### Michigan State University

**Human Research Protection Program**

**Subject:** Applicability

**Section:** 4-1  
*This policy and procedure supersedes those previously drafted.*

<table>
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<th>Approved by:</th>
<th>Vice President for Research and Graduate Studies, 4-21-2005; Revision 1 approved by the VP Research &amp; Graduate Studies on 11-2-2005. Revision 2 approved by VP Research &amp; Graduate Studies on 3-9-2008. Revision 3 approved by VP Research &amp; Graduate Studies on 5-6-2008. Revision 4 approved by VP Research &amp; Graduate Studies on 9-3-2009. Revision 5 approved by the VP Research &amp; Graduate Studies on 7-21-2011.</th>
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<td>Related Sections:</td>
<td>1-1, 2-2-A, 4-3, 4-3-A, 5-4, 6-9-A, 8-8, 12-1</td>
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The policies and procedures included in the Michigan State University (MSU) Human Research Protection Program (HRPP) and this Manual apply to all of MSU’s human subject research related activities regardless of funding support or location where the research will be conducted (i.e. domestic, international), and to all activities of its Institutional Review Boards (IRBs). These policies and procedures apply to the human subject research activities conducted by employees of MSU (faculty and staff), by students of MSU, by agents of MSU (i.e. individuals engaged by MSU to conduct human subject research on behalf of MSU), or by individuals conducting research at entities that have a formal written agreement with MSU for review and approval of their human subject research. The MSU HRPP does not apply to adjunct or clinical faculty who are not employees or agents of MSU (volunteer faculty), unless they have a formal written agreement to conduct human subject research on behalf of MSU or are conducting research at an entity that does have such an agreement.

When a planned activity meets the definitions of “research” involving a “human subject,” the HHS regulations (45 CFR 46) regarding the protection of human subjects apply, with limited exceptions specified in HRPP Manual 8-8 “Demonstration Projects.” When a planned activity meets the definitions of “clinical investigation” involving a “human subject,” the FDA regulations (e.g., 21 CFR 50, 21 CFR 56, 21 CFR 312, 21 CFR 812) regarding the protection of human subjects apply. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of the FDA regulations. 21 CFR 56.102 (c). In instances when both HHS and FDA regulations apply and conflict, the stricter regulatory requirement must be followed. See HRPP Manual 4-3 “Determination of Human Subject Research” for policies and procedures on how the determination of whether an activity is human subject research is made. For additional guidance on activities considered outside of the scope of IRB review, see HRPP Manual 4-3-A “Clinical Case Reports,” 6-9-A “Student Classroom Research,” and 12-1 “Quality Assurance, Quality Improvement, or Program Evaluation.”

Human subject research must be approved by an IRB or determined to be exempt from IRB review prior to any research activity, including contact with human subjects or data collection. An investigator planning to conduct human subject research must submit an application to the MSU HRPP, with limited exceptions specified in HRPP Manual 1-1,
“Federal Wide Assurance” (i.e. reliance on a non-MSU IRBs review). All human subject research submitted to the MSU HRPP will be assigned to the appropriate IRB (i.e. Biomedical and Health IRB, Community Research IRB, Social Science / Behavioral / Education IRB).

The Community Research Institutional Review Board (CRIRB) reviews biomedical applications for research that will be conducted at two or more partner institutions or multi-community research. The Biomedical and Health IRB (BIRB) and Social Science / Behavioral/ Education IRB (SIRB) review applications based primarily on the Principal Investigator's college or unit affiliation.

The BIRB reviews human subject research studies for investigators in the biomedical and clinical departments, with the exception of multi-community research. These colleges include the College of Human Medicine, College of Nursing, and College of Osteopathic Medicine.

The SIRB reviews non-biomedical human subject research studies from the non-biomedical or clinical departments. These colleges and units include the College of Agriculture and Natural Resources, College of Arts and Letters, College of Education, Eli Broad College of Business, College of Communication Arts and Sciences, College of International Studies and Programs, James Madison College, College of Music, College of Natural Science, College of Social Science, College of Urban Affairs Program, MSU Libraries, MSU Museum, Women’s Resource Center, Residence Life, Counseling Center, and Career Services and Placement.

However, some individual departments in a college reviewed by the SIRB may be reviewed by the BIRB, and vice-versa (e.g., Department of Kinesiology in the College of Education is reviewed by BIRB, not SIRB). For a listing of such exceptions, see the HRPP website. Research studies from a department reviewed by the SIRB that involve the use of drugs, devices, or medical interventions (e.g. fMRI) may be reviewed by the BIRB or CRIRB. The IRB chair will be consulted if there is question of which IRB has the appropriate IRB member expertise to review the research. Additional expertise will be obtained as needed. See HRPP Manual 5-4 “Additional Expertise.” Research subject to FDA regulations must be reviewed by the BIRB or CRIRB.

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.”