MU HRPP Roles and Responsibilities

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1.0 Purpose

The purpose of the Human Research Protection Program (HRPP) is to protect the rights and welfare of human subjects participating in research conducted at the University of Missouri or elsewhere by University faculty, staff, students, and trainees. Its goals are to promote compliance with relevant legal requirements and ethical standards at all levels, while also addressing the needs and concerns of researchers and enhancing support of their endeavors.

2.0 Scope

Ensuring success of the HRPP is a joint responsibility. The program is directed by the University of Missouri Division of Research, Innovation, and Impact, but its implementation requires the active participation and collaboration of many stakeholders.

OVERVIEW OF MU RESEARCH ENVIRONMENT

The University of Missouri – Columbia (MU) is the flagship campus of the University of Missouri. It is an institution of higher education, is a public, research-extensive, land grant university dedicated to enriching the lives of people through excellence in teaching, research, and service. The role of the MU research enterprise in developing new knowledge for transfer through teaching and service is critical to the broader institutional mission.

MU, as Missouri's land-grant university, honors the public trust placed in it and accepts the associated accountability to the people of Missouri for its stewardship of that trust. Our duty is to acquire, create, transmit, and preserve knowledge, and to promote understanding. The students, faculty, and staff of MU hold the following values to be the foundation of our identity as a community.

Respect for one's self and for others is the foundation of honor and the basis of integrity. A hallmark of our community is respect – for the process by which we seek truths and for those who engage in that process. Such respect is essential for nurturing the free and open discourse, exploration, and creative expression that characterize a university. Respect results in dedication to individual as well as collective expressions of truth and honesty. Respect is demonstrated by a commitment to act ethically, to welcome difference, and to engage in open exchange about both ideas and decisions.

A sense of responsibility requires careful reflection on one's moral obligations. Being responsible imposes the duty on us and our university to make decisions by acknowledging the context and considering consequences, both intended and unintended, of any course of action. Being responsible requires us to be thoughtful stewards of resources - accountable to ourselves, each other, and the public we serve.

Learning requires *trust in the process of discovery.* Discovery often fractures existing world views and requires acceptance of uncertainty and ambiguity. Therefore, the university must support all its members in this lifelong process that is both challenging and rewarding. As we seek greater understanding and wisdom, we also recognize that knowledge itself has boundaries – what we know is not all that is.

We *aspire to an excellence* which is approached through diligent effort, both individual and collective. Pursuing excellence means being satisfied with no less than the highest goals we can envision. Pursuing excellence involves being informed by regional, national, and global standards, as well as our personal expectations. We recognize and accept the sacrifices, risks, and responsibilities involved in pursuing excellence, and so we celebrate each other's successes. We commit ourselves to this process in an ethical and moral manner.

MU's Human Subjects Research Protections Program (HRPP) is a vital component of the University's continuing efforts to support research while remaining true to the values of our institution. Respect for human subject participants, responsibility for their safety and care, discovery through their participation in research, and excellence in all areas of the research conducted at MU are the hallmarks of our HRPP.

As a postsecondary institution with extensive human research activity, MU recognizes its institutional obligation to provide research participants with the highest standards in research protection. The HRPP at MU is a multi-faceted enterprise designed to protect participants across broad-ranging research activities through established policies and procedures. The institution's comprehensive plan for human research protection provides a guide to institutional authorizations, ethical principles, standard operating procedures, responsible units and personnel, and the supporting documents laying the foundation for the protections provided to research subjects. Essential components of the HRPP include policy, education, procedures, protocol

review, study conduct, study monitoring, and program assessment. All HRPP policies and operating procedures relevant to these components are incorporated into the comprehensive plan.

MISSION STATEMENT

The Division of Research, Innovation, and Impact (RII) exists to foster an academic environment in which MU's research, instruction, service, and economic development missions are permeated by the joy and rigor of original research, creativity, and scholarship. The RII promotes an environment in which the intellectual and creative activities and achievements of MU's faculty, students and staff are facilitated, celebrated and, when appropriate, transferred to the private sector.

