Michigan State University
Human Research Protection Program

Subject: Research Site Visits

Section: 8-10

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 3-9-2008. Revision 2 approved by VP Research & Graduate Studies on 7-21-2011. Revision 3 approved by VP Research & Graduate Studies on 3-13-2013.

Related Sections: 9-2, 9-3

“An IRB shall conduct continuing review of research covered by this policy [regulations] at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.” 45 CFR 46.109 (e), 21 CFR 56.109(f) [FDA]

The Institutional Review Board (IRB) has the responsibility and authority to directly observe or have a third party observe ongoing research studies and the consent process, as well as conduct continuing review of the study, including review of research records. The Human Research Protection Program (HRPP) will review research records randomly, for cause, and based on the compliance records of the researchers. Full cooperation by the principal investigator (PI) and other members of the research team (if necessary) is expected.

The purpose of the site visit is to ensure protection of the human subjects involved in research by providing oversight and if needed, education for the researchers. The information gathered during the site visit is used to monitor the implementation of research studies, identify areas that need improvement, target education, and to gather information for continuous improvement of the HRPP.

Procedures for Immediate Action

If information is discovered at the time of the site visit that indicates that subjects may be at a greater risk than previously identified, the Human Research Liaison (HRL) will promptly notify the IRB chair.

At any time during the review process the IRB chair or IRB may determine that it is necessary to act to protect subjects by suspending, modifying, or permanently closing the research study. If this occurs, policy and procedures in HRPP Manual 9-3 “Termination or Suspension of Research” would be followed.

The PI is notified in writing of any exceptions or problems requiring corrective action. If possible non-compliance is discovered during the site visit, the non-compliance policies and procedures will be followed. See HRPP Manual 9-2 “Noncompliance” for policies and procedures.
The site visit report includes observations from the HRL(s) and may include actions from the IRB. The HRPP director is copied on all HRL/IRB letters sent to the PI. The IRB chair may determine what, if any, corrective actions are required or may determine that review and action by the IRB is necessary.

Site Visit Procedures
The basic site visit procedures are described below but due to the high variability in research studies, it is anticipated that modifications will be made to tailor each site visit to the specific study.

The HRL(s) typically perform the following:

1. Review the IRB documentation and correspondence to identify approved elements for record review, e.g., protocol eligibility criteria, informed consent procedures, interventions, security/confidentiality procedures.
2. Assemble site visit materials, e.g., specific site visit tool, interview forms.
3. Notify the PI of the site visit and make site visit arrangements, e.g., scheduled time and space, names/titles of research team members, location of records, number of subjects enrolled.
4. Visit the research site(s) to review procedures and records.
   - Informed consent obtained
   - Confirmation of eligibility of subjects
   - Confirmation of interventions/treatments used
   - Unanticipated problems that may involve risks to subjects or others reported to the IRB
   - Security/confidentiality measures employed
   - Subject complaints
5. Meet with researchers to obtain additional input, if necessary.
6. Schedule follow-up meeting or discussion with PI to clarify any outstanding questions, discuss specific deficiencies found, and obtain input on possible corrective actions if necessary.
7. Draft compliance report for review by others as appropriate (e.g. HRPP director, IRB chair, HRPP manager, HRL).
8. Finalize compliance report including requirements for corrective actions.
9. Present the compliance report to the IRB when necessary or as requested.
10. Notify the PI of corrective/protective actions required. Investigators should respond to the report and make requested changes within a set timeframe provided to the PI by the HRPP.
11. The PI’s response will be brought to the HRPP director or the IRB chair to determine if any further action is needed.