8 Participant Protections: 8.1 Risks and Benefits	Effective Date: 10/16/2009 Revised: 8/9/2013

In accordance with federal regulations, research risks shall be minimized, and reasonable in relation to anticipated benefits to protect the safety and welfare of participants. Investigators consider risks and benefits in the design and conduct of research. The IRB considers risks and benefits in the review and approval of research.

1.0 Research risks:

The potential risks of research should be minimized to the extent possible to protect subjects' safety and welfare.

1.1 Risk Assessment.

Participants may experience a variety of risks of harm while participating in research. These may be categorized as:

- Physical risks (e.g., pain, injury, discomfort, allergic reactions, etc.)
- Psychological risks (e.g., stress, depression, guilt, loss of self-esteem, etc.)
- Sociological risks (e.g., stigma, embarrassment, damage to reputation, etc.)
- Economic risks (e.g., loss of employment or health insurance, financial costs, etc.)
- Legal risks (e.g., criminal prosecution, etc.)

Physical risks are more common in biomedical research. The primary risks for social and behavioral research involve psychological, social, economic or legal risks, and some may occur as a result of invasion of privacy or breach of confidentiality.

All reasonably foreseeable risks of harm that participants may experience shall be identified so that the research is designed to minimize these risks as much as possible. Risks may be transitory or permanent, minor or severe, and the perception of risk may vary between individual participants. In addition, vulnerable groups may also be more susceptible to some risks. Risks of research participation should be clearly delineated from any other risks participants would ordinarily encounter during their normal daily activities or with standard medical care or exams.

1.2 Level of risk.

Individuals encounter some level of risk in the course of their daily lives, and while receiving standard medical care or tests. Research risks are measured against this 'minimal risk' standard. Risks that a participant may encounter while participating in a research project are characterized as:

- no more than minimal risk
- a minor increase over minimal risk, or
- more than a minor increase over minimal risk.

Research approved by the IRB involving more than minimal risks require additional safeguards to protect the safety and welfare of subjects. Safeguards may include:

- requirement for full board review
- restrictions on involvement of vulnerable groups
- restrictions on use of waivers or alterations of informed consent
- more frequent continuing review intervals
- data safety monitoring plans
- plans for emergency treatment or care.

1.3 Measures to minimize risks.
Potential risks to research participants may be minimized by a variety of means:

- use of sound research design that does not impose unnecessary risks
- use of procedures already being performed for diagnostic or treatment purposes
- appropriately trained and qualified investigators and research team
- adequate facilities and equipment to conduct the research
- prior pre-clinical or animal testing
- pre-screening tests
- inclusion or exclusion criteria
- provision of counseling services or referrals
- monitoring health of participants during and/or after participation
- sufficiently robust data safeguarding procedures to prevent confidentiality breaches
- provisions to protect privacy
- adequate plans to handle emergency events or injuries
- debriefing procedures after participation

2.0 Risk/benefit ratio.
The risks to subjects must be reasonable in relation to any anticipated benefits. Research may benefit subjects directly (e.g., through improved health or well-being), in addition to benefits to society through the advancement of important knowledge. Potential benefits should always outweigh the risks; research involving significant risk is justified only when potential benefits are also significantly greater. Payment or other compensation to subjects for research participation is not considered a benefit, and is not taken into consideration when determining the risk/benefit ratio.

The following are some considerations in evaluating risk/benefit ratio of a research project:

2.1 Vulnerable groups.
Certain subject populations (e.g., children, pregnant women, fetuses, and neonates, prisoners, mentally disabled, physically disabled, institutionalized, medical illness or condition) may be at greater risk than others while participating in research.

2.2 Scientific merit.
Research involving human participants should be well designed to yield valid results and contribute to the advancement of knowledge to benefit society. Scientific merit is a more important consideration when research will involve more than minimal risk to subjects. The IRB considers the issue of scientific merit primarily when the research design itself contributes to excessive or unnecessary risks. Such studies would likely require revisions to study design to meet criteria for IRB approval.

2.3 Availability of alternative standard treatments.

Some clinical research may involve therapeutic treatment with potential for direct benefit to participants. Where an alternative standard treatment exists, the research must involve a risk/benefit ratio at least as favorable as this standard of care. Where no alternative acceptable treatment exists, and the research involves treatment of a life-threatening illness, greater risks may be justified, provided that greater potential benefits have been demonstrated.

3.0 Informed Consent.
Potential subjects or their legally authorized representative(s) must be provided with a complete and accurate description of all reasonably foreseeable risks and discomforts to make an informed decision regarding their participation in research. When research involves more than minimal risks, information must include availability of medical treatment and compensation for that treatment, if any.

4.0 Unanticipated Problems.
Investigators are required to promptly report to the IRB all unanticipated problems involving risks to participants. Other parties with knowledge of unexpected problems may also make a report to the IRB. Refer to *7.7 Unanticipated Problems and Serious Adverse Events* for more information.

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.

Privacy: having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Confidentiality: pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

Benefit: a research benefit is considered something of health-related, psychosocial, or other value to a participant, or something that will contribute to the acquisition of generalizable knowledge.

REFERENCES:
45 CFR 46.111 and 21 CFR 56.111 Criteria for IRB Approval of Research
45 CFR 46.102 and 21 CFR 50.3 Definitions
OHRP Guidance: Written Procedures
OHRP IRB Guidebook, Chapter III, A. Risk/Benefit Analysis
Institutional Review Board Member Handbook, 2nd Ed., Chapter 3-9. R. Amdur and E. Bankert, 2007

RELATED FORMS:
IRB Protocol Form
Report of Unanticipated Problem or Serious Adverse Event

RELATED HRPP SECTIONS:
7.2 Criteria for IRB Approval
7.7 Unanticipated Problems and Serious Adverse Events