

### Appendix 3: Risks of Harm

Risks of harm in social and behavioral sciences generally fall into three categories:

- Invasion of privacy
- Breach of confidentiality
- Study procedures

**Invasion of privacy** can occur if personal information is accessed or collected without the subjects' knowledge or consent. For example, if a researcher studying interaction patterns in an online support group joins the group and does not reveal her true identity online, the support group participants could feel that their privacy had been invaded by the researcher, if or when her true identity as a researcher is revealed to the group.

Invasion of privacy also can occur if a subject's participation in a study is revealed despite assurances that this would not happen. For example, a researcher is studying emotional reactivity in women who have experienced sexual abuse. The research is conducted in a designated university lab on a particular day each week. Another university staff person sees an acquaintance entering the meeting room and therefore discovers that the acquaintance has experienced sexual abuse.

**Breach of Confidentiality:** Perhaps the primary source of potential harm in the social and behavioral sciences is that information obtained by researchers could adversely affect subjects if disclosed outside the research setting. Confidentiality can be compromised through an unauthorized release of data, which could have a negative impact on the subjects' psychological, social, or economic status. For example:

- . An unintended disclosure of a subject's health status could result in the subject's loss of employment or health insurance coverage.
- . Public revelations of data collected about sexual orientation could result in psychological stress.
- . Workers asked to share their attitudes about the effectiveness of their managers could lose their jobs or be denied promotions if the information is not adequately protected.
- . Information about illegal activities or immigrant status can have serious legal consequences for subjects.

**Study Procedures:** In some cases, simply taking part in research can put subjects at risk. For example, if a researcher is conducting interviews with individual gang members, it may be necessary to find places to meet where other gang members could not observe the interaction. Another situation in which merely taking part in research might pose some risk to subjects is when there is a potential for a breach of confidentiality, not because of inadequate confidentiality procedures on the part of the research team, but from subjects themselves when data are collected in a group setting such as a focus group. Even though participants typically are cautioned not to share information outside the data collection setting, subjects should be made aware that the researcher cannot guarantee confidentiality.

Often it is assumed that the very nature of the research inquiry can pose risk of harm to subjects. For instance, when reviewing research plans that involve asking subjects questions about trauma or abuse, IRB members may be concerned about re-traumatization. However, current research findings indicate that when appropriate protections are built into the study design, such as

ensuring that interviewers are trained to ask questions in a supportive, respectful manner and respond to subjects' reactions appropriately, very few subjects were upset. In fact, most subjects, including those who may have experienced fleeting negative emotions, reported feeling good about taking part in the study (Cromer and Newman 2011, 1536-48). Thus, it is important to review the literature in a given field to determine what, if any, risk of harm the research topic or design might pose to the participant and what, if any, additional protections may be necessary.

### **Assessing Risk**

**Probability and Magnitude of Harm:** When assessing risks of harm associated with participation in a research study, there are two distinct elements of risk that must be considered. One is the probability of harm - the likelihood that a specific harm might occur. The fact that not all possible harms are equally probable should be taken into consideration when assessing risk. The second element of risk is the magnitude or severity of harm should it occur. The interaction between these two elements is a crucial factor in determining the level of risk of harm in a study. Often there is disparity between the probability and the magnitude of risk of harm in a study. For example, a researcher wants to do a web-based survey of college students to collect information about their sexual behavior and drug use. Direct identifiers will not be collected; however, Internet Protocol (IP) addresses may be present in the data set. Although the probability that an individual subject could be identified is low, the magnitude of the possible risk of harm is high given the sensitivity of the information. For more information on managing risks in Internet-based research, see CITI Program module *Internet-Based Research - SBE*.

**Situation and Time:** Risks of harm in research participation are specific to time, situation, and culture. What may be a socially sensitive issue or topic at one time or place may not be so at another time or place. For example, asking women if they have had an abortion would carry very different risks in a country where abortion is a routine medical practice, a country where it is illegal, or a country in which it is legal but the issue is fraught with religious and political controversy.

**Subject Population:** Risks of harm will differ according to the subject population, too. Consider this case: A study on the efficacy of a behavioral intervention for smoking cessation involves both adults and teenagers. Purchasing tobacco products is generally illegal for persons under 18 years of age. For adults, however, it is a health hazard, but not an illegal activity. Thus, any assessment of the risk for teenagers will have to consider that the research focuses on an illegal activity.

Similarly, a survey about sexually transmitted diseases would carry different risks for middle class suburban men, clergy, and gang members.

**Assessing Risks:** People, including researchers, may underestimate risks involved in activities with which they are familiar and overestimate the benefit of things that are important to them.

### **Potential Subjects**

Regardless of the true probability of harm, research indicates that when potential harms are severe, people tend to overestimate the probability. When potential harms are less severe, such as embarrassment, people tend to underestimate the probability.

An independent assessment of risk is critical. One function of IRBs is to provide this

independent assessment.

**Balancing Risks and Benefits:** Federal regulations, based on the ethical principle of beneficence, require that risks of harm associated with research are reasonable in relation to the potential benefits.

A great deal of research in the social and behavioral sciences offers little potential for direct benefits to the subjects themselves. The benefits of the research often lie in the importance of the knowledge to be gained, the contributions it makes to science, or the contributions to society in general. There also might be cases in which a specific community, rather than individual subjects, benefits from the research. This should be balanced with the fact that most research in the social and behavioral sciences poses little or no risk of harm to the individual subject. Federal regulations stipulate that risks of harm must be minimized to the extent possible, consistent with sound research design.

In order to minimize risk, potential research subjects need to be given sufficient information to make a decision about whether they are willing to accept risks and participate in the research. If research questions will be of a sensitive nature, subjects need to be forewarned. Subjects also need to know what steps will be taken to protect confidential information, including disposition of recorded material. Any limits to the extent to which a researcher can protect identifiable personal information should be clearly explained. State and local laws may limit confidentiality, such as reporting requirements for child and elder abuse. Confidentiality cannot be guaranteed for information shared in a focus group.