MU is committed to the highest ethical standards in the conduct of research and to ensuring the protection of participants involved in human research. This commitment governs the structure of the institutional HRPP.

ETHICAL PRINCIPLES

All MU research involving human participants shall be conducted in accordance with the ethical principles outlined in the Belmont Report and specifically in accordance with the three key concepts outlined with the report:

1. Respect for persons (consent, privacy and confidentiality including additional safeguards for special populations)

2. Beneficence (minimization of risks and maximization of benefits)

3. Justice (fair sharing of benefits and burdens of research)

FEDERAL/STATE REGULATORY GUIDANCE

All human research conducted by MU personnel at institutional or non-institutional performance sites, domestic or international, is to be conducted in compliance with the Department of Health and Human Services (DHHS) Code of Federal Regulations (CFR) 45 CFR 46 and, as applicable to the research, Food and Drug Administration (FDA) 21 CFR 50, 56, 312, 812 (drug) 814 (device), Veterans Affairs (VA) 38 CFR 16, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) 45 CFR 160 and 164 Subparts A and E, and as subsequently amended and augmented.

Additional regulations/policies are applied on a case-by-case basis for projects funded by or covered by federal agencies such as the U.S. Department of Agriculture, Department of Education, Department of Defense, Department of Justice, Department of Energy, Environmental Protection Agency, or National Science Foundation as appropriate to the Sponsor. Guidance set forth by the International Conference on Harmonization (ICH)/Good Clinical Practice is applied to industry sponsored studies with contract requirements for

institutional adherence. See the MU HRPP/IRB ICH-GCP Guidance Document for additional information.

MU (represented by the Vice Chancellor for the Division of RII) has filed a Federalwide Assurance (FWA) with the U.S. DHHS Office of Human Research Protections (OHRP), affirming that MU is in compliance with the Common Rule (45 CFR 46). This assurance applies to all research at MU involving human subjects (see section 410.010 *Research Involving Humans in Experiments,* in the UM Collected Rules and Regulations). The full text of the FWA is available in hard copy by contacting the RII and is posted on the website of the HRPP/IRB.

In addition, research shall comply with all applicable federal and state laws and regulations.

All institutional policies and procedures related to human research protection shall be developed and implemented in alignment with this ethical and regulatory framework.

PROTECTION OF HUMAN SUBJECTS IN RESEARCH

In accordance with federal and institutional regulations, any undertaking in which any MU faculty, staff, or student conducts research and/or clinical investigations with human subjects is subject to the MU HRPP and review by the MU Institutional Review Board (IRB) regardless of the funding source. Any MU activity meeting the federal definitions (as presented in the Definitions SOP) requires review and approval by the MU IRB and is subject to all provisions of the institution-wide HRPP. With applicable approvals and written agreements, MU may also use the IRB of another organization to ensure effective and timely IRB review.

The RII has delegated to the HRPP/IRB the determination of whether an activity is exempt and is subject to IRB review. The MU IRB, working under the umbrella of the HRPP, makes available to the investigators information to aid in the determination of whether an activity is human subject's research and the MU IRB staff are also available to answer questions and guide the investigator in the determination. The MU HRPP/IRB SOP's outline the procedures and documentation necessary to be provided to the IRBs to aid in the determination of human subject research. See Initial Review SOP for additional information.

MU policy requires all investigators/key personnel conducting research involving human subjects or clinical investigations, including conduct of research exempt from federal regulations, to successfully complete mandatory CITI training in the protection of human subjects. All investigators involved in clinical studies must also complete Good Clinical Practice (GCP) training in CITI. These mandatory trainings must be renewed every three years and investigators/key personnel will be required to update training before being allowed to continue new research activities.

