



SUBJECT: Investigator Responsibilities for
Minimizing Risk, Monitoring Subjects, and
Reporting in Greater than Minimal Risk
Research

POLICY: RA:HRPP:10.06

DATE EFFECTIVE:

PAGE: 1 of 2

I. POLICY

Investigators conducting greater than minimal risk research must make all attempts to minimize risk to study subjects by employing sound study design in accordance with the standards of the discipline, and implement reporting mechanisms that provide information to monitor the rights and welfare of subjects enrolled in the research.

Definitions

Minimal Risk: 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. An example of minimal risk is the risk of drawing a small amount of blood from a healthy individual for research purposes (because the risk of doing so is no greater than the risk of doing so as part of a routine physical examination). (45 CFR 46.102(i); 21 CFR 56.102(i))

Greater than Minimal Risk: Does not meet the definition of minimal risk.

II. ACCOUNTABLE EXECUTIVE AND REVIEWER(S)

- A. Accountable Executive: Chief Academic Officer/Institutional Official for the Federalwide Assurance
- B. Department Responsible for Review: Office for the Protection of Human Subjects
- C. Committee Responsible for Review: Institutional Review Board Executive Committee
Research Policy/Procedure Working Group

III. APPROVAL

Approved by:

IRB Executive Committee

10/01/2009
Date

Research Policy/Procedure Working Group

Date

Mark L. Batshaw, M.D., Chief Academic Officer

Date

IV. APPLICABILITY

Areas where the policy and procedure applies: Children's Research Institute, Children's National Medical Center

Persons to whom the policy and procedure applies: Investigators conducting greater than minimal risk human subjects research

V. REVIEW OR REVISION DATE

Original:

VI. REFERENCES

AAHRPP Element(s):

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.102(i)
Food and Drug Administration (FDA) 21 CFR 56.102(i)



SUBJECT: Investigator Responsibilities for
Minimizing Risk, Monitoring Subjects, and
Reporting in Greater than Minimal Risk
Research

PROCEDURE: RA:HRPP:10.06P

DATE EFFECTIVE:

PAGE: 1 of 2

I. PROCEDURE

- A. Principal Investigators (PIs) are expected to assure protection of human subjects' rights and safety by designing scientifically sound research and providing oversight of all research processes, procedures, and research personnel involved in the research.
- B. Investigators are expected to understand the concept of minimizing risk and to consider it as a guiding principle in all research activities.
- C. Investigators should consider whether other procedures involving less risk are appropriate when designing a research study.
 - 1. Wherever possible, an investigator should substitute a less risky procedure that will yield the same data.
 - 2. Rationale for this substitution should be specified in the Procedures section of the research application.
- D. Investigators should design research that, whenever possible, uses procedures already being conducted on the subjects for non-research reasons.
 - 1. The study schedule should clearly specify all procedures that are a part of standard of care treatment.
 - 2. The investigator should provide the rationale and justification for instances when research activities do not include any standard of care procedures. This applies to pharmacokinetic studies or any study presenting greater than minimal risk where treatment regimens are not being evaluated as part of the research.
- E. Investigators must submit all required to the Institutional Review Board (IRB) so that the committee can determine whether the research includes adequate provisions for monitoring the data collected to ensure the safety of subjects.

- F. Investigators must report to the IRB, Data and Safety Monitoring Boards, sponsors and appropriate Federal agencies any serious and unexpected adverse events and/or unanticipated problems involving risks to subjects or others that occur in the course of the research. (RA:HRPP:06.02 and 06.02P, *Unanticipated Problems Involving Risks to Subjects or Others, Including Adverse Events*; RA:HRPP:08.09 and 08.09P, *Data and Safety Monitoring*)
- G. Investigators must modify research designs to mitigate potential injuries in on-going research.
 - 1. It is the responsibility of the investigator not to deviate from the protocol approved by the IRB, except to avoid immediate hazard to the subject (RA:HRPP:05.07 and 05.07P, *Protocol Deviations*). The investigator must submit a modification request to the IRB and receive written approval prior to implementation of any change to the protocol. (RA:HRPP:05.06 and 05.06P, *Protocol Modifications and Revisions*)

II. REVIEW OR REVISION DATE

Original:

III. REFERENCES

AAHRPP Element(s):

Federal Regulations: U.S. Department of Health and Human Services (DHHS) 45 CFR 46.102(i)
Food and Drug Administration (FDA) 21 CFR 56.102(i)

Policies and Procedures: RA:HRPP:05.06 and 05.06P, *Protocol Modifications and Revisions*
RA:HRPP:05.07 and 05.07P, *Protocol Deviations*
RA:HRPP:06.02 and 06.02P, *Unanticipated Problems Involving Risks to Subjects or Others, Including Adverse Events*
RA:HRPP:08.09 and 08.09P, *Data and Safety Monitoring*
RA:HRPP:10.05 and 10.05P, *Initial Protocol Application: Submission Materials*