Michigan State University
Human Research Protection Program

Subject: Termination or Suspension of Research

Section: 9-3
This policy and procedure supersedes those previously drafted.

Approved by: Vice President of Research and Graduate Studies, 4-21-2005. Revision 1 approved by VP Research & Graduate Studies on 3-9-2008. Revision 2 approved by VP Research & Graduate Studies on 7-22-2011.

Related Sections: 4-8

“An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB’s action and shall be reported promptly to the investigator, appropriate institutional officials, and the Department or Agency head [Food and Drug Administration].” 45 CFR 46.113, 21 CFR 56.113 [FDA]

Authority
Michigan State University has given the authority and responsibility to its Institutional Review Boards (IRB) to suspend or terminate research studies in order to protect human subjects, uphold ethical principles, protect the research integrity of the institution, and comply with university policy and state and federal laws and regulations. Termination means that the IRB approval is terminated permanently and the research activities cannot recommence at a later date. Suspension means that the IRB approval is suspended in whole (all research activities must stop) or in part (e.g. enrollment must stop), but allows for potential recommencement of the research study.

The IRB may suspend or terminate a research study it previously approved, or a research study that has not been approved and is in noncompliance. Suspension or termination may be in response to a noncompliance investigation or unanticipated problem. Investigators will be notified in writing of a termination or suspension of research. Through communication with the Office of Sponsored Programs, the IRB may freeze research study funds to facilitate a suspension or termination.

Immediate Actions for Imminent Protection of Human Subjects
The IRB has given the authority and responsibility to the IRB chair, vice-chair, or Human Research Protection Program director to suspend temporarily or terminate research studies for the imminent protection of human subjects. The IRB chair, vice-chair, or the Human Research Protection Program (HRPP) director may reach this decision with consultation from others (e.g., members of the IRB) if needed. If the IRB chair, vice-chair, or HRPP director exercises this authority, he/she will communicate with the IRB immediately to inform the members of the action and the IRB will determine the proper course of action from that point forward. The IRB chair may call an emergency IRB meeting to discuss appropriate actions or the vice-chair or HRPP director may request an emergency IRB meeting. The decision to terminate or suspend a research study may also be reached at the time of the regularly scheduled convened IRB meeting.
Research that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB, or if it has been suspended or terminated by the IRB.

**Determination Considerations**
In determining whether to suspend or terminate the study, the IRB chair, vice-chair, HRPP director, and/or the IRB may consider, but are not limited to:

- Effect the suspension or termination will have on the subjects’ rights and welfare
- Whether the suspension or termination is in the best interests of the subjects

If the research is suspended or terminated, the IRB chair, vice-chair, HRPP director, and/or the IRB may consider, but are not limited to:

- Necessity of subject follow-up for safety reasons
- Notification of current subjects
- Procedures for withdrawal of enrolled subjects, taking into account rights and welfare (e.g., making arrangements for medical care off a research study, transfer to another investigator, continuation of research under independent monitoring)
- Reporting requirements to subjects (e.g., unanticipated problems)
- Reporting requirements to IRB such as adverse events or outcomes
- Other actions to protect the rights and welfare of currently enrolled subjects
- Other actions as the IRB sees fit

**Reporting**
The IRB will ensure prompt reporting as defined in, and as required by, the policies and procedures in HRPP Manual 4-8 “Reporting Policy.”