Investigators serving as a Principal Investigators (PI) must have a current and active MU appointment. Individuals with a visiting scholar/faculty or courtesy appointment (including adjunct faculty without a significant time appointment as an MU employee) will be required to indicate support from their home/sponsoring department and will be required to have an active MU faculty member with human subject research experience serving in a Co-Investigator (Co-I) role on human subject research studies.

ORGANIZATIONAL STRUCTURE OF THE HRPP

An organizational chart identifies key officials and units in the Human Research Protection Program (HRPP) and illustrates their relationships with one another.

MU regards research as an academic enterprise and thus the Provost, as Chief Academic Officer, has overall responsibility for research oversight. This is delegated by the Chancellor and the Provost to the Vice Chancellor for the Division of RII.

The HRPP is one of the research compliance activities under the oversight of the Associate Vice Chancellor for Research (AVCR). It reports day-to-day to the Vice Chancellor for the Division of RII, but is an autonomous unit in the sense that, if and when necessary, the AVCR has direct access to MU's Provost and Chancellor.

Research Compliance is an essential element of MU's Institutional Compliance structure, which also includes MU Health Corporate Compliance, as well as elements reporting to both the Research Division and MU's Environmental Health & Safety (Institutional Biosafety and Radiation Safety). Additional compliance committees impacting the HRPP are described below.

Compliance entities reporting to the RII are integrated and coordinated by the AVCR. Other compliance committees are included by common membership (e.g. Biosafety) or through routine administrative meetings (e.g. MU Health Corporate Compliance).

Research Compliance, under the AVCR has overall responsibility for MU's human research protection program including the MU IRB.

Direct oversight of the IRB is accomplished by the HRPP/IRB Director reporting to the AVCR. The IRB is chaired by a member of the campus faculty. The IRB also has at least two Vice Chairs who are MU faculty members.

It is important to note that while the IRB program is administered by the AVCR under the HRPP, the Board and its actions are independent of the RII, HRPP, and IRB program offices.

Vice Chancellor for the Division of Research, Innovation, and Impact

The institutional leader responsible for the oversight and management of all aspects of MU research is the Vice Chancellor for the Division of RII. The Vice Chancellor for the Division of RII is authorized to act for the institution, specifically committing the university to compliance with all requirements of 45 CFR 46 and other applicable federal regulations, not only for all federally sponsored RII research but for all human research activities regardless of sponsorship.

Associate Vice Chancellor for the Division of Research, Innovation, and Impact

The AVCR provides oversight for research compliance and support units and reports directly to the Vice Chancellor for the Division of RII. The AVCR provides guidance and oversight to the HRPP, interacting with the IRBs and all university constituencies engaged with the HRPP to

facilitate effective human research protections. The AVCR reports directly to the Vice Chancellor for the Division of RII and has been delegated official responsibility for administrative oversight and coordination, implementation, and review of all HRPP policies, procedures, and functions. The AVCR is the designated institutional official for human research protection in MU's Federalwide Assurance with the DHHS and for all components of the institutional HRPP.

The AVCR plays a critical leadership role in institutional efforts to remain abreast of current knowledge in the field, including regulatory and other relevant issues. Further, the AVCR serves as a liaison with federal and other agencies in implementing the MU HRPP and oversees institutional communication and education to ensure that the MU community as a whole and the units specifically responsible for protection of human subjects are informed of all relevant issues in human research. To maintain a high degree of cross-unit communication, collaboration, and interaction, the AVCR may attend the IRB meetings and facilitate communication between the IRBs and other committees and MU leadership with significant roles in protecting human subjects.

