The Michigan State University (MSU) Human Research Protection Program’s (HRPP) primary mission is the protection of individuals who are the subjects of research. MSU is committed to follow the ethical standards described in the Belmont Report, and all applicable federal, state and local regulations and university policies and procedures. The HRPP at MSU sets forth the structure, policies, and procedures to implement this mission and commitment. The processes of education, review, and monitoring described in the HRPP serve to ensure the safe and ethical conduct of research that will protect human subjects in an atmosphere of mutual trust and integrity in the pursuit of knowledge and human benefit.

While the HRPP office provides the primary oversight and coordination for the protection of human subjects in research, it is not the only MSU office that is involved in the protection of human subjects in research. This responsibility is broader and is shared and distributed with other MSU offices and units. Each of these offices or units plays an important role in the protection of human subjects. Integration between such components is essential for the protection of human subjects in the research. This policy describes the roles, responsibilities, and coordination among the MSU offices and units for the protection of human subjects in research. While this policy focuses on the communications related to human subject protection, the units also communicate closely on other areas related to research (e.g., execution of a contract or grant, other regulatory compliance areas such as biosafety).

Communications between the MSU offices and units may occur on a protocol specific basis or may be of a programmatic nature. When issues arise on a specific research study, meetings may be scheduled as needed between the units. In addition, representatives from the groups described below meet regularly to provide input on the development of a comprehensive research administration electronic system that would enhance electronic linkages between the research administration components. Additional meetings may be scheduled on an as needed basis between the units to discuss issues or communication strategies that are programmatic in nature.
Communication between the MSU units related to human research protection also helps to assure that all institutional approvals will be in place before the research is initiated. However, it is the responsibility of the principal investigator (PI) to assure that all appropriate institutional approvals, including those related to human subject protection, are in place prior to initiation of the research. Some research studies may only require Institutional Review Board (IRB) review and approval; others may require other institutional approvals. The communications and additional requirements described in this policy between the HRPP and other university offices and units provide steps and communication mechanisms to facilitate and assist the PI to assure that all appropriate institutional approvals are in place before the initiation of the research.

Institutional Review Boards (IRB)
Michigan State University (MSU) has established Institutional Review Boards (IRBs) under its Federal Wide Assurance #00004556. For more information about the IRBs structure and function, see the MSU HRPP Manual sections including but not limited to Sections 4-2, Authority of IRBs; 4-5, Responsibilities of the IRBs; and 5-3, IRB Membership.

Office of the Vice President for Research and Graduate Studies (OVPRGS)
The Vice President for Research and Graduate Studies (VPRGS) has been designated as the Institutional Official for MSU; see HRPP Manual 4-4 "Institutional Official" for a full description of the role and responsibilities of the IO for the protection of human subjects. Organizationally, the HRPP office reports to the OVPRGS through the Office of Regulatory Affairs (ORA). Other units involved in the protection of human subjects also report to the OVPRGS including the Office of Sponsored Programs, MSU Technologies, and Conflict of Interest.

Coordination with the IO occurs as needed for the protection of human subjects. Regular meetings with the IO and staff from the HRPP and with the assistant vice president for the ORA (AVP ORA) occur as well. The OVPRGS regular staff meetings attended by senior VPRGS staff and the heads of VPRG units facilitate communication between the units in the OVPRGS.

Office of Regulatory Affairs (ORA)
The ORA is organized under OVPRGS and provides administrative oversight of the HRPP, the Animal Care Program, the Environmental Health and Safety Program, and the Conflict of Interest office. These units report to the AVP ORA. ORA facilitates research review processes in accordance with federal regulations to protect the rights and welfare of research subjects, to protect public health and safety, and to assure the proper execution of research.

Senior staff meetings with ORA unit heads facilitate communication between the units in ORA. The AVP ORA also meets regularly with the director of the HRPP. Staff from units within ORA also communicates directly with each other regarding human subject protection as described below.
Human Research Protection Program (HRPP)
The HRPP office is organized under the ORA under the VPRGS. The HRPP includes the offices of the IRB and Compliance. The HRPP encompasses not only the IRB requirements for the protection of human subjects, but other additional areas of human research regulatory oversight that are broader than the IRB requirements (e.g., U.S. Food and Drug Administration regulations, interactions with Pharmacy, clinical research billing compliance) that provide protections for human subjects.

