



MU HRPP Roles and Responsibilities

Effective Date: January 21, 2019
Original Approval Date: January 21, 2019
Revision Date:

Approved By: Michele Kennett, JD, MSN, LLM
Associate Vice Chancellor for Research

1.0 Purpose

The purpose of this policy is to outline the processes for measuring and improving, when necessary, the quality, effectiveness, and efficiency of the MU Human Subjects Research Protections Program (HRPP).

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri.

3.0 Policy/Procedure

The mission of the MU HRPP is to verify and promote continual ethical conduct of human subject research. The MU HRPP has a quality improvement plan that periodically assesses compliance with organizational policies, applicable laws, regulations, ethical principles, and guidance. The expectation is that the plan, through audits, education, surveys, and other methods, will provide the MU HRPP with data to make improvements and monitor compliance on an ongoing basis.

The quality improvement plan includes multiple stakeholders with shared responsibilities. The stakeholders include, but are not limited to:

- MU IRB staff, chairs, vice-chairs, and board members
- Departments within Office of Research at the University of Missouri
- Institutional Official
- Radiation and Biosafety Committee
- Investigational Drug Services

SOP – MU HRPP Roles and Responsibilities

Page 2 of 19

- Conflict of Interest Committee
- VA R&D Committee
- Accounting Services Office for Subject Payment Approval
- MU Researchers
- Research Participants
- Any other entity or person who is directly involved with the conduct or review of human subject research

The necessity of involving multiple stakeholders in the quality improvement plan is to be able to acquire and evaluate information, as needed, to ensure the highest ethical standards in the conduct of human subject research at MU are followed.

The HRPP Director, including any additional stakeholders, will ensure high quality research using the plan and methods below.

MU HRPP Quality Improvement Plan:

The quality improvement plan consists of four overall objectives. The objectives, including the methods to measure them, are annually reviewed and modified, as needed.

1. Compliance
2. Quality
3. Effectiveness
4. Efficiency

Compliance

The MU HRPP assures human subject research is being conducted in accordance with Federal, State, and local regulations/laws, MU policies, guidance and ethical principles.

The methods to measure compliance include, but are not limited to:

- A. Review a sample of Exempt and Expedited studies to determine if appropriate review categories were applied.
- B. Review board meeting Minutes to ensure all required documentation was included.
- C. Review a sample of studies involving vulnerable populations to determine if protocol specific findings were properly documented.
- D. Review a sample of approved studies to determine if the assessment of engaged institutions and/or key personnel was appropriately determined, and when required, authorization agreements were executed.

Quality

The MU HRPP supports high quality research while providing the utmost protection to research participants.

SOP – MU HRPP Roles and Responsibilities
Page 3 of 19

The methods to measure quality include, but are not limited to:

- A. Administer satisfaction surveys to the MU community regarding different aspects of the HRPP and make necessary improvements to the program.
- B. Provide educational training and/or information to IRB members and other stakeholders, as needed or requested.
- C. Meet with a representative from each area within the HRPP annually to discuss and evaluate any required systematic improvements to the program.

Effectiveness

The MU HRPP functions as a unit and makes every effort to provide exceptional service to those working with and within the MU HRPP.

The methods to measure effectiveness include, but are not limited to:

- A. Initiate development of an internal auditing system, including the creation of audit tools, internal feedback forms for suggested improvement; identifying who will conduct the audits, and the frequency of audits.
- B. Create feedback forms/surveys for completion by a sample of research participants regarding their research experience.
- C. Administer feedback forms/surveys to a sample of researchers who utilize multiple departments within the Office of Research and inquire about their overall experience working with the MU HRPP and suggestions for improvement.

Efficiency

The MU HRPP provides timely responses/reviews and accurate information to those seeking assistance and/or approval.

The methods to measure efficiency include, but are not limited to:

- A. Review IRB forms, checklists, and letters to ensure appropriate information and determinations would be captured during the submission, review and approval process.
- B. Review a sample of studies to determine if board member review turn-around times are reasonable.
- C. Review overall turn-around times from a sample of IRB submissions and determine what can be improved to increase efficiency, if necessary.
- D. Ensure the ongoing and active communication between members of the MU HRPP when issues arise and when changes are made to a process affecting the group within the HRPP.

The Quality Improvement Plan allows for continual assessment and feedback regarding the MU HRPP. It provides the opportunity to identify issues, develop solutions, and make necessary changes. This plan is periodically reviewed and modified, as needed.

