SingHealth CIRB:

Illuminaté

"To Énlighten... Ethics, above all"

Adapted version for researchers, investigator and study coordinators

SingHealth
Defining Tomorrow's Medicine

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In this issue >>>

Minimizing Risk

1. What is risk >>>

- Risk is the probability and magnitude of harm or discomfort occurring as a result of participation in the research study.
- Minimal risk is defined as "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".
  - Minimal risk may determine whether study may be reviewed under expedited procedures, the way informed consent would be obtained.
  - Risk assessment of investigator may differ from that of the IRB. The Review Types (e.g. Expedited or Full Board Review) based on the risk level will be determined by the IRB.

2. Type of risk and their example >>>

Physical	Physical risk refers to the physical discomfort, pain, injury, illness or disease as a result from participation in the research. (e.g. adverse effects which result from medical procedures or drugs)
Psychological	Psychological risk refers to the production of negative/ undesired thought processes and emotions (such as anxiety, depression, confusion, guilt, shock and loss of self-esteem and altered behavior). (e.g. stress and feelings of guilt or embarrassment that may arise from interview on sensitive topics)
Social	Social risk refers to alterations in relationships with others that are to the disadvantage of the participants (such as labeling a subject in a way that will have negative consequences, or in some way diminishing those opportunities and powers a person has by virtue of relationships with others). (e.g. stigmatize)
Economic	Economic risks include loss of wages or other income and any other financial costs due to participation in research. (e.g. loss of employment)

In all research involving human subjects, there may be a potential risk from the breach of confidentiality. Confidentiality of identifiable information must be maintained. The more sensitive the research data, the greater care must be exercised when obtaining, handling, and storing data.

- To minimize the risk for breach of confidentiality, investigators should only collect personal information that is absolutely essential to the research activity.
- If an investigator wishes to use identifiable data for other purpose, consent should be obtained from the participants.

Reference:

1. Assessing Risks and Benefits. (2021). University of California, Irvine Office of Research. Retrieved February 14, 2022, from https://services-web.research.uci.edu/compliance/human-research-protections/irb-members/assessing-risks-and-benefits.html
2. OVPRI. (n.d.). Examples of Potential Risks to Subjects | Research and Innovation. Retrieved February 14, 2022, from https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/examples-potential-risks-subjects

3. Assessing and minimizing risk >>>

Initial Review – Criteria For Approval (SHS-RSH-CIRB-215)

The following criteria were extracted from the PnP:

Section 6.2.3 - Risks to participants are minimized by using procedures which are:

a) consistent with sound research design
b) do not unnecessarily expose participants to risks
c) when appropriate, already being performed for diagnostic or treatment purposes

Section 6.2.4 – Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may be reasonably expected. Board will consider only those risks and benefits that may result from the research (as distinguished from the risks and benefits of therapies participants would receive even if not participating in the research).

Risk Assessment:

Step 1: Identify and distinguish risk associated with:

- Procedures performed solely for research
- Procedures or therapies participants would receive even if not participating in research
- Procedures that are experimental or investigational

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Step 2: Identify the context in which research procedures are performed:

- Are the research procedures added to a standard care event?
- E.g. Extra blood draw at routine draw, additional time in CT scanner for research imaging, additional biopsies, longer anesthesia time to measure oxygen saturation levels.

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Step 3: Consider the participants population:

- Age, health status.
- Are they more sensitive or vulnerable to the risks poses by the research?
- How are they identified and recruited?
- Should additional protections be in place to minimize risks and maximize benefits?

Ways to Minimize Risk

- Study Team Members should provide complete information in the protocol regarding the experimental design and the scientific rationale underlying the proposed research (including the results of previous animal and human studies).
- Study Team Members should have sufficient expertise and experience to conduct the research.
- Ensure that the projected sample size is sufficient to yield useful results.
- Collect data/ human biological material from standard-of-care procedures to avoid unnecessary risk.
- Adequate safeguards:
  - Appropriate data safety monitoring plan
  - Procedures to protect the confidentiality of the data (e.g., encryption, codes, and passwords)

Reference:

1. Conducting risk-benefit assessments and determining level of IRB Review. UCLA Office of the Human Research Protection Program. (n.d.). Retrieved June 27, 2022, from https://ohrpp.research.ucla.edu/assessing-risks/
2. OVPRI. (n.d.). Examples of Potential Risks to Subjects | Research and Innovation. Retrieved February 14, 2022, from https://research.uoregon.edu/manage/research-integrity-compliance/human-subjects-research/examples-potential-risks-subjects

Takeaway message...

Minimal risk is not the same as minimizing risk. All research would have some risks. For minimal risk studies, there may be a potential risk from breach of confidentiality. For more than minimal risk studies, the study team must include safeguard to minimize risk and state all potential risk in the informed consent document.

If you have any questions, please contact CIRB at irb@singhealth.com.sg