Title:	Risks to Research Participants
Policy:	1.7
Version:	2.06
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Responsible Office:	Institutional Review Office (IRO)
Responsible Official:	Karen Hansen, IRO Director for Karen Hansen 1/17/2019 *Signature/date*

Version History	Effective Date
2.05	07-03-2017
2.04	04-24-2013
2.03	01-31-2012
2.02	03-18-2011
2.01	12-07-2009
2.00	08-01-2007
1.00	11-28-2006

POLICY STATEMENT

It is the policy of the Fred Hutchinson Cancer Research Center (Fred Hutch) that human subject research studies should employ sound research principles and minimize risks associated with participation. The Institutional Review Office (IRO) Staff and the Institutional Review Board (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

See *IRB Glossary of Terms and Acronyms* (050) for full definitions of the following:

Minimal Risk

Risk

INDIVIDUALS AFFECTED BY THIS POLICY

The contents of this policy apply to IRO staff, IRB members, employees of Fred Hutch and investigators from other institutions who submit research studies to the Fred Hutch 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, continuing 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. [1]
- Ensure risks are reasonable relative to anticipated benefits[2]

The IRB Staff, IRB Chair or IRB Members will review the completed appropriate *Application for Review* (0324, 0325, or 0326), *Continuing Review Report* (045), or *Research Modification Form* (062) to evaluate and minimize risk to research participants.

- The *IRB Member Checklist* (071) 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* (0335, 0336, or 0337), *Screener: Modification* (0139), and *Screener: Continuing Review Report* (0124), 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 special populations noted in *IRB Policy 2.15 Research Involving Special Populations* (033).

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

[1] HHS: 45 CFR 46.111(a)(1); FDA: 21 CFR 56.111(a)(1)
[2] HHS: 45 CFR 46.111(a)(2); FDA: 21 CFR 56.111(a)(2)

The IRB shall consider the Data and Safety Monitoring Plan outline in the appropriate *Application for Review* (0324, 0325, or 0326) 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* (024) 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 appropriate *Application for Review* (0324, 0325, or 0326), a *Continuing Review Report* (045), or a *Research Modification Form* (062) 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

IRB Policy 1.6 Meeting and Meeting Records (024)
IRB Policy 2.15 Research Involving Special Populations (033)
Application for Review Interventional Research (0324)
Application for Review Observational Research (0325)
Application for Review Human Specimen and Data Research (0326)
Continuing Review Report (045)
IRB Glossary of Terms and Acronyms (050)
IRB Member Checklist (071)
Research Modification Form (062)
Screener: Continuing Review Report (0124)
Screener: New Application Human Specimen or Data Research (0337)
Screener: New Application Intervention (0335)
Screener: New Application Observation) (0336)
Screener: Protocol Modification (0139)
Fred Hutch / UW Cancer Consortium Data and Safety Monitoring Plan

REFERENCES

45 CFR 46.111
21 CFR 56.111
OHRP guidance on the Genetic Information Nondiscrimination Act (GINA)