



Assessing Risk in Social and Behavioral Sciences

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This module has 5 parts and will require 10 to 15 minutes to complete. Take the short quiz at the end of the module before proceeding to the next module.

Introduction

One of the most important and challenging tasks that investigators face is identifying and evaluating risks associated with participation in research. Unlike biomedical research studies or clinical trials, in which the sources of risk may be more readily identifiable and quantifiable, risks associated with participation in social and behavioral science research are often more elusive and less predictable. However, this does not mean that these risks are any less serious or less real. For example, discrimination due to an inadvertent disclosure of sensitive personal information, such as sexual orientation or a diagnosis of mental illness, could have serious consequences.

In rare circumstances, the risks associated with social and behavioral sciences may be physical in nature and not trivial. For example, physical harassment or arrest was identified as a risk in a study of the black market economy in Cuba. Similarly, those who study victims of domestic violence need to consider that their subjects may become the victims of retaliatory violence.

It is also possible that when groups or communities rather than individuals are the focus of a study, the group as a whole may be at risk of harm. For example, studies comparing the average IQ of "racial" groups or the prevalence of HIV-infected individuals in communities may stigmatize the community being studied.

Module Contents:

1. Risks associated with participation in social and behavioral sciences

research

2. Assessing risks
3. Balancing risks and potential benefits
4. Minimizing and managing risks
5. Consent Issues

When subjects will be surveyed about illegal activities it may be appropriate to obtain a waiver of documentation of consent to insure confidentiality. Other strategies may also be employed to reduce risks to the subject.

1.0 Risks Associated with Participation in Social and Behavioral Sciences Research.

1.1 Risk in social and behavioral sciences generally fall in three categories:

- ▶ Invasion of privacy.
- ▶ Breach of confidentiality.
- ▶ Study procedures.

1.2 Invasion of Privacy

Invasions of privacy can occur if personal information is accessed or collected without the subjects' knowledge or consent. Invasions of privacy can occur if a subject's participation in a study is revealed without the subject's knowledge. For example, if an investigator communicates via email with subjects in a study about recovering from childhood sexual assault, family members with access to email may learn about the assault.



1.3 Breach of Confidentiality

Perhaps the primary source of risk in the social and behavioral sciences is that information obtained by researchers

could harm 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 HIV status could result in the subject's loss of employment or health insurance coverage.
- ▶ Public revelations of data collected about sexual preference could result in a loss of social status or discrimination in housing or employment.
- ▶ Workers asked to reveal 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 status (drug use or immigrant status) can have serious legal



consequences for subjects.

1.4 Study procedures

In some cases, simply participating in research can put subjects at risk. For example, responding to questions about

a sensitive topic or traumatic event may be distressing to a subject, even if the information divulged is kept in strict confidence.

Another situation in which merely participating 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 is collected in a group setting such as a focus group. Even though participants are typically cautioned not to share information outside the data collection setting, subjects should be made aware that the researcher cannot guarantee confidentiality.

2.0 Assessing Risk

2.1 Probability and Magnitude of Harm.

When assessing risk associated with participation in a research study, there are two distinct elements of risk that need to be considered. One is the probability of harm – the likelihood that a specific harm might occur. Not all possible harms are equally probable, and this fact should be taken into consideration when assessing risk. The second element of risk is the magnitude of such harm.



Sometimes there is great disparity between the probability and the magnitude of harm in a study. For example, a researcher wants to do a web-based survey of college students to elicit information about their sexual behavior and drug use. Identifiers will not be collected; however, the data are vulnerable in transit from an individual's PC to the web server hosting the survey, much in the same way credit card information is vulnerable during transit. Although the probability that the data could be "snatched" in transit and identified is low, it could be done. The magnitude of the possible harm is very high given the sensitivity of the information. (For more information on managing risks in Internet-based research, see the module titled "Internet Research.")

2.2 Situation and Time

Risks in research participation are specific to time, situation, and culture. Thus, 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 abortions would carry very different risks a country where abortion is a routine medical practice, a country where it is illegal, and a country in which it is legal but the issue is fraught with religious and political controversy.

2.3 Subject Population.

Risks 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.



4.0 Minimizing and Managing Risk

4.1 When the Primary Source of Risk is the Data

When a possible disclosure of subjects' responses is the primary source of potential harm, collecting data anonymously provides the best protection. For example, a mail survey can be constructed without a follow up procedure, thereby negating the need for identifiers.

If, however, the study design makes the collection of identifiers necessary, for example a longitudinal study, safeguarding the data from unauthorized access can be accomplished in various ways, including:



1. Remove all direct identifiers as soon as possible.
2. Substitute codes for identifiers.
3. Maintain code lists and data files in separate secure locations.
4. Use accepted methods to protect against indirect identification, such as aggregate reporting or pseudonyms.
5. Use and protect computer passwords.
6. Encrypt stored data.
7. Access and store data on computers without Internet connections.

4.2 Certificates of Confidentiality.

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. Certificates of Confidentiality may be secured for any research, regardless of funding. The research does not have to be funded by NIH.

Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

A Certificate of Confidentiality will allow the investigator, and others who have access to research records, to be protected from disclosing identifying information on research participants in

- ▶ Civil,
- ▶ Criminal,
- ▶ Administrative,
- ▶ Legislative, or

- ▶ Other proceedings, whether at the federal, state, or local level.

The kinds of information that can be protected include:

- ▶ Substance abuse or other illegal behaviors.
- ▶ Sexual attitudes, preferences, or practices.
- ▶ Genetic information.
- ▶ Psychological well-being.

Certificates of Confidentiality do not override the requirement to report the suspicion of child abuse or neglect, or any other state mandated reporting requirements, such as elder abuse.

Other federal agencies, such as the Department of Justice, provide agency-specific protections that would apply to research conducted by or funded by the agency.

4.3 Managing Other Risks

Subjects may be placed at risk simply by being involved in a study on a stigmatizing or illegal activity. One way to diminish their risk of exposure is to consider applying to the IRB for a waiver of documentation of consent, if the consent form is the only document that links the participants to the study. A waiver of documentation of consent does not imply that any of the required elements of consent are



waived. The elements of consent must be provided in some fashion such as in a cover letter, informational sheet, or verbal script. See the module Informed Consent for more information about waivers.

It may be necessary to find ways to guard against subjects being observed participating in a study. For example, if an investigator is conducting a case study of a gang member, it may be necessary to find places to meet where other members of the gang could not observe the interaction.

Subjects may also be placed at risk by the nature of the inquiry. Studies on strategies for recovery from post-traumatic stress disorder, for example, may involve a complete assessment of the nature and impact of the trauma. In research that has the potential to be distressing to the subjects, investigators need to plan appropriate resources such as supportive counseling, referral, or access to research staff.

5.0 Consent Issues

Potential research subjects need to be given sufficient information to make a decision about whether they are willing to accept potential risks.

If questions will be of 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.

Summary

When assessing risk, focusing on the research methodology and/or topic alone is insufficient since it neglects to take into account another source of risk – that associated with findings or impact of the research results on subjects themselves or specific groups or communities. Common social and behavioral science methodologies such as surveys, questionnaires, and interviews are considered (sometimes erroneously) low risk since they do not involve physically invasive procedures with associated risk of physical harm. However, it is not the procedures *per se* that engender potential harm, but the interaction of different elements, including the research topic and the population being studied.

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