THE FENWAY INSTITUTE

Towards Inclusive Research Ethics

IRB Review that Includes Consideration of Sexual Orientation, Sex, and Gender Minorities

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Objectives

- Familiarize you with the work of the Fenway Community Health IRB (FCH IRB) and its approach to review
- Describe Sexual Orientation and Gender Identity Minority (SOGI) and Sexual Minority Considerations for the IRB and Researchers
- Answer any human subject research questions, and get your input!

Fenway Community Health Institutional Review Board (FCH IRB)

- FCH IRB has been in existence since the late 1980s.
- FCH IRB is comprised of diverse community volunteers who bring their insights and perspectives to the responsibility of reviewing research activities involving humans.
- FCH IRB is charged with protecting the rights and welfare of research participants.
- We oversee about 80 active biomedical, behavioral, and epidemiologic research protocols.

What is an Institutional Review Board (IRB)?

- Independent Ethics Committee
- Charged with the initial review and oversight of human subject research.
- Guiding Principles:
  - Respect for Persons
  - Justice
  - Beneficence

Who tells the IRB what to do?

- Federal and state laws/regulations
- Case Law
- Condition of Grant Award
- Headlines and 24 hours news cycle

AND ALSO…

Our community.

What's the IRB do?

- An IRB operating under a Federal-wide Assurance must approve all non-exempt human-subject research subject to its oversight.
- The IRB serves as a gatekeeper, charged with upholding national standards, as described in the Common Rule/FDA/related agency regulations – but also **community standards.**

FCH IRB asks our researchers to model the inclusiveness and cultural competency Fenway Health expects from its caregivers.

DURING INITIAL REVIEW, WE ASK SOME BIG QUESTIONS:

1. Are risks to subjects minimized?
2. Are risks to subjects reasonable in relation to anticipated benefits (if any) to subjects, and the importance of the knowledge that will result?
3. Is the selection of subjects equitable?
4. Is the informed consent process and documentation appropriate to the work?
5. Are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data?
6. Are appropriate additional protections in place for vulnerable populations?

ARE RISKS TO SUBJECTS ARE MINIMIZED?

Build an inclusive board.

ARE RISKS TO SUBJECTS ARE MINIMIZED?

- Were community stakeholders engaged in a meaningful way when designing this protocol, and in framing the risks or will they be before the study is implemented?
- Are there additional risks for sex and SOGI minority subjects that perhaps weren't considered when preparing the protocol? Examples:
  - SOGI minorities are more at risk for stigmatization and violence or threats of violence, and bullying
  - They also are at greater risk than the general population for social victimization, abuse, poverty, suicide, HIV infection, unemployment, and homelessness
- Is the language used throughout mindfully chosen to promote study efficacy by building trust?

RISK:BENEFIT

- Considering your population of interest – are there intersections of oppression that may impact some research subjects in a disparate way?
- Have you thought of ways to minimize and/or control for these disparate impact and have you summarized this for your IRB?
- Have you reviewed your data collection instruments for gendering language/assumptions?

EQUITABLE SUBJECT SELECTION

- Think through inclusion/exclusion criteria – are folks being unnecessarily or unintentionally excluded?
- If certain genders are not included – has an adequate rationale been provided?
- Recruitment strategies – are they likely to get a representatively diverse sample?
- Are you thinking about gender/sexual orientation diversity in your analysis?

INFORMED CONSENT PROCESS

- Review informed consent document(s)/screeners/scripts for micro-aggressions.
- Train staff to be sensitive to and competent on SOGI language, issues, and concerns

PRIVACY

- Privacy breaches may have additional implications for sexual orientation and gender identity minority populations
- Are you collecting identifiers? Do you need to?
- Will there be group sessions/focus groups or will study visits be conducted in a place subjects are likely to be recognized? Is this likely to be good or bad for your subjects?

PROTECTIONS FOR VULNERABLE POPULATIONS

Specific regulatory definition:

- Pregnant
- Minor
- Prisoner
- Decisionally Impaired

Expand to consider any specific vulnerabilities of the population of interest in the context of the proposed research.

- Fact heavy assessment

GENERAL IRB RESOURCES

Office of Human Research Protections Regulations and Policy Page

https://www.hhs.gov/ohrp/regulations-and-policy/index.html

Harvard Catalyst's Regulatory Foundations, Ethics, and Law Program

https://catalyst.harvard.edu/programs/regulatory/

- Also, check out your local CTSA for free workshops or trainings.

COMMENTS OR QUESTIONS?

As researchers in this field, what would you like the IRB to know or consider when reviewing your work?