

Title:	Risks To Research Participants
Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director
	<i>Signature/date</i>
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Policy:	1.7

POLICY STATEMENT

It is the policy of the FHCRC that human subject research studies should employ sound research principles and minimize risks associated with participation. The IRB Staff and the IRB Members will conduct a systematic evaluation of the potential risk and benefits to research participants as part of the initial review and ongoing review of the research study. In minimizing risks, the IRB should consider physical, psychological, legal, economic and social risks. The investigators of the research study should be aware of the risks associated with all study activities and procedures.

DEFINITIONS

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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 [Federal Policy §___.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults. [See 45 CFR 46.303(d) and IRB Guidebook Chapter 6, Section E, "Prisoners."]

Greater Than Minimal Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant.

REFERENCES

45 CFR 46.102
45 CFR 46.111(a)(1)
45 CFR 46.111(a)(2)
21 CFR 56.111(a)(1)
21 CFR 56.111(a)(2)

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to Institutional Review Office (IRO) staff, IRB members, employees of FHCRC and investigators from other institutions who submit research studies to the FHCRC IRB for review and approval.

PROCEDURES

1. Minimizing Risk

Risks to research participants must be minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose research participants to risk.

2. IRB Review

At the time of initial review, continuation review and review of modifications to the research study the IRB should:

- Consider physical, psychological, legal, economic and social risks.
- Analyze the levels of risk
- Ensure risks are minimized and procedures:
 - Are consistent with sound research
 - Do not expose research participants to unnecessary risk
 - Have already been performed on research participants for diagnostic or treatment purposes when appropriate.
- Ensure risks are reasonable relative to anticipated benefits

The IRB Staff, IRB Chair or IRB Members will review the completed *Application For Review*, *Continuation Review Form*; and *Protocol Modification Form* to evaluate and minimize risk to research participants.

- The *IRB Member Checklist* will be used to assist the IRB Chair and Members in identifying, evaluating and documenting the most current information about the any potential risk and benefits of the interventions involved in the research.
- The IRB Staff will use the *Screener: New Application*, *Screener: Protocol Modification*, and *Screener: Continuation Review Report*, to assist the IRB Staff to identify and document any possible risk related issues and also remind IRB Staff to identify when a consultant may be needed depending on any unique considerations for Vulnerable Populations noted in *IRB Policy 2.15 Research Involving Vulnerable Populations*.

The IRB may need to obtain consultants with additional experts when aspects of the research design seem to pose a significant concern or when Vulnerable Populations will be included in the research.

The IRB shall consider the Data and Safety Monitoring Plan outline in the *Application For Review* as well as the Data Safety Monitoring Board, when applicable, as described in the *Cancer Consortium Data and Safety Monitoring Plan*.

The IRB Staff will document the findings of the IRB and communicate those findings to the Principal Investigator (PI) and study staff as outlined in *IRB Policy 1.6 Meeting and Meeting Records* and screeners noted above.

3. The PI should:

- Be aware of the risks associated with study procedures and consider that risks to research participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose research participants to risk. For example:
 - Substituting less risky procedures for riskier procedures when adequate to answer the study question
 - Use of the minimal number of procedures to answer the study question
 - Enrollment of the minimum number of research participants needed to answer the study question
 - Modification of inclusion/exclusion criteria to exclude research participants who might be at increased risk if they undergo the research procedures, or include research participants who might be at less risk if they undergo the research procedures
- Complete and submit to the IRO for IRB review an *Application For Review*, a *Continuation Review Report* or a *Protocol Modification Form* and provide a description of:
 - Potential risks to research participants
 - Frequency, severity, and reversibility
 - Planned procedures and plans to minimize, monitor, and report risk to the IRB to include the risk of confidentiality
 - Potential benefits to be gained by research participants and future research participants
 - Any potential changes in risk and benefit when revising the research study

SUPPORTING DOCUMENTS

RTO Cancer Consortium Data and Safety Monitoring Plan
IRB Policy 1.6 Meeting and Meeting Records
IRB Policy 2.1 New Application
IRB Policy 2.15 Research Involving Vulnerable Populations
Application For Review
Continuation Review Report
Protocol Modification Form
IRB Member Checklist
 Screener: New Application
 Screener: Continuation Review Report
 Screener: Protocol Modification