Community Outreach

A. Research Participant as a Volunteer

- I. The IRB will provide a contact number to each participant consented to participate in research in which the IRB has jurisdiction. The number should appear on every informed consent document following a statement about whom the participant may contact regarding questions (i.e., need for additional information), concerns, or complaints regarding his/her rights as a research participant.
- II. The IRB has a participants section on the website to provide potential and current research participants additional information regarding participation in a research study. The website is located at: <http://research.missouri.edu/irb/participants>
- III. A participant brochure is available entitled, “Becoming a Research Volunteer” developed by OHRP and includes the following:
 - A. A lay definition of research;
 - B. Why research is important;
 - C. Points to consider;
 - D. Questions to ask about participation in a research study;
 - E. Who to contact for questions concerning participation in a research study.
- IV. A Veteran Participant brochure entitled, “I’m a Veteran: Should I Participate in Research?” has been developed by the Department of Veterans Affairs and includes the following:
 - A. A lay definition of a research study;
 - B. List of questions to ask before agreeing to participate in a research study;
 - C. Lay description of the informed consent process;
 - D. Information in the informed consent document;
 - E. Who will see my medical records and/or research records if I participate in a research study;
 - F. A description of the IRB and its role; and
 - G. A description of the VA R&D committee and its role.
- V. MU faculty who are also (VA) investigators can participate in VA Research Day, held each spring nationwide to educate both the veteran population and the campus community regarding research protocols and programs occurring within the VA.
- VI. MU faculty and the MU IRB have the opportunity to participate in the MU School of Medicine “Research Day” held each fall as well as other research sponsored events for faculty and students held on campus.
- VII. Representatives from the IRB and HRPP participate in community outreach activities such as speaking engagements to patient support groups or other community organizations. Individuals from outside MU are also included as presenters for educational seminars focused on broadening the scope of research at MU.

SOP – MU HRPP Roles and Responsibilities

Page 5 of 19

- VIII. The IRB along with the HRPP will annually evaluate the quality and effectiveness of community outreach activities. Improvements will be made as needed based on this evaluation to promote continual improvement of community outreach activities.
- B. Research Involving the Community
- I. The IRB needs to have an awareness of the unique challenges that may present themselves when research seeks to engage the community in the process.
- A. There is increasing community (lay) involvement in research.
- B. There needs to be greater awareness of the potential for community or collective risks in research.
- C. There is rising demand for and occurrence of disclosure of individual results to research participants.
- II. Additional considerations for the IRB:
- A. Community participation:
- a. Who is the community
- b. Who represents the community
- c. Who speaks for the community
- B. Identify Roles
- a. Researcher/IRB/Community
- b. Educate the IRB
- c. Encourage community participation on the IRB's- Currently all panels have community participants
- C. Dissemination of Research Results
- a. How do research results get re-presented
- b. Are findings presented in a meaningful way for community members

References:

Combined Policies January 21, 2019:

HRPP QI

Approval Dates: March 1, 2015; July 1, 2015; June 8, 2017

Community Outreach

Approval Dates: December 1, 2006; June 10, 2010; July 1, 2011; March 1, 2015;
July 1, 2015; June 8, 2017

MU HRPP Document included in Appendix A

Approval Date: 2015

Appendix A

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,

SOP – MU HRPP Roles and Responsibilities

Page 7 of 19

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 regulations, policies, and operating procedures relevant to these components are incorporated into the comprehensive plan.

MISSION STATEMENT

The Office of Research 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 Office of Research 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 (device) 814

SOP – MU HRPP Roles and Responsibilities
Page 8 of 19

(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. Regulations set forth by the International Conference on Harmonization (IHC)/Good Clinical Practice, and other regulatory bodies are also applied as necessary unless these guidelines conflict with DHHS or FDA regulations.

MU (represented by the Vice Chancellor for Research and the Office of Research) 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 Office of Research and is posted on the website of the 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.

RESEARCH ACTIVITIES COVERED UNDER THE HRPP

In accordance with federal and institutional regulations, any undertaking in which any MU faculty, staff, or students investigate and/or collect data on human participants for research purposes is subject to the MU HRPP and review by the MU Institutional Review Board (IRB) regardless of the funding source. Specific institutional procedures which correlate with the assurance and cooperative research guidance of the OHRP govern data collection occurring at “off-site” locations. With applicable approvals and written agreements, MU may also use the IRB of another organization to ensure effective and timely research review.