Specific institutional responsibilities in meeting HRPP requirements include:

- Approving policies and procedures that ensure human research protections
- Establishing an appropriate number of boards and members sufficient to meet institutional research needs
- Appointing qualified members to serve on the IRB
- Ensuring education of HRPP/IRB members, staff, and research personnel
- Providing sufficient resources and staff support to implement the HRPP
- Ensure the effective operation of the HRPP/IRB
- Supporting IRB decisions
- Implementing mechanisms for institutional oversight
- Ensuring effective institution-wide communication and access to human research information for all MU entities
- Ensuring submission of and sign-off on appropriate assurance and certifications for the institution and cooperating performance sites
- Issuing final approval for reports to regulatory agencies

The AVCR is notified of necessary IRB findings and actions by the Director of the HRPP/IRB, according to the IRB Reporting policy, who is the point of contact for the institution to report IRB findings and actions. The AVCR is notified of all IRB actions and findings by having complete access to the eCompliance system. This access includes but is not limited to, all protocol related documents, board correspondence, reviewer checklists, reports, and minutes. In addition, the AVCR attends board meetings periodically to provide monitoring and oversight and meets on a regular basis with the Director HRPP/IRB and IRB Chair.

Director HRPP/IRB

The Director of the HRPP/IRB reports directly to the AVCR and provides effective management of the HRPP and IRB and oversight of applicable laws, regulations, and policies as they pertain to human subject research occurring at MU or where MU is the IRB of record.

Specific responsibilities include:

- Supervision of HRPP/IRB staff
- Evaluations of IRB members, chairs, and HRPP/IRB staff annually
- Attend IRB meetings regularly and review board agendas and minutes
- Establish education and training for staff, board members, and researchers
- Develop and implement policies and procedures to ensure human research protections
- Maintain communication with IRB chair, vice chairs, and board members
- Report resource needs, concerns, or opportunities to the AVCR
- Identify changes in federal, state, local, or institutional rules pertinent to human subject research using various sources (i.e., PRIMR, FDA, AAHRPP, OHRP, MU General Counsel), then disseminate the information and communicate with the research community.
- Interact with internal and external stakeholders to ensure human subject research protections are in place, in compliance, and appropriately monitored and improved

Associate Director HRPP – Compliance – Regulatory and Quality Assurance
The Associate Director reports directly to the Director HRPP/IRB and will direct activities related to compliance with respect to human subject research ensuring compliance with federal regulations, accrediting body standards, and quality assurance and improvement.

Specific responsibilities include:

- Apply understanding of federal regulatory requirements and accrediting body standards to functions and strategies of the HRPP/IRB
- Provide technical guidance to employees, colleagues, and/or customers inside and outside the HRPP/IRB
- Implement policies and practices which increase compliance and efficiency, in consultation with Director HRPP/IRB
- Adapt department plans and priorities to meet short-term service and/or operational objectives
- Provide compliance related guidance to the IRB members, investigators, and stakeholders
- Develop and provide education related to human subject research compliance

REVIEW OF HUMAN SUBJECT RESEARCH BY OTHER MU COMMITEES AND ADMINISTRATIVE OFFICES

The MU IRB coordinates review with other institutional committees and offices as described below. None of these committees represent a formal component of the MU HRPP/IRB structure; however, communication between the committees/offices is facilitated by MU's RII regarding status of review and/or conditions of project approval. No subject enrollment can be initiated until approval has been obtained from all entities applicable to the conduct of the research.

Each of the committees listed below are under the administrative purview and authority of the Vice Chancellor for the Division of RII. As such, Standard Operating Procedures (SOPs) for the

HRPP/IRB and each of these MU committees delegating a responsibility to another committee will be binding through the authority and delegation of the RII.

MU Conflict of Interest Committee

The Conflict of Interest Committee (COIC) reports administratively to the Provost with day-to-day administrative support from the RII. All University employees are required to disclose any direct or indirect financial interest with outside business entities and such disclosures are then reviewed by the COIC and a decision of "no conflict" or an appropriate management plan must be in place before final IRB approval is given and MU enters into any such contractual arrangements. To facilitate adequate information flow, the following individuals serve as *non-voting* COIC members in addition to COI staff:

Associate Vice Chancellor for Research
Dean, Graduate School
Assistant Vice Chancellor, Technology Advancement Office
Director, Sponsored Program Administration
Director, HRPP/IRB
Director, Export Compliance and Research Security
General Counsel Office, Legal Representative
Finance Administration, Contracts Representative

When conflicts are identified, the IRB is the final decision maker on resolution of those conflicts. The eCompliance system provides a flag for IRB staff to note when a member of a research project already has reported conflicts of interest. For more information, refer to the HRPP/IRB Conflict of Interest policy.

