Subject: Minimization of Risks

Section: 6-2

This policy and procedure supersedes those previously drafted.

Approved by: Vice President of Research & Graduate Studies on 3-9-2008. Revision 1 approved by VP Research & Graduate Studies on 7-21-2011.

Related Sections: 6-2-A, 6-2-B, 6-3

“(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.” 45 CFR 46.111, 21 CFR 56.111

Risks are the harm or injury (e.g., physical, psychological, social, legal, economic) that could occur as a result of participation in a research study. Minimal risk “means that 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” 45 CFR 46.102(i), 21 CFR 50.3(k). As stated in the Belmont Report, “Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures.” Institutional Review Board (IRB) members should evaluate research studies to determine whether risks to subjects are minimized.

Assessment Criteria
When submitting an application to the IRB for review, the investigator must describe (as appropriate to the research):

• Potential risks to subjects
• Where possible, an estimate of the frequency and severity of the risk
• How risks will be minimized
• When appropriate, provisions for monitoring the data during the conduct of the research

In the process of evaluating the minimization of risks, the IRB considers the following:

• Risks to subjects associated with the research
• Degree of risk (i.e., minimal risk, more than minimal risk)
• Whether the proposed research design reduces the probability and / or magnitude of risk
• Whether the procedures involved in the research are already being performed for diagnostic or treatment purposes
Additional Considerations
For additional policies and procedures on minimization of risks, see the following sections of the Human Research Protection Program (HRPP) Manual:
6-2-A Sound Research Design
6-2-B Adequate Resources
6-3 Risk Benefit Ratio