Any MU activity meeting the following federal definitions requires review and approval by an MU IRB and is subject to all provisions of the institution-wide HRPP. See Definitions SOP.

The Office of Research Compliance has delegated to the HRPP the determination of whether an activity is exempt and is subject to the HRPP. The IRBs make available to the investigators worksheets to aid in the determination of whether an activity is human subject’s research and the IRBs are also available to answer questions and guide the investigator in the determination. The 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.

SOP – MU HRPP Roles and Responsibilities

Page 9 of 19

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 training in the protection of human subjects. The mandatory training must be renewed every three years.

ORGANIZATIONAL STRUCTURE OF THE HRPP

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 Research.

The Office of Research Compliance is part of MU's Research Division and is headed by the Associate Vice Chancellor for Research (AVCR). It reports day-to-day to the Vice Chancellor for Research, but is an autonomous unit in the sense that, if and when necessary, the AVCR has direct access to MU's Provost and Chancellor.

The Office of Research Compliance is an essential element of MU's Institutional Compliance structure, which also includes University Hospital & Clinics 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 Office of Research are integrated and coordinated by the Associate Vice Chancellor. Other compliance committees are included by common membership (e.g. Biosafety) or through routine administrative meetings (e.g. Hospital Corporate Compliance).

The Office of Research Compliance, under the Associate Vice Chancellor for Research has overall responsibility for MU's human research protection program including the MU Institutional Review Board (IRB).

Direct oversight of the IRB is accomplished by the Director HRPP/IRB reporting to the Associate Vice Chancellor for Research. Each IRB is chaired by a member of the campus faculty. The HS IRB has two separate panels, each run day to day by a Vice Chair who is a faculty member.

It is important to note that while the IRB program is administered by the Associate Vice Chancellor for Research and the Office of Research – Compliance under the HRPP, the Board and its actions are independent of the Research-Compliance, HRPP, and IRB program offices.

Vice Chancellor for Research

The institutional leader responsible for the oversight and management of all aspects of MU research is the Vice Chancellor for Research. The Vice Chancellor for Research 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 research but for all human research activities regardless of sponsorship.

Associate Vice Chancellor for Research and Director of Compliance

The Office of Research Compliance is a research support unit reporting directly to the Vice Chancellor for Research and plays a primary role in the institutional HRPP, interacting with the IRBs and all university constituencies engaged in the HRPP to facilitate effective human research protections. The Associate Vice Chancellor for Research and Director of Compliance (AVCR) reports directly to the Vice Chancellor for research 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 UMC'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 attends the meetings of both the Health Sciences and Campus IRBs and facilitates communication between the IRBs and other committees with significant roles in protecting human subjects.

Specific institutional responsibilities in meeting HRPP requirements include:

- Developing policies and procedures that ensure human research protections
- Establishing an appropriate number of IRBs sufficient to meet institutional research needs
- Appointing qualified members to serve on the IRBs
- Ensuring education of IRB members, staff, and research personnel
- Providing sufficient resources and staff support to implement the HRPP
- Ensure the effective operation of the IRBs
- 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 Office of Research Compliance is now notified of IRB findings and actions through the AVCR, who is the point of contact for the institution to report all IRB findings and actions. The AVCR is notified of all IRB actions and findings by receiving a copy of the meeting information including the minutes, agenda, applications, protocols, and protocol related documents, as well as having complete access to the e-compliance system. This access includes but is not limited to, all protocol related documents, board correspondence, reviewer checklists, and minutes. In

addition the AVCR regularly attends the board meetings and meets on a regular basis with the Director HRPP/IRB.

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

The MU IRB coordinates review with other institutional committees and offices as described below. None of these committees are a formal component of the MU IRB structure; however, communication between the committees/offices is facilitated by MU's Office of Research regarding status of review and/or conditions of project approval. No research may 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 Research, Office of Research. As such, standard operating procedures for the IRB and each of these MU committees delegating a responsibility to another committee will be binding through the authority and delegation of the Office of Research.

MU Conflict of Interest Committee

The Conflict of Interest Committee (COIC) reports administratively to the Deputy Chancellor with day-to-day administrative support from the Office of Research. 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 *voting* COIC members:

Assistant Vice Chancellor for Research

Director, Technology Transfer

Director, Office of Sponsored Program Administration

Director, Corporate Compliance, University Hospital and Clinics

Director, Office of Compliance, School of Medicine Associate Vice Chancellor for Research

When necessary, the MU IRB forwards information regarding detected or suspected conflicts-of-interest to the COIC. When conflicts are identified, the IRB will not give final approval to associated protocols until resolution by the COIC has been made. The COIC will send a written statement to the IRB regarding the identified conflict and the requested resolution.