No member of the COIC is permitted to vote on resolutions and conditions for any entities they are associated with, employees/students they supervise, or research for which they are engaged. No member of the IRB is permitted to vote on any protocols on which he or she is listed as a research member. If there is a conflict of interest for an IRB member with respect to a research project, the name of the IRB member will be noted in the minutes as being excused due to a conflict of interest.

Individuals who are responsible for business development functions related to outside entities are prohibited from:

- Serving as members on the IRB.
- Carrying out day-to-day operations of the review process.

MU Radiation Safety Committee and Radiation Medical Quorum

MU's Radiation Safety Committee (RSC) oversees all use of radioisotopes and other radiation sources (except MU's nuclear research reactor (MURR)) under MU's broadscope license with the U.S. Nuclear Regulatory Commission. The RSC is run day-to-day by MU's Environmental Health & Safety (EHS) office, which reports to the Vice Chancellor for Administrative Services,

but the RII coordinates membership. To facilitate communications, the AVCR serves as an *ex officio* member of the RSC.

A special subcommittee of the RSC, known as the RSC Medical Quorum (MQ), is composed of radiologists and nuclear medicine specialists and has as its charge review of all protocols where human subjects will be exposed to radiation sources. Protocols are referred to the Medical Quorum by the Principal Investigator or by another MU review committee (most frequently by the IRB). If a project under IRB review involves radiation therapy and the investigator marked all therapy is standard of care, the project will be sent to a consultant who is also a member of the MQ to confirm standard of care and the consultant checklist will be completed in eCompliance prior to IRB approval. If the project involves therapy that falls outside of standard of care, it will be forwarded to the Radiation Safety office for review and approval. Subject enrollment cannot begin until the Radiation Safety approval is received. No RSC or MQ member is permitted to vote on any protocols on which he or she is listed as a research member.

Institutional Biosafety Committee

MU's Institutional Biosafety Committee (IBC) is charged with oversight responsibility and compliance with NIH guidelines in the research use of rDNA molecules and potentially harmful biological materials such as pathogens and toxins (including Select Agents). Similar to the RSC, the IBC is administered day-to-day by EHS but membership is coordinated by the RII. The AVCR serves in an *ex officio* role on the IBC.

Issues regarding biological safety may be referred to the IBC by other campus committees (such as the IRB and Animal Care and Use Committee) or by the PI. If the IRB reviews a project which includes biohazardous materials requiring biosafety review, a copy of the application, consent, and the protocol will be sent to the Biosafety office for review and approval. Subject enrollment cannot begin until biosafety approval is received for both the material being utilized and the location where it will be utilized/stored. No IBC member is permitted to vote on any protocols on which he or she is listed as a research member.

Sponsored Program Administration

In addition to the IRB review process, all human research with external support (funding, drugs or devices) must be processed through the Sponsored Program Administration (SPA). SPA has the final authority for approval of any contract to conduct human subject research, however SPA and the IRB work in close concert in the review of contracts to determine that all regulatory requirements are met.

SPA will not release funds to conduct human subject research until final IRB approval has been obtained. Further, SPA will not release funds until appropriate approvals have been obtained from other oversight committees, if needed.

Research cannot commence until the research contract is finalized. Refer to the IRB/SPA Coordination policy for more information.

