

## Guidance for Risks in Social, Behavioral, and Educational Research

It can be difficult to identify and minimize risks in Social, Behavioral, and Educational research. What often appear to be very minimal risks can have dramatic consequence for participants or others connected to the research. This guidance addresses identifying and minimizing risks in these research environments.

### 1. What is Minimal Risk?

When assessing potential risks of research, IRBs and researchers need to consider the nature of the study procedures, data collection and management, and characteristics of participants. According to 45 CFR 46.102, Minimal Risk “means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

This definition poses several important issues to consider:

- The experience of “daily life” is different for every participant. For this reason, a risk evaluation is not based on the types of risks ordinarily encountered in the daily lives of the proposed subjects of the research. “Minimal Risk” is an ethical threshold derived from the routine experience of “the average person” in the “general population.”
- The “daily life” standard is a difficult balance to achieve. According to the Secretary’s Advisory Committee on Human Subject Protections: “minimal risk should be applied in manner that recognizes that risks are procedure-specific and population-dependent, but that the notion of “acceptably-low” risk is fixed. When the harms and discomforts of the proposed research as they are anticipated to impact the study participants are judged to fall below this acceptably-low risk threshold, the research is said to be ‘minimal risk.’”
- Research risks include harms not just to participants, but “others.” Research can pose risks to researchers, research teams, third parties linked to participants, and even communities or institutions affected by research findings.
- Risks in research do not just emerge from research interventions, but also from features of the research design, such as the timing or location of the research intervention.

## 2. How can Researchers Identify and Minimizing Potential Research Risks?

Nature of Risk	Methods for Minimizing Risk	Example
<p>1. Participants may lose privacy or confidentiality during collection of sensitive data.</p>	<ul style="list-style-type: none"> <li>• Use strategies to anonymize data at point of collection or allow participants to opt out of parts of data collection.</li> <li>• Increase the sample size for the study to help reduce identifiability of specific participants.</li> </ul>	<p><i>A researcher will collect data on sexual and behavioral health. To minimize risks, the survey will be sent to a broad and anonymous pool of participants, not limited to a specific class, athletic team, or demographic.</i></p>
<p>2. Participants may become identifiable during the research process. This may occur through a flaw in the data collection process or a feature of the research design (e.g. timing or location).</p>	<ul style="list-style-type: none"> <li>• Use strategies to anonymize data at point of collection or allow participants to opt out of parts of data collection.</li> <li>• Increase the sample size for the study to help reduce identifiability of specific participants.</li> <li>• Schedule research visits or interventions in private locations at times limiting potential exposure of the individual as a research participant.</li> <li>• Paraphrase or Code any material quoted from recorded focus groups or interviews.</li> </ul>	<p><i>A researcher will collect extensive demographic data to describe a participant population in detail. To minimize risks, the researcher removes any unnecessary demographic questions and uses a broad scale or range for specific identifiers, such as ages.</i></p>
<p>3. Research may reveal poor student or employee performance.</p>	<ul style="list-style-type: none"> <li>• Increase the sample size for the study to help reduce identifiability of specific participants.</li> <li>• Use strategies to anonymize data at point of collection or allow participants to opt out of parts of data collection.</li> <li>• In Education Research, Have a non-evaluative individual perform surveys or focus groups.</li> </ul>	<p><i>A researcher, who is the principal of a school, will conduct focus groups on faculty perception of school culture. To minimize risks, the researcher will have a third party conduct the focus group, such as their dissertation chair.</i></p>

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<p>4. Poor research design may produce misleading data, and negatively affect the standing of an institution or community.</p>	<ul style="list-style-type: none"> <li>• Use Community-Engaged Research practices to ensure the research meets the expectations and needs to of the research population.</li> <li>• Develop a plan to share study findings with the research population in a constructive way.</li> <li>• Present research findings in aggregate and use more generic descriptions of specific participant qualities or experiences.</li> <li>• Adjust vocabulary and labeling in consent documents and surveys to ensure diverse and welcoming language is used.</li> <li>• Use good research design to ensure that all questions or interventions connect integrally to an intended study aim or outcome.</li> </ul>	<p><i>A researcher will collect survey and focus group data from a population with limited access to health care in a specific county or neighborhood. To minimize risks, the research will focus research on questions related to health care, present findings only in aggregate, and share results at a community meeting.</i></p>
<p>5. Participants may experience lengthy or stressful research with no potentially viable benefit.</p>	<ul style="list-style-type: none"> <li>• Simply what participants are being asked to do by performing the minimal necessary interventions.</li> <li>• Use good research design to ensure that all questions or interventions connect integrally to an intended study aim or outcome.</li> <li>• Avoid creating “kitchen sink” surveys, which collect more demographic data or information than necessary.</li> </ul>	<p><i>A researcher will collect data on sleep patterns and habits. To minimize risks, the researcher will combine three standardized instruments into a shorter 25 question survey tool focused on meeting the specific study aims.</i></p>
<p>6. Randomizing participants to different research interventions may lead to participants experiencing different standards of care or practice.</p>	<ul style="list-style-type: none"> <li>• Establish a Data and Safety Monitoring Plan to ensure all participants are exposed to equivalent risks and benefits throughout the duration of the study.</li> <li>• Have a plan to un-blind data or un-randomize participants to ensure equipoise during the study.</li> </ul>	<p><i>A researcher will randomize three third grade classes to different math teaching strategies. To minimize risks, the researcher will either have each class rotate through each teaching strategy, or plan to move all classes to the most effective strategy when there is a clear best practice.</i></p>

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<p>7. Participants may feel isolated or stigmatized through research designs that include or exclude specific groups or types of people.</p>	<ul style="list-style-type: none"> <li>• Increase the sample size to minimize the possibility someone will feel singled out or stigmatized by sensitive data collection or social/behavioral interventions.</li> <li>• Avoid convenience sampling and use standard or community-engaged research recruitment strategies.</li> <li>• Adjust vocabulary and labeling in consent documents and surveys to ensure diverse and welcoming language is used.</li> </ul>	<p><i>A researcher is studying disciplinary practices in a 5<sup>th</sup> grade classroom. To minimize risks, the research will study the entire class rather than selecting only students with disciplinary challenges as participants.</i></p>
<p>8. Participants may feel embarrassed or distressed during or after research involving deception.</p>	<ul style="list-style-type: none"> <li>• Use best practices for research involving deception, such as maximizing information shared during the consent process and providing a debrief experience after the research.</li> <li>• Have a counselor available for referral, in case participants are particularly distressed during or after the research.</li> </ul>	<p><i>A researcher will observe participants attempting to complete a series of unsolvable math problems. To minimize risks, the research will provide a debrief experience to all participants after the research.</i></p>
<p>9. A researcher may damage their relationship to participants, such as when participants are teachers, counselors, or employers.</p>	<ul style="list-style-type: none"> <li>• Use participants with analogous demographics or characteristics from a different area or location.</li> <li>• Increase the sample size for the study to help reduce identifiability of specific participants.</li> <li>• Paraphrase or Code any material quoted from recorded focus groups or interviews.</li> <li>• In Education Research, Have a non-evaluative individual perform surveys or focus groups.</li> </ul>	<p><i>A researcher, who is also a coach, will collect data on social bonding in college athletics. To minimize risks, the researcher will not recruit participants from their own team.</i></p>