



RISK ASSESSMENT

Description

The IRB must conduct an assessment of the risks to participants in order to determine whether a study is approvable. In order to approve research, the IRB must find that:

- Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.

The investigator is responsible for describing the risks to participants in the IRB application. Additionally, the investigator must describe the overall experience that will be encountered and must inform the participants of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity during the consent process and documentation.

If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform research participants. Currently enrolled participants may be required to be re-consented.

Investigators should consider the following specific guidelines when describing risks to participants:

Medical Risks

The consent procedure and documentation must include a description of any reasonably foreseeable risks, discomforts or side-effects the participant may experience for each procedure, drug, or device (including the possibility that an experimental treatment may be ineffective). List all side effects which are life-altering or potentially life-altering, no matter how rare.

Explain if the research activity is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). The study design may impact the participant's exposure to risk so it is important to explain this during the consent process.

For studies involving **placebo or withheld treatment**, potential risks must be adequately explained, including any risks of non-treatment.

Standard of Care Risks

OHRP guidance states that IRBs should consider only those risks that may result from the research (as distinguished from risks of therapies subjects would receive even if not participating in the research.... (45 CFR 46.111(a)(2)). When the exposure to the risks of the standard of care occurs as a matter of clinical care, and not because of study participation, the risks associated with the standard of care should not be included in the description provided to participants.

If the standard of care itself is being studied, the standard of care risks become research risks. These should then be included in the description of reasonably foreseeable risks. If evaluating a particular risk of research associated with a standard of care is a purpose of research, it should be included in the description of reasonably foreseeable risks. For more comprehensive guidance on this topic, please refer to the [Draft Guidance on Disclosing Reasonably Foreseeable Risks in Evaluating Standards of Care](#).

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



Reproductive Risks

For studies involving possible reproductive risks, the investigator must:

1. State any known risks in pregnancy, either to mother or child.
2. State that there may be unforeseeable risks to the participant or to the embryo or fetus if the participant is pregnant or becomes pregnant during the study.
3. List the acceptable methods of birth control for this research project.
4. Describe what action will occur in the event of pregnancy (i.e. follow-up of pregnancy outcome, immediate withdrawal from the study, etc.)

Social/Psychological Risks

Include a description of any reasonably foreseeable risks or discomforts such as emotional distress/discomfort, psychological trauma from remembering past experiences, invasion of privacy, embarrassment, loss of social status, potential adverse economic or employment consequences, etc.

Vulnerable Populations

Special consideration should be given to risks when the study involves vulnerable populations such as children, prisoners, pregnant women, and people with impaired decision-making capacity, etc. The investigator should also consider that the study may involve other vulnerable populations such as socially or economically disadvantaged persons, students, faculty and staff of the University, undocumented immigrants, refugees, etc. Risks to specific populations should be addressed in the consent document.

Confidentiality & Privacy

The investigator should describe any risk to the loss of confidentiality of information about the participant and any risk to the loss of the participant's privacy. The investigator must describe the procedures used to maintain the confidentiality of the records and data pertaining to the participant, and how the participant's privacy will be protected. In some studies, there will be an expected loss of confidentiality or privacy (e.g., in focus groups, confidentiality cannot be guaranteed since third-party individuals will be present for the disclosure of information). In other studies, the loss of confidentiality or privacy is not expected. In any case, the participant must be informed about the confidentiality and privacy risks.

Points to Address

New Study Application:

1. **Risks and Benefits page:** Describe in detail how anticipated risks to participants will be minimized.
2. **Data Monitoring page, Privacy Precautions:** Include an explanation of the procedures in place to protect the privacy of the participants.
3. **Data Monitoring page, Confidentiality Precautions:** Include an explanation of the methods for maintaining confidentiality of the study data. Describe the procedures used to maintain the confidentiality of the records and data pertaining to the participant.

Consent Document:

1. **Risks:** Please list any reasonably foreseeable risks to participants.
2. **Confidentiality ("How we will protect and share your information"):** Describe the procedures used to maintain the confidentiality of the records and data pertaining to the participant.
3. **Unforeseeable Risks:** If applicable, state that participation in the study may involve risks that are currently unforeseeable.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



References & Links

IRB Consent Template

<http://irb.utah.edu/forms/>

*Draft Guidance on Disclosing
Reasonably Foreseeable Risks
in Research Evaluating
Standards of Care*

<https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-disclosing-risk-in-standards-of-care/index.html>

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