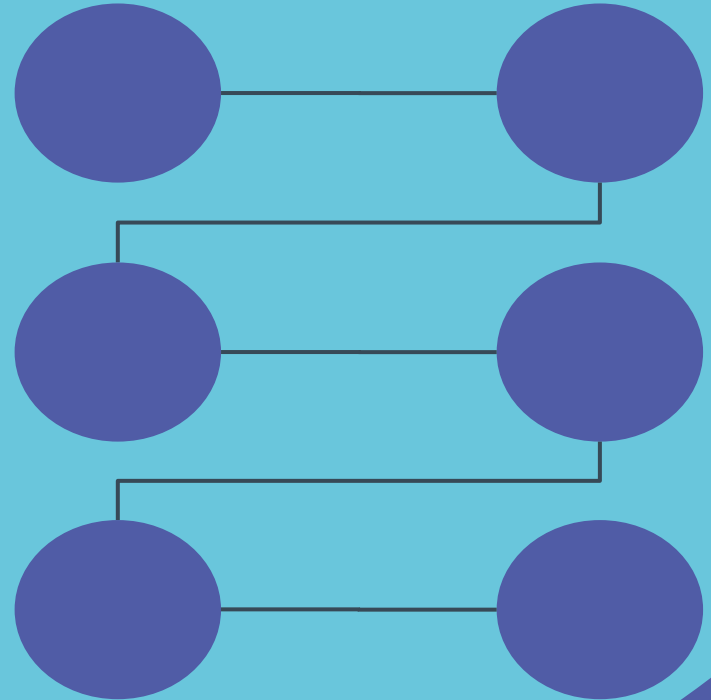


Types of Research Conducted by Penn Researchers

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!