RELATIONSHIPS WITH EXTERNAL ENTITIES

Harry S Truman Memorial Veterans Hospital

Under a Memorandum of Understanding (MOU) between MU and the Truman VA, MU serves as the IRB of record for human subjects research conducted at the Truman VA. The agreement specifies the conditions of the MU FWA and VA-specific regulations as outlined in VA Handbook 1200.5. A copy of this document is available upon request from the HRPP/IRB. In addition, the Truman VA Hospital Human Subjects Research – Special Considerations SOP provides detail regarding the daily processes, responsibilities, and reporting for research under the MU IRB oversight and is available on the HRPP/IRB website.

The Truman VA is responsible for oversight of its HRPP but Truman VA research is reviewed in the same manner as all other research under the purview of the MU IRB. Post approval monitoring occurs in conjunction with the Truman VA research office. Truman VA research is expected to comply with the federal regulations, VHA Directive 1200.05, other applicable VA Handbooks, and adhere to the MU IRB SOPs for all research. Truman VA research cannot commence until Truman VA R&D Committee (RDC) approval is granted and the ACOS/R&D has provided written notification to begin in accordance with VHA Directive 1200.01. Therefore, research may not commence until R&D approval has been obtained. The ACOS/R&D will provide a written approval letter to the investigator with a copy sent to the MU IRB for inclusion in the study files. The Truman VA does not conduct planned emergency research (see 21 CFR 50.24) or classified research involving human subjects.

Relationship with the National Cancer Institute Central IRB

Under an Authorization Agreement between the MU IRB and the National Cancer Institute Central IRB (NCI CIRB), the NCI CIRB provides IRB review for Phase III Cooperative Group adult cancer treatment protocols and selected other cancer trials conducted at MU. A copy of this document is available on request from the HRPP/IRB. NCI and all studies which rely on another IRB are submitted within the eCompliance system for documentation and tracking.

Relationship with Missouri University of Science and Technology (Missouri S&T)

Under a Memorandum of Understanding between MU and Missouri S&T, MU serves as the IRB of record for human subjects research conducted by Missouri S&T researchers. The agreement specifies the IRB transfer process of approved projects from Missouri S&T's IRB to the MU IRB. It further outlines the MU IRB and Missouri S&T responsibilities regarding the oversight of human subjects research. Missouri S&T researchers follow MU IRB SOPs, and their studies will follow the same submission and review processes as MU researchers.

Multi-Site Research

In the conduct of multi-site research projects, each institution or entity is responsible for safeguarding the rights and welfare of any human subjects and for complying with applicable regulations. Federal regulations from DHHS and FDA (45 CFR 46.114 and 21 CFR 56.114) allow for cooperative research projects that involve more than one institution. To avoid duplication of review by IRBs, MU may choose to conduct joint reviews, rely upon the review of another qualified IRB, or make other arrangements to establish oversight responsibility. Refer to the HRPP/IRB Multi-Site Research and Reliance Process policy for more information.

OVERVIEW OF THE INSTITUTIONAL REVIEW BOARD

Institutional Authority and Independence of the IRB

The MU HRPP has one IRB.

All activity meeting the regulatory definitions outlined in this document for research involving human subjects is subject to institutional review through the MU IRB.

The MU IRB reviews research which is being conducted by MU faculty, staff, and students.

The IRB is independent and does not answer to individuals, departments, or other units that rely on the IRB for review of their research. The IRB is the final authority for all decisions regarding the protection and welfare of humans participating as subjects in research activities. University administrators at any level may not approve research that has not been approved by the IRB.

Specific authority granted to the IRB includes:

- Approval, require modifications or disapproval of all human research activities overseen and conducted by the organization;
- Monitoring of the consent process and the conduct of the research;
- Suspension or termination of approval of research that is not conducted in accordance with regulatory or institutional requirements or that has resulted or may result in unexpected serious harm to participants, even if previously approved.

The IRB has been delegated the responsibility to investigate allegations of: noncompliance with human subjects regulations and reports of unanticipated problems, and, in cases where corrective action is needed, issues appropriate actions, including, but not limited to:

- Requesting minor changes;
- Determining data collected cannot be used for publication;
- Suspending or terminating approval;
- Disqualifying investigators from conducting research involving human subjects at the University;
- Recommending to the University administration that further administrative action be taken.