Institutional Review Board (IRB) Office
The IRB office facilitates the IRB review processes in accordance with federal, state, and local regulations, university policies, and ethical standards.

The IRB staff notifies other offices involved in the protection of human subjects when research studies require input from various offices. Some notifications are built into the IRB electronic database, while others are captured on the IRB application and during the staff pre-review process.

Compliance
The Compliance office encompasses post approval monitoring activities, education, and non-IRB regulatory oversight (e.g. FDA requirements, protected health information, clinical research billing compliance).

The Compliance office coordinates and works with other units (e.g., Pharmacy, Environmental Health and Safety, Radiology) to accomplish its role in the oversight of clinical research compliance (e.g. Compliance office will provide coordination when an IRB application involves protected health information).

The Clinical Research Billing Compliance (CRBC) office is organized within the Compliance office and provides resources to the research community and others involved in patient care activities during research studies to ensure proper billing of health care services and items according to federal, state, and local regulations.

Post approval monitoring serves to educate researchers and to assure that the research study is being conducted in accordance with federal, state, and location regulations, university policies, and ethical standards.

Environmental Health and Safety (EHS)
EHS is organized under ORA and promotes and establishes programs in health and safety, protection of the environment, and regulatory compliance. Committees within EHS include Radiation Safety Committee (RSC), Institutional Biological Safety Committee (IBC), and the Chemical Hygiene Committee (CHC). The CHC reviews and monitors the effectiveness of MSU’s Chemical Hygiene Plan and key areas of compliance such as training and use of controlled or hazardous materials. The RSC reviews, approves, and continually monitors the use of radioactivity on campus. The IBC is a regulatory required committee that approves the use of recombinant DNA, and provides guidance on the use of infectious agents. The MSU Biosafety Officer oversees the transport of these materials
and provides training on use of infectious agents. EHS also includes areas such as occupational health and safety, hazardous waste, environmental compliance, and controlled substances.

An email notification mechanism to EHS is built into the IRB online system when an investigator discloses on the IRB application the use of biological materials, radiation, or controlled substances. The email includes linkages to the IRB protocol specific information regarding biological materials, radiation, or controlled substances. The respective office then communicates with the investigator as needed (e.g., training needs, appropriate review).

Conflict of Interest (COI)
The COI office is organized under ORA and facilitates the COI processes. The Conflict Resolution Committee (CRC) reviews and manages disclosures of COI. The Faculty Conflict of Interest Officer (FCOIO) assists with implementation of the Faculty COI policy and is available to answer questions about conflict of interest, including questions about COI as it relates to the protection of human subjects.

HRPP staff communicate with the COI office and/or FCOIO regarding conflict of interest disclosures, review, and management. The IRB chair communicates with the FCOIO regarding advice, consultation, and notification of IRB determinations of conflict of interest that affect the rights and welfare of subjects. These may include but are not limited to instances of conflict of interest of IRB members, IRB consultants, investigators, students, sponsors, or administrators. The FCOIO works with the Conflict Review Committee (CRC) which is responsible for developing and enforcing a management plan and informing the IRB of their decisions. The IRB has the authority to approve the research, to require modifications that incorporate the CRC management plan and/or additional IRB determined modifications, or to not approve the research. The CRC may not approve the research if it has not been approved by the IRB.

Office of Sponsored Programs (OSP) and Business Connect (BC)
OSP reports to the VPRGS and the Controller and manages financial and contractual aspects of submitting proposals to non-industrial external sponsors. Any non-industry agreement that involves financial transactions and obligations between MSU and other parties must be reviewed by OSP. OSP post award is responsible for the administration of awards (industrial and non-industrial) according to sponsor's and MSU regulations.

Business Connect reports to the VPRGS and manages financial and contractual aspects of submitting proposals to industrial external sponsors. Any industry agreement that involves financial transactions and obligations between MSU and other parties must be reviewed by Business Connect.