No member of the COIC is permitted to vote on any protocols on which he or she is listed as investigator or co-investigator.

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.

IRB members are prohibited from owning equity in outside business entities conducting projects requiring review by the MU IRB.

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 Office of Research coordinates membership. To facilitate communications, the Associate Vice Chancellor for Research 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).

Final IRB approval to any project where humans will be exposed to radiation outside of normal, standard of care, will not be given until Medical Quorum has reviewed and approved the protocol.

No RSC or MQ member is permitted to vote on any protocols on which he or she is listed as an investigator or co-investigator.

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 Office of Research. The Associate Vice Chancellor for Research 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. Protocols involving biosafety issues will not be approved by the IRBs until appropriate clearances have been obtained from the IBC. No IBC member is permitted to vote on any protocols on which he or she is listed as an investigator or co-investigator.

Office of 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 Office of Sponsored Program Administration (OSPA). OSPA has the final authority for approval of any contract to conduct human subject research, however OSPA and the IRB work in close concert in the review of contracts to determine that all regulatory requirements are met.

SOP – MU HRPP Roles and Responsibilities
Page 13 of 19

OSPA will not release funds, drugs or devices for use in research involving human subjects until final IRB approval has been obtained. Further, OSPA 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.

RELATIONSHIP WITH OTHER REVIEWING BODIES

Harry S Truman Memorial Veterans Hospital

Under an IRB Authorization Agreement and Memorandum of Understanding (MOU) between MU and the HSTMVH, MU provides IRB review for human subjects research conducted at the HSTMVH. 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 IRB Administrative Office.

Harry S Truman Memorial Veterans Hospital Research & Development Committee

Research to be undertaken by or under the direction of the HSTMVH, or research that involves HSTMVH patients, requires review and approval by both the MU IRB and HSTMVH R&D Committee.

Completion of the IRB review is documented within the e-compliance system and a report forwarded to the HSTMVH R&D. To facilitate interactions between the HS IRB and the R&D, a member of the MU IRB Administrative Office staff attends the R&D Committee meetings.

IRB approval is not valid for VA research until R&D approval has been obtained.

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 IRB Administrative Office. NCI and all studies which rely on another IRB are submitted within the e-compliance system for documentation and tracking.

Cooperative Research

In the conduct of cooperative 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. MU makes a determination about whether or not a cooperating outside institution is engaged in human subject research (that is, in collaboration with MU). This determination is made by the

SOP – MU HRPP Roles and Responsibilities
Page 14 of 19

Associate Vice Chancellor for Research, based on the outside institution's role and whether that role meets any of the criteria for "engaged in research" as defined in OHRP guidance dated January 26, 1999.

When the outside institution is determined to be engaged in research and is receiving federal funds through a subcontract with MU, the MU Office of Sponsored Program Administration (OSPA) requires documentation that the outside institution holds an FWA through the subcontract process. If the outside institution does not hold its own FWA, MU requires they obtain one prior to finalization of the subcontract. Under limited circumstances, when MU is able to assure understanding of local context in relation to the proposed research and has sufficient resources to provide appropriate oversight during the conduct of the research, MU may choose to extend its FWA to cover the outside institution's role in such single project.

When the outside institution is determined to be engaged in research, but is not receiving federal funding for this study through a subcontract with MU, MU's IRB requires that the research be conducted either under another entity's IRB oversight or the MU IRB takes on oversight of the research. In the former case, MU's IRB will require documentation that the outside IRB will provide this oversight; in the latter case, the agreement is documented with a formal IRB Authorization Agreement. The MU IRB will oversee research for an outside institution only when the MU IRB is able to assure understanding of local context in relation to the proposed research and has sufficient resources to provide appropriate oversight during the conduct of the research.

When the outside institution is determined to be engaged in research as described in paragraphs 1 and 2 above, and MU determines that the outside institution's IRB will provide more appropriate review expertise, oversight, and/or knowledge of local context for the MU role in such study, MU may choose to sign an IRB Authorization Agreement or other equivalent agreement to make the non-local IRB the IRB of record for that particular project. When this occurs and the research is federally funded, the outside IRB is added to MU's FWA.

