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**i** There are pending regulatory changes that have a general compliance date of 21 January 2019. This module will be updated in January 2019 to reflect these changes. We invite you to review the [CITI Program's Final Rule Resources](#) for information on the changes to the Common Rule.

## ASSESSING RISK - SBE

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## INTRODUCTION

One of the most important and challenging tasks researchers and Institutional Review Boards (IRBs) face is identifying and evaluating risks of harm associated

with participation in research. Unlike biomedical research studies and clinical trials in which the sources of risk may be more readily identifiable and quantifiable, potential harms associated with taking part in social and behavioral science research may be more ambiguous and less predictable, such as individual reactions to certain events or questions. However, identifying and assessing risks in such situations should be informed by a growing body of research literature on risks associated with research participation.

The risks of harm typically associated with social and behavioral research are social, psychological, economic, and legal in nature. However, in rare circumstances, the risks may involve physical harm. For example, those who study victims of domestic violence need to consider that individuals taking part in the study may become the victims of retaliatory violence if the subjects' involvement in the research is discovered.

It also is 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, research on the prevalence of HIV-infected individuals in communities may stigmatize the community being studied.

Identification, assessment, and minimization of risk are paramount to the conduct of ethical social and behavioral research.

## **Learning Objectives**

By the end of this module, you should be able to:

- Identify risks of harm associated with participation in social and behavioral sciences research.
- Distinguish between probability and magnitude of harm when assessing risk.

- Apply the concepts of minimizing and managing risk.

## IDENTIFYING RISKS ASSOCIATED WITH PARTICIPATION IN SOCIAL AND BEHAVIORAL SCIENCES RESEARCH

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

- Invasion of privacy
- Breach of confidentiality
- Study procedures

### INVASION OF PRIVACY

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 RISK OBJECTIVELY

### RESEARCHERS

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 POTENTIAL 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.



## **MINIMIZING AND MANAGING RISK**



### **WHEN THE PRIMARY SOURCE OF RISK IS THE DATA**



When a possible disclosure of subject responses is the primary source of potential harm, collecting data anonymously may provide the best protection. For example, a mailed 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:

- Remove all direct identifiers as soon as possible.
- Substitute codes for identifiers.
- Maintain code lists and data files in separate secure locations.
- Use accepted methods to protect against indirect identification, such as aggregate reporting or pseudonyms.
- Use and protect computer passwords.
- Encrypt transmitted and stored data.
- Access and store data on computers without Internet connections.
- Obtain a Certificate of Confidentiality.

In the past, when data were usually recorded and stored on paper and/or devices such as floppy disks, researchers restricted access to data by storing the records in locked file cabinets, in locked offices. With increasing use of digital technologies to acquire, transmit, analyze, and store data, data security has become much more complex. Researchers are not often information technology (IT) experts. Therefore, research teams should consult with their institutional IT security contacts for guidance regarding the most secure means of obtaining, transferring, analyzing, and storing data when the primary source of risk stems from a security breach.

## CERTIFICATES OF CONFIDENTIALITY

[Certificates of Confidentiality](#) are issued by the National Institutes of Health (NIH) to protect identifiable research information from compelled disclosure. Certificates of Confidentiality may be obtained for any research, regardless of funding, so long as the research is relevant to the mission of the NIH/HHS.

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 researcher, and others who have access to research records, to be protected from required disclosure of 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 health

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 apply to research conducted or funded by the agency.

Under a new policy issued 7 September 2017 (effective 1 October 2017), NIH-funded investigators do not need to apply for a Certificate of Confidentiality, nor will they receive a document certificate. The NIH issues Certificates of Confidentiality automatically for “NIH funded grants, cooperative agreements, contracts and intramural research projects research funded wholly or in part by the NIH that collect or use identifiable, sensitive information” (NIH 2017).

Certificates of Confidentiality contain conditions for disclosure of the identifiable,

sensitive information that the investigator must comply with , including more restrictive requirements for disclosure in the new policy.

The Certificates of Confidentiality policy remains the same for non-federally funded research, in that investigators must apply for a Certificate of Confidentiality from the NIH or other HHS agency for specific research studies.

Researchers must inform subjects about the protections and limitations provided with a Certificate of Confidentiality.



## **WHEN THE PRIMARY SOURCE OF RISK IS THE CONSENT DOCUMENT**



Subjects may be placed at risk if others know they are taking part in a study of a stigmatizing or illegal activity. If the consent form is the only document that links the participants to the study, one way to diminish their risk of exposure is to consider applying to the IRB for a waiver of the requirement to document consent. 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. For more information about waivers, see CITI Program module: "Informed Consent - SBE."

## SUMMARY

Common social and behavioral sciences methodologies such as surveys, questionnaires, and interviews are considered (sometimes erroneously) low risk because they do not involve physically invasive procedures with associated risk of physical harm. However, it is not the procedures *per se* that engender potential risks of harm but the interaction of different factors. It is necessary to assess both the probability and magnitude of harm, as well as the context (situation, place, and time) of the research as it relates to the particular study population.

A blue folder icon with the text "Case Study" written inside in white.

[Assessing Risk](#)

## REFERENCE

- Cromer, Lisa DeMarni, and Elana Newman. 2011. "Research ethics in victimization studies: widening the lens." *Violence Against Women* 17(12): 1536-48.
- National Institutes of Health (NIH). 2017. "[Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality](#)." Accessed 14 September.

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