Investigators are required to disclose on the contract or grant transmittal form whether the proposal includes human subject research. Communication between the IRB and OSP or BC includes the review of funding or contract agreements to assure inclusion of the Association for the Accreditation of Human Research Protection Programs (AAHRPP)
funding or contract agreement language. IRB staff notifies the contract negotiator when an IRB application that is supported by a contract or funding agreement is submitted. IRB staff provides the consent document(s) to the contract negotiator. The contract negotiator evaluates whether the AAHRPP required language has been included in the agreement, negotiates with the sponsor to include AAHRPP required language, and compares the consent document language to the agreement. The contract negotiator completes a worksheet to document his or her review. The IRB staff and the contract negotiator communicate as needed to address any questions or comments (e.g. how to translate contract language to easily readable consent language). The contract negotiator provides the completed worksheet to the IRB staff who verifies that the agreement includes the required AAHRPP language and that the consent and agreement are congruent. The IRB staff communicates and works with the contract negotiator if there is any question of whether the agreement includes the necessary AAHRPP language or if the agreement and consent are congruent.

Funds awarded to MSU investigators for human subject research will not be made available by OSP until the research is approved by an MSU IRB. When a research study is externally funded, the IRB sends a notice of the IRB approval to OSP.

**MSU Technologies**

MSU Technologies is organized under the VPRGS and is responsible for managing MSU's intellectual property. MSU Technologies executes Material Transfer Agreements (transfer of materials from MSU to another entity or to MSU from another entity), reviews and manages invention disclosures and the patent process, and handles confidential disclosure agreements. This office is also responsible for licensing MSU technology.

The IRB staff provide notifications to MSU Technologies if it appears that there will be a transfer of materials.

**MSU Office of the General Counsel (OGC)**

Generally, the OGC must review in advance all contracts and agreements that could bind MSU or involve potential legal liabilities. Legal counsel from the Office of General Counsel is assigned to ORA and the IRB, and is contacted when legal questions arise.

The legal counsel assigned to ORA and IRB meets regularly with the unit heads and is also contacted on an as needed basis. Legal counsel may be contacted on protocol specific questions or on broader legal issues.

**Pharmacy**

The Pharmacy is organized under the MSU Health Team and offers clinical services to the MSU community. In addition to clinical services, investigational articles may be stored separately from standard inventory by the MSU Clinical Center Pharmacy. The Pharmacy is available to provide information to investigators on the requirements for proper investigational drug and devices storage and control.
When an IRB protocol involves investigational drugs and devices, the Pharmacy will be consulted as needed to determine if the methods described meet the requirements for proper storage and control of investigational drugs and devices.

Clinical and Translational Sciences Institute (CTSI)/Office of Clinical Research (OCR)
The CTSI and Office of Clinical Research (OCR) is organized under the VPRGS and assists researchers with the development, implementation, management, and completion of industry and government-funded clinical research (i.e., clinical trials, investigator-initiated research, etc.) conducted through MSU and its community partners, to expedite the research administration process, and to facilitate research compliance.

Graduate School
The Graduate School serves as an advocate for graduate education to the university and beyond and to enhance the quality of graduate education at MSU in all its diverse dimensions. The Graduate School offers resources such as the lectures and information on the Responsible Conduct of Research.

Graduate students who conducted human subject research for their thesis/dissertation must provide a copy of their IRB approval letter to the Graduate School with their form for final submission of their thesis / dissertation.

Research Integrity Officer (RIO)
The RIO reports to the President and administers the MSU Faculty Handbook Procedures Concerning Allegations of Misconduct in Research and Creative Activities. They provide the procedures for investigation and evaluation of alleged or apparent misconduct.

Any case of research misconduct or serious or continuing noncompliance with government regulations pertaining to research and/or university policy can be reported to the RIO as an allegation of misconduct. These allegations can be presented to the RIO by the chair of the IRB, any member of the IRB, IRB staff, human subject of the research, or any other individual. When reporting as required by HRPP Manual 4-8, “Reporting,” any incident that may also involve research misconduct is report to the RIO. Such reporting may also occur at the beginning of the incident investigation.