Inappropriate attempts to influence the IRB process, individual IRB members, or IRB office staff will be reported to the AVCR, who will respond to and stop any attempts at inappropriate influence. If necessary, the situation will be reported to the Vice Chancellor for the Division of RII, who has the authority to limit or remove an investigator's privilege to conduct research.

Institutional Review Board Responsibilities – Reference Board Structure and Responsibilities SOP Section 3.0

Responsibilities of the IRB Chair/Vice Chair - Reference Board Structure and Responsibilities SOP Section 3.0, Chair Responsibilities and Vice-Chair Responsibilities

Institutional Review Board Membership - Reference Board Structure and Responsibilities SOP Section 3.0, IRB Membership

IRB Expertise and Qualifications - Reference Board Structure and Responsibilities SOP Section 3.0, IRB Membership

Conflict of Interest of IRB Members, Office Staff, and Consultants

IRB Chairs, members, staff, and consultants may not participate in research review in which a conflict of interest exists. Specific policies and procedures govern the conduct of individuals serving in these positions and the process for recusal from the review process.

Investigator/Research Personnel Responsibilities

Direct responsibility for ethical conduct of human research and protection of research participants lies with each individual investigator and the research personnel engaged in human research activities. Investigators are charged with the following key responsibilities:

- Design and implement ethical research with sound study designs according to the Belmont Report;
- Involve research personnel qualified by training and experience for their research responsibilities;
- Obtain IRB approval, and the approval of any other institutional committee applicable to the research, prior to initiating human research activity;
- Comply with federal and state regulations, institutional and IRB requirements;
- Implement research as approved and in compliance with all IRB decisions, conditions, and requirements;
- Maintain appropriate project and personnel oversight and appropriately delegate research responsibilities;
- Conduct recruitment of subjects fairly and equitably while assessing risks/benefits to research participants;
- Obtain and document informed consent/assent/authorization, when applicable, and provide a mechanism for receiving and responding to subject's complaints or requests for information;

- Monitor data integrity as well as the rights, safety, and welfare of human subjects;
- Submit progress reports;
- Report unanticipated problems;
- Obtain prior approval for modifications to research protocols;
- Maintain written documentation of activities;
- Retain records.

To enable researchers to be knowledgeable and to perform their responsibilities appropriately, MU has established mandatory education requirements regarding human research protection for investigators and their research personnel to complete. Documentation of completion of the educational requirements is maintained in the electronic eCompliance system. Additionally, policies and procedures, guidance and other tools to aid the investigator are made available on the HRPP/IRB website.

In designing the human subject protections specific to a project, the PI shall consider any and all conflicts of interest and identify and develop a plan to manage said conflicts of interest. Conflicts must be disclosed to the Conflict-of-Interest Committee, which must approve all such management plans.

The PI is responsible for determining, prior to the conduct of the study, that the appropriate resources to protect human subjects are or will be in place, including monetary, personnel and time resources, and resources to address adverse events and possible research-related injuries.

For research protocols involving greater than minimal risk, the PI shall specifically detail plans for data safety and monitoring (i.e., plans for determining harm to research subjects and mitigating potential injuries).

If applicable to the research project, the PI and research personnel must also comply with the policy, procedures and requirements as specified by other MU institutional committees that may review and approve the conduct of the research.

Appeals of IRB Decisions and Other Investigator Concerns

Concerns raised by an investigator regarding a specific IRB decision should be resolved at the lowest level possible, beginning with direct communication between the investigator, the Director of the HRPP/IRB, and the IRB Committee. The IRB has specific policies for further action and appeals of decisions when initial resolution cannot be obtained.

