WSIRB In-service Training 03/20/2008
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Assessing Risks and Benefits in Social/Behavioral Research

RISK ASSESSMENT:

Assessment of risk is a judgment call. It may not even be possible to quantify the likelihood or magnitude or harm in social and behavioral research, as it is driven by context of the research. Baseline rates of risk/harm and therapeutic misconception are usually unknown. Almost no research has been conducted with research subjects on the benefits of research participation, or how they perceive/define benefits.

Minimal risk should be identified in a specific context. "Minimal risk to what end, from whose point of view, and under what situations?" Risks of *daily* life are the baseline--risks that all of us encounter. "By specifying a threshold at or near the risks in daily life, we determine almost a common denominator of risk, the level at which most reasonable people feel 'safe enough' so that their choices can be made without considering the small risk repercussions… Not simply accepted but socially acceptable." Minimal risk is a flexible definition in terms of time and circumstance. (from Freedman et al).

Considerable debate over the above relativist vs. an absolutist definition of risk. OHRP appears to follow a relativist approach.

Prisoners: "Risk of *physical or psychological harm* that is no greater in probability and severity than that ordinarily encountered in the daily lives, or in the routine medical, dental or psychological examinations of healthy persons" [45 CFR 303(d), italics added]. This definition differs somewhat from the definition in Subpart A, as it does not include legal, social, economic, or other harms.

Children: Minor increase over minimal risk (45CFR 46.406(a)) is not defined in the regulations. Other ethicists have suggested a threshold as decisions that could be made by "informed and scrupulous parents…parental decision to permit exposure to new risks is not governed by but is anchored to the risks of everyday life… (*and) must be made relative to the child's actual situation"*. (Freedman et al, italics added)

I. Types of risks in social/behavioral research:
- breach of confidentiality (actual or potential)
- violation of privacy, even when confidentiality is assured
- validation of inappropriate or undesirable behaviors of subjects, perhaps based on misunderstanding of researcher's intent
- presentation of results in a way that does not respect (or agree with) the subjects, interests
- possible harm to individuals not directly involved in the research, but about whom data are obtained indirectly (secondary subjects), or who belong to the class or group from which subjects were selected
- harm to subjects' dignity, self-image, or innocence as a result of indiscreet or age-inappropriate questions in an interview or questionnaire

II. Framework for identifying risks: (adapted from University of Washington Human Subjects Division)

A. Identify potential sources of harm

Risk-relevant study **procedures**
- Randomization
- Survey
- Observation
- Participant observation
- Behavioral manipulation
- Informant
- Interview, focus group
- Deception
- Context in which research would take place (coercive or high-risk environments)

Risk-relevant study **topics**
- Substance abuse
- Aggression
- Prejudice
- Family relationships
- Risk behaviors
- Abuse
- Mental health
- Experience of violence
- Illegal behaviors or criminal history
- Suicide
- Attitudes about self or others

B. Identify the nature of the risks

Type of risks
- Burden (time, data collection intervals, inconvenience, travel, etc.)
- Physical
- Psychological
- Social: group, relationships, cultural
- Economic
- Legal
- Timing (anniversary events, such as a death, violent act, catastrophic event, recent disease diagnosis, etc.)
- Dignitary
- Risk to others

Probability
Magnitude
Duration
(transient, recurrent, reversible, permanent, cumulative)

May not be possible to identify in social/behavioral research

Subject characteristics
- Vulnerable populations (45 CFR Part 46)

Pregnant women, fetuses, neonates (Subpart B)
Prisoners (Subpart C)
Children (Subpart D)

Other potential vulnerabilities:
Physical disability
Legal vulnerability
Mental health issues
Social desirability/deviance or social class
Environmental stressors
Educational or language issues
Economic, access to resources
Cognitive deficits

C. Identify potential protections

Are there ways in which study procedures could be altered that would lessen risks to subjects?

Possible considerations:
Selection of subjects (inclusion/exclusion criteria)
Recruitment
Informed consent process
Confidentiality
Referrals for care or services
Incentives appropriate to the research and study pop.
Voluntariness
Debriefing
Monitoring
Involvement of community

ASSESSMENT OF BENEFITS:

Definition: "A research benefit is considered to be something of health-related, psychosocial, or other value to an individual research subject, or something that will contribute to the acquisition of generalizable knowledge. Money or other compensation for participation in research is not considered to be a benefit, but rather compensation for research-related inconveniences." (NIH Office of Human Subjects Research) May be to the individual, the class of subjects, or to society, or combinations of these.

The *same* framework for assessing risks can be applied to assessment of benefits, by identifying the sources, nature, and procedures to increase benefits.

I. Types of possible benefits of social/behavioral research (often rather intangible):
- Access to information --prevention materials, resource lists, eligibility for other benefits or services, clean needles/condoms
- Access to services offered in the research that ultimately prove beneficial to the individual participant
- Greater awareness or understanding of oneself or one's situation
- Assist those in similar situation in the future through knowledge gained

SUMMARY:

- Research *is not* conducted to benefit individual subjects who participate, although it may. "The beneficiaries of research are *statistical* persons" (Miller and Wertheimer, italics added)

- Risks and benefits should be evaluated in the context in which the research will occur. What is the "allowable maximum" of research risk? IRBs should make their *own* assessment of risk, rather than automatic acceptance of a researcher's assessment.

- Decisions about level of risk should be made on a categorical rather than quantitative basis, "anchored to common social norms and similar risks in everyday life… The rigorous protection of subjects should not lose sight of common social norms." (Freedman et al)

- It is not possible to eliminate all risks, and there is no research that does not pose some risk. The key is to minimize them so that the benefits of the research outweigh any risks. Risks can be managed, but not eliminated. IRB's task is to *reduce* the probability of harm or *limit* its severity or duration.

- "If only minimal risks are involved IRBs do not need to protect competent adult subjects from participating in research considered unlikely to yield any benefit". (OHRP Guidebook) Protection should be proportionate to the risks involved.

- There is no *upper limit* in federal regulations on approvable research risk with adults who can give their own consent for participation.

- Research *findings* may be used to influence public policy and in other ways such as marketing, but the role of the IRB is not to evaluate how research results will be used or the expenditure of public dollars to carry out research activities.

- Incentives (gift cards, coupons, cash, checks) *should not* be considered as potential benefits of research participation.

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