

Human Subjects Protections: What you need to know, even if you were afraid to ask!

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Human Subjects Protections

- Six distinct entities may be involved in a human subject protection program
 - The individual investigators
 - The institutional review board (IRB)
 - Research ethics consultation (REC)
 - Research subject advocate (RSA)
 - Data safety monitoring plan (DSMP)
 - Data safety monitoring committee (DSMC)
 - Community Advisory Board
- Three are federally regulated (the role of the investigators; the IRB; and a DSMP)

Code of Federal Regulations Title 45 Part 46 (1981, rev. 1991, 2001)

- Outlines federal policy for the protection of human subjects in research
- Based on The Belmont Report
 - Three Principles
 - Respect for persons
 - Beneficence
 - Justice
 - Application
 - Informed Consent
 - Assessment of Risks and Benefits
 - Selection of Subjects the Belmont Report
- Establishes mandate for Institutional Review Boards (IRBs)
- Discusses additional protections for vulnerable populations (pregnant women, human fetuses, neonates, prisoners, and children)

Subpart A: The Common Rule

- Specifies that research on human subjects requires IRB review
 - Technically only applies to federally-funded research; but all institutions that hold an FWA (federalwide assurance) must hold all research to these standards. Hence all U of C research.
- Specifies IRB structure and function.
- Specifies what minimum level of review different types of research must have.
- Specifies requirements for informed consent
 - Specifies surrogate decision-making

Vulnerable Populations: Special Protections

- Subpart B: Pregnant women and fetus
- Subpart C: Prisoners
- Subpart D: Children

Human Subjects Protections

- Question: What is research with human subjects?
 - Answer: “A systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge” 45 CFR46.
- Who or what is a “Human Subject”?
 - A living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual by
 - Physical procedures by which data are gathered;
 - Manipulation of the subject or the subject’s environment that are performed for research purposes
 - Identifiable private health information

Human Subjects Protections

- Research studies include:
 - Invasive or non-invasive procedures including removal of body tissues or fluids
 - Administration of drugs
 - Exposure to various forms of radiation
 - Alteration of diet or environment
 - Interviews/ surveys
- NOT research:
 - Case studies
 - Works of journalism
- Quality assurance data may or may not be research.
 - Depends on what you will do with the research.

Institutional Review Boards

- Dual Purposes of IRBs:
 - Ensure that research is scientifically sound;
 - Ensure human subjects protections
 - Ensure safety (risks are minimized)
 - Respect for subject's autonomy (informed consent)
- IRB Composition:
 - Sufficient scientific and technical expertise
 - Non-scientific members
 - Unaffiliated (independent) members

Criteria for IRB approval of research

- 1) the risks of the research are minimized;
- 2) the risks to subjects are reasonable in relation to anticipated benefits;
- 3) the selection of subjects is fair
- 4) each participant gives a voluntary and informed consent;
- 5) informed consent is appropriately documented;
- 6) when appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects; and
- 7) when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
- 8) Additional safeguards for vulnerable populations

These are not the only human subjects protections issues

- The Federal Regulations were designed for clinical trials...
- Does not consider risks for communities
- The regulations also state that “The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.” §46.111 a2
- **BUT REMEMBER, other mechanisms to promote HUMAN SUBJECTS PROTECTIONS**

What other issues need to be addressed for human subjects protections in CBPR?

- Risks not only of individuals, but also of groups and communities

What is Community?

- Group versus Community
 - Both have shared trait (for example, based on geography, but also culture, ethnicity, education, disease)
- Community = Structured groups
 - Has its own internal structure and leadership
- Unstructured groups
 - Internal: Can be empowered to create structure
 - External: By a CBO

What other issues need to be addressed for human subjects protections in CBPR?

- Risks not only of individuals, but also of groups and communities
 - Potential risks to non-participant members of the group
- What is the significance of the role of the group (community) as both research partner and research subject?

A Taxonomy of Risks

LEVEL OF RISK	Process Risks to Well-Being	Outcomes Risks to Well-Being	Risks to Agency
Individual [A]	Clinical and psychosocial risks of the research interaction	Clinical and psychosocial risks of research findings	Risk of undermining personal autonomy/authority
Individual by group association [B]	Clinical and psychosocial identity risks of the research interaction	Clinical and psychosocial identity risks of research findings	Risk of group decisions undermining personal autonomy/authority
Community [C]	Risks to group cohesion or structure because of engagement in research	Risks to group cohesion or structure because of research findings	Risk of undermining the group's moral and sociopolitical authority

Interpreting Risk & Agency in CBPR

● RISK

- Incommensurability of Risks (esp. between A-level and C-level)
- Benefit: Risk Ratio
- Non-Participant Third Parties (B-type harms)

● AGENCY

- The Complexity of Relationships and Agency in CBPR
 - A-level process concerns are addressed by informed consent and respect privacy/confidentiality
 - Agency tension between individual and group
- Structured versus Unstructured Groups
 - Structure is a necessary but not sufficient condition for group agency
 - Only structured groups can have C-level risks

● PARTNERSHIPS

- Memorandum of understanding

Conclusion

- 360 degrees of Human Subjects Protections from both the academic medical center (IRB*, REC) and from the community (CAB)
 - Other human subjects protection entities may be joint efforts (role of individual investigators, the establishment of a DSMP, and possibly the RSA)
- Human subjects protection training must be developed that is culturally sensitive and linguistically appropriate for non-health care professionals.

*community members are encouraged to serve on IRBs.