INSTITUTIONAL RESOURCES

Allocation of institutional resources to support effective functioning of the MU HRPP is the responsibility of the RII. The RII is responsible for assessing on a continual basis the needs of the IRB and support for its infrastructure. Requests from the HRPP/IRB for budgetary support and resource allocation to meet the needs identified during regular review of the volume and nature of the research being conducted and the protocols being reviewed by the IRB are submitted to the RII.

The RII receives and processes requests for Chair and Vice Chair stipends and any additional special requests for board development. Additional basic operating costs including education for staff, supplies, office furniture, educational materials, and selected equipment are covered in the HRPP/IRB budget administered by the RII, Fiscal Manager.

Division of Research, Innovation, and Impact Computer Services

The RII Computer Services supports the computing and networking infrastructure for all units responsible to the RII including support to the HRPP/IRB. RII Computer Services is responsible for enhancing and maintaining the electronic IRB system. ORCS also provides resources such as equipment procurement and installation and user support.

INSTITUTIONAL PROGRAM REVIEW AND ASSESSMENT

The AVCR is responsible for monitoring and measuring the quality, efficiency, and effectiveness of MU's HRPP including, but not limited to, resources, policies and procedures, personnel, composition and numbers of IRBs and participant outreach. This is currently done by benchmarking against peer institutions, either by viewing and comparing appropriate web sites or by personal communication with Director and/or Administrators of other institutions. Attendance at national meetings by RII and HRPP/IRB Administrators, investigators and IRB Board members, such as the annual PRIM&R conference, is encouraged and also used to assist with benchmarking. Local and regional meetings are used whenever possible to maximize travel funds.

Once an issue has been identified, it will be raised at the regular meetings held with the Director and/or the regular meetings held between the AVCR and the IRB Chair. The issues will be discussed, and if determined necessary, a plan for resolution and timetable for implementation will be developed. The AVCR will use feedback from the research community and subsequent benchmarking activities to measure the effectiveness of any implemented improvements.

HRPP SUGGESTIONS, COMMENTS, COMPLAINTS and CONCERNS

As part of the commitment to continuous improvement to the HRPP and IRB policies and procedures, comments are always welcome. Comments may be made to the HRPP/IRB or the RII. Issues raised will be resolved as quickly, fairly, and amicably as possible through cooperative exchange of information. Suggestions or concerns regarding the HRPP, research compliance and IRB administrative procedures should be filed with the Director of HRPP/IRB who evaluates and investigates the concerns and determines what actions, if any, should be taken by the RII and/or HRPP/IRB to address the issue. Suggestions or concerns regarding the research compliance and/or the HRPP/IRB administrative procedures that cannot be resolved at the level of the AVCR will be forwarded to the Vice Chancellor for the Division of RII, who shall make the final determination of action.

CONCERNS ON THE RIGHTS, SAFETY AND WELFARE OF PARTICIPANTS IN SPECIFIC STUDIES

It is the mission of the RII and the HRPP/IRB to provide a safe, confidential, and reliable channel for current, prospective, or past research participants or their designated representatives to discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with specific research protocol. Each IRB approved consent document includes the telephone number for the IRB office as the primary point of contact to express concerns or ask questions. Any issues that cannot be answered by the HRPP/IRB will be forwarded to an appropriate entity.

ALLEGATIONS OF NONCOMPLIANCE

Procedures surrounding the reporting and handling of allegations of noncompliance are outlined in the policies and procedures of the IRB.

PROPOSED PLAN FOR INTERACTION ENSURING IRB CONSISTENCY

To facilitate interaction and consistency of the MU IRB, the AVCR and Director of HRPP/IRB will meet on a monthly schedule. These meetings will discuss issues arising in the HRPP and IRB environment, new regulatory guidance and interpretations and implementation of policy and procedures for the HRPP and IRB.

Additionally, the HRPP/IRB staff and the Director HRPP/IRB will meet regularly to discuss IRB issues, regulatory guidance, and interpretations and implementation of policy and procedures for the HRPP/IRB.