Human research protection is a complex process with ever increasing and changing regulations. Because of the complexity and the importance of human research protection to the conduct of effective research and the mission of the university, it is imperative to have a highly trained, experienced, and competent Institutional Review Board (IRB) staff, investigators, research staff, and IRB members. Thus, the Human Research Protection Program (HRPP) requires such individuals to be qualified by training and experience to perform their role and responsibilities. This includes the knowledge of federal, state, and local laws and regulations, relevant professional standards, and the policies and procedures of Michigan State University regarding the protection of research subjects and the conduct of research. The HRPP, working closely with the other university offices such as the Clinical and Translational Sciences Institute, conducts activities designed to enhance the understanding of human research protection subjects or their communities when appropriate. These activities are evaluated on a regular basis. See HRPP Manual 3-3 “Evaluation and Quality Improvement” for a description of evaluation mechanisms.

The Human Research Liaison program is complementary to the IRB and encompasses post approval monitoring, education, and non-IRB regulatory oversight. The additional areas of human research and regulatory oversight include areas such as the U.S. Food and Drug Administration regulations, Public Law 110-85, Title VIII Clinical Trial Databases, interactions with Pharmacy for appropriate research drug and device storage, Investigational New Drug or Device submissions, the Protection of Pupil Rights Amendment (PPRA), Family Educational Rights and Privacy Act, (FERPA), post approval monitoring of non-IRB activities, etc.

The HRPP director coordinates communication on human subject protection issues, involving other individuals as appropriate. For a description of how the HRPP director communicates and makes available new or revised HRPP policies and procedures, see HRPP Manual 3-2 “Policy Development and Approval.”

For training requirements and activities specific to individual roles, see the following sections of the HRPP Manual:

11-1-A  Investigators and Research Staff
11-1-B  IRB Member
11-1-C  IRB Staff
For a description of outreach and engagement policies and procedures, see HRPP Manual 12-2 “Outreach and Engagement.”

Additional Considerations
For research studies subject to the requirements of the U.S. Department of Defense, see HRPP Manual 2-2-A “U.S. Department of Defense.”