As required by the federal government for institutions engaged in human subjects research that is supported by any agency of the U.S. Department of Health and Human Services (DHHS), Michigan State University (MSU) has an approved Federalwide Assurance (FWA) with the Office for Human Research Protections (OHRP). Through the FWA, MSU assures that it will comply with DHHS regulations (45 CFR 46) for the protection of human subjects. MSU also maintains active Institutional Review Board (IRB) registration with OHRP as required by the U.S. Food and Drug Administration (FDA) in compliance with 21 CFR 56.106 and assurances as required by the U.S. Department of Defense.

With limited exceptions specified in Human Research Protection Program (HRPP) Manual 8-8 “Demonstration Projects,” MSU applies 45 CFR 46 and all of its subparts to all of its human subject research, regardless of the source of support. MSU will also comply with any additional human subject regulations and policies of supporting federal agencies and of the FDA (21 CFR 50 and 56) as well as the Health Insurance Portability and Accountability Act Privacy Rule (45 CFR 160 and 164).

MSU has established three IRBs that have oversight for all research conducted under its FWA #00004556. Under MSU’s IRB Organization Information (IORG# 0000182), the designated IRBs are:

1. Michigan State University IRB #1 – Biomed & Health IRB – BIRB – IRB registration #00000297

2. Community Research Institutional Review Board (CRIRB) IRB #2 – IRB registration #00003392


These IRBs provide oversight for all research conducted under the assurance and for research that is subject to MSU HRPP oversight as defined in HRPP Manual 4-1 “Applicability.” With limited exceptions for research that is subject to a fully executed reliance agreement, no human subject research may be initiated by MSU employees, staff, students, or any other individuals to whom the MSU HRPP policies and
procedures apply to prior to approval or an exempt determination by one of the designated IRBs. See HRPP Manual 4-1 “Applicability.”

The FWA Terms of Assurance establish additional requirements and responsibilities that apply to MSU and the designated IRBs. These requirements are incorporated in other policies and procedures in the HRPP Manual.

For descriptions of the types of human research each MSU IRB reviews, see HRPP Manual 4-1 “Applicability.”