Michigan State University
Human Research Protection Program

Subject: Minimization of Risks

Sub-Topic: Sound Research Design

Section: 6-2-A

This policy and procedure supersedes those previously drafted.

Approved by: Vice President of Research and Graduate Studies, 3-3-2005. Revision 1 approved by VP Research & Graduate Studies on 8-22-2011.

Related Sections: 2-2-A, 2-2-C, 2-4, 5-4

“(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

In order to approve research, the Institutional Review Board (IRB) must determine that risks to subjects are minimized by using procedures which are consistent with sound research design. The IRB performs this review in conjunction with their regulatory and ethical review.

Review of sound research design addresses the following issues:

- Does the research use procedures consistent with sound research design?
- Is the research design sound enough to yield the expected knowledge?

The diverse colleges and departments at Michigan State University (MSU) have developed many processes to ensure that research studies from faculty and students have appropriate design before they are submitted to the IRB.

For faculty proposals, these processes include:

- Formal research committees that review protocols
- Offices of Associate Deans of Research
- Informal review networks
- Mentoring committees
- Emeritus committees

For student research, these processes include:

- Thesis committees
- Dissertation committees
- Mentors for undergraduate research and research practicums
In addition, many research studies are grant funded (externally and internally) and peer reviewed for merit and design. In the medical field, many clinical trials are performed in cooperation with national programs (NSABP, SWOG) and are reviewed by the U.S. Food and Drug Administration and national review committees.

Documentation of such reviews may be requested by an IRB member to assist in his/her review. A checklist has been developed to assist members in their review of sound study design.

In the course of conducting its review of proposed protocols, the IRB may need the assistance of members of the faculty or other consultants who possess scientific expertise relevant to the research in question. When appropriate expertise is not available upon the IRB committee, the IRB chair or IRB may enlist consultants or expert committees to provide opinions to the IRB concerning the study design of a protocol. Consultants are requested to assess relevance of proposed study to the field or assess technical issues beyond expertise of IRB members. See the Human Research Protection Program (HRPP) Manual 5-4 “Additional Expertise” for further policies and procedures.

Additional Considerations
For research studies subject to the requirements of the U.S. Department of Defense, the U.S. Department of Justice, and the International Conference on Harmonization Good Clinical Practice, see the following sections of the HRPP Manual:

2-2-A U.S. Department of Defense
2-2-C U.S. Department of Justice
2-4 International Conference on Harmonization Good Clinical Practice (E6)