

Group Risks

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Group vs. Community

- GROUPS

- Individuals belong to many groups, some of which they belong to voluntarily, and others involuntarily; some of which they embrace, and others which are imposed upon them.
- Group membership may be defined at birth or later in life because of the development of some particular attribute. Traits may be permanent, due to genetic inheritance, or may be transient due to changing preferences or geographic mobility.

- Communities

- structured group with its own social structure often with identifiable leaders.

A Taxonomy of Risks

| LEVEL OF RISK | Process Risks to Well-Being | Outcomes Risks to Well-Being | Risks to Agency |
|---|--|---|---|
| Individual (Research subject) [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 (may or may not be research subject) [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. (bi-directionality) |
| Community (whose members are research subjects, in part b/c on their membership) [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 |

Foreseeable Risks to Groups?

- Federal Regulations (45 CFR 46.111.a.2) clearly states:
- In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research).
 - [outcome risks]
- 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.
 - [B-level and C-level risks]

Groups and Communities as Human Subjects?

- Groups and communities are not “human subjects” under the federal regulations governing research.
- Both the members of the groups who participate (and possibly the non-members) are at risk of outcome harms.
 - The federal regulations do not require IRBs to evaluate the risks to these third-parties
- Still, it is essential for academic-community partnerships to address these issues as part of a comprehensive human subjects protection (HSP) program.

Which risks should be reviewed by an IRB?

- A-level risks
- B-level risks
- C-level risks

- Process risks
- Outcome risks
- Agency risks

Group Risks

- IRBs should ask researchers to consider the group and community risks that their research poses; and to discuss how these will be managed.
- IRBs should ask researchers if any of these group risks
 - Need to be discussed in the consent form
 - Need to be discussed with community leaders, community advisory board, etc.

Review of risks: Which? By whom?

| LEVEL OF RISK | Process Risks to Well-Being | Outcomes Risks to Well-Being | Risks to Agency |
|-------------------------------------|---|--|---|
| Individual [A] | Yes, IRB | Yes, IRB | Yes, IRB |
| Individual by group association [B] | HSP entity other than IRB? | HSP entity other than IRB | HSP entity other than IRB? |
| Community [C] | HSP entity other than IRB?: Researchers should be encouraged to have support of community's leadership; these issues should be explored. | HSP entity other than IRB: Researchers should be aware of unintended but foreseeable risks and these should be discussed with community's leadership and included in the consent for individual members to make their own assessment. | HSP entity other than IRB: Researchers should be encouraged to discuss possible risks and benefits with the leadership; who then get to decide whether researchers can have access. |

There are 7 distinct entities or mechanisms that can provide Human Subjects Protections

- (1) the individual investigator(s);*
- (2) Institutional Review Board (IRB);*
- (3) Conflicts of Interest Committee (COIC);
- (4) Research Ethics Consultation (REC) program;
- (5) Research Subject Advocacy (RSA) program;
- (6) Data Safety Monitoring Plan (DSMP) for all research;
 - and a Data Safety Monitoring Committee (DSMC) when constituted; and
- (7) Community Advisory Boards (CABs), when constituted.

*mandated in the *Federal Regulations*

Whose concern?

- Individual investigator must be concerned about all risks (A, B, C, Process, Outcome and Agency).
- IRB: focus on A-level risks; may ask researchers to consider outcomes risks (all 3 levels).
- Conflict of interest committee: focus on outcomes risks at all levels and ensure that agency is robust.
- Research Ethics Consultation (REC) program can be concerned about any and all risks.
- Research Subject Advocacy (RSA) program may want to focus on A-level risks; as well as agency risks at all levels.
- Data Safety Monitoring Plan (DSMP): process and outcome risks at A level.
- Community Advisory Board: all risks, but especially C-level risks and then B-level risks. May also consider risks to non-participant (third party) risks.

Group Risks

- Group risks and harms are real. They should be acknowledged, even if they do not affect IRB decisions.
- IRBs could ask researchers to consider B-level and C-level risks.
- IRBs could ask researchers to incorporate some outcomes risk into consent form.
- IRBs may want to ask researchers to discuss group risks, and third party (non participant) risks with community advisory boards or community leaders when appropriate.
- IRBs decision making may depend, in part, on the vulnerability and identifiability of the group.