The Organization's transnational research activities are consistent with the ethical principles set forth in its Human Research Protection Program and meet equivalent levels of participant protection as research conducted in the Organization's principal location while complying with local laws and taking into account cultural context.

The final determination to enter into any agreement described in this section is made by the Associate Vice Chancellor for Research.

OVERVIEW OF THE INSTITUTIONAL REVIEW BOARD

Institutional Authority and Independence of the IRB

The MU Human Subjects Research Protections Program has established one IRB. All activity meeting the regulatory definitions previously outlined in this document for research involving human subjects is subject to institutional review through the appropriate MU IRB.

SOP – MU HRPP Roles and Responsibilities
Page 15 of 19

The IRB reviews research emanating from:

College of Agriculture, Food and Natural Resources
 School of Natural Resources
College of Arts and Science
 School of Fine Arts
 School of Music
College of Business
 School of Accountancy
College of Education
 School of Information Science and Learning Technologies
College of Engineering
Graduate School
 Harry S Truman School of Public Affairs
College of Human Environmental Science
 School of Social Work
School of Journalism
School of Law
University of Missouri HealthCare
 Children’s Hospital
 Ellis Fischel Cancer Center
 Howard A. Rusk Rehabilitation Center
 Missouri Rehabilitation Center
 University Hospital and Clinics
Columbia Regional Hospital
Missouri Institute of Mental Health
School of Medicine
School of Health Professions
Charles and Josie Smith Sinclair School of Nursing
School of Veterinary Medicine
Harry S Truman Memorial Veterans Hospital

The IRB is independent and does not answer to individuals, departments or other units that rely on these 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

SOP – MU HRPP Roles and Responsibilities
Page 16 of 19

- 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: non-compliance with human subjects regulations and reports of unanticipated problems, and, in cases where corrective action is needed, issues appropriate sanctions, 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 Associate Vice Chancellor for Research, who will respond to and stop any attempts at inappropriate influence. If necessary, the situation will be reported to the Vice Chancellor for Research, 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:

SOP – MU HRPP Roles and Responsibilities

Page 17 of 19

- 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/adverse events
- 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 e-compliance system. Additionally, policies and procedures, guidance and other tools to aid the investigator are made available on 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 IRB Administrative Office 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 Office of Research. The Office of Research is responsible for assessing on a continual basis the needs of each IRB and support for its infrastructure. Requests from the 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 Office of Research.

The Office of Research receives and process requests for Chair stipends, cost of refreshments for IRB meetings, travel and other professional development costs for IRB members to attend professional meetings, and any additional special project requests. Additional basic operating costs including education for staff, supplies, office furniture, educational materials, and selected equipment are covered in the IRB budget administered by the Office of Research Fiscal Manager.

Office of Research Computer Services

The Office of Research Computer Services (ORCS) supports the computing and networking infrastructure for all units responsible to the Office of Research including support to the Campus and Health Sciences IRBs. ORCS is responsible for enhancing and maintaining the electronic IRB system in use by both Campus and Health Sciences IRB. ORCS also provides resources such as equipment procurement and installation and user support.

INSTITUTIONAL PROGRAM REVIEW AND ASSESSMENT

The Associate Vice Chancellor for Research 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 Compliance Officer and/or Administrators of other institutions. Attendance at national meetings by Office of Research and 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 Associate Vice Chancellor for Research and the

SOP – MU HRPP Roles and Responsibilities
Page 19 of 19

IRB Chair. The issues will be discussed, and if determined necessary, a plan for resolution and timetable for implementation will be developed. The Associate Vice Chancellor for Research will use feedback from the campus 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 IRB or the Office of Research. Issues raised will be resolved as quickly, fairly, and amicably as possible through cooperative exchange of information. Suggestions or concerns regarding the HRPP, Office of 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 Office of Research Compliance and/or IRB to address the issue. Suggestions or concerns regarding the Office of Research Compliance and/or the IRB administrative procedures that cannot be resolved at the level of the Assistant Vice Chancellor for Research will be forwarded to the Vice Chancellor for Research, who shall make the final determination of action.

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

It is the policy of the Office of Research Compliance and the IRBs 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 conducting the review as the primary point of contact to express concerns or ask questions. Any issues that cannot be answered by the IRB Administrative Office 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 Associate Vice Chancellor for Research and Director of HRPP 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 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 IRB.