Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

MU HRPP Quality Improvement and Community Engagement

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1.0 Purpose

The purpose of this policy is to outline the processes for measuring the quality, effectiveness, and efficiency of the MU Human Subjects Research Protections Program (HRPP), and make improvements, when necessary. It also outlines the process to engage the community and participants in the research process as an additional way to measure quality, effectiveness, and efficiency of the MU 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 support 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 HRPP/IRB staff, chairs, vice-chairs, and board members
- Departments within Office of Research and Economic Development at the University of Missouri
- Institutional Official
- Radiation and Biosafety Committees and Consultants
- Investigational Drug Services
- Conflict of Interest Committee
- Accounting Services Office and corresponding departmental units 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/IRB 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 conducted in accordance with Federal, State, and local regulations/laws, MU policies, guidance, and ethical principles.

Examples to measure compliance include:

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.
E. Review of DHHS and FDA regulations and guidance to ensure all appropriate IRB determinations were made.
F. Conduct pre and post approval-monitoring visits with MU research teams to ensure compliance with IRB regulations and MU standards. This includes Site Initiation Visits, Tracer reviews, HRPP/IRB Audits, etc. See the Post Approval Monitoring SOP for additional information.

Quality

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

Examples to measure quality include:

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 stakeholders 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.

Examples to measure effectiveness include:

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 Economic Development 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.

Examples to measure efficiency include:

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 and Participant Engagement

In order to enhance the public's understanding of research, the MU HRPP/IRB performs outreach activities. The scope is proportional to the size and complexity of our research program.

Some ways the MU HRPP/IRB enhances the understanding of participants, prospective participants, and the community (internal and external) are described below:

I. The HRPP/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, complaints regarding his/her rights as a research participant, or to offer input.

II. The HRPP/IRB has a participants section on the website to provide potential and current research participants additional information regarding participation in a research study. It also links directly to the OHRP website providing additional information about research participation. 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;

V. MU faculty who are also VA investigators can participate in the Truman VA's Research Day, held each fall. The national VA research week is held each Spring. Both are available to educate the veteran population and the campus community regarding research protocols and programs occurring within the VA.

VI. MU faculty, MU staff, MU students, community members, and the IRB have the opportunity to participate in Research Days at University of Missouri, including:

A. Health Sciences Research Day held each Fall;
B. CAFNR: Both School of Natural Resources and Division of Animal Sciences held each Spring;
C. Education held each Spring;
D. College of Veterinary Medicine held each Spring;
E. Undergraduate Research Day at the Missouri State Capitol held each Spring;
F. Engineering held each Spring; and
G. Cardiovascular Day held each winter.

VII. The Office of Research and Economic Development distributes a monthly online newsletter to an audience of internal faculty, staff, and students.

VIII. The Office of Research and Economic Development distributes the Core Facilities book to UM System researchers and potential corporate R&D partners. In production are brochures and flyers as well as an Annual Report that will be distributed to other universities.

IX. 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.

X. 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/engagement activities.

Research Involving the Community

The HRPP/IRB supports researchers involving the community in the research process, including the design and implementation of research and the dissemination of results. The HRPP/IRB has an awareness of the unique challenges that may present themselves when research seeks to engage the community in the process and works with individual investigators on a case-by-case basis to make sure these challenges are appropriately identified and managed.

The HRPP/IRB evaluates board member representation on an annual basis to ensure community perspective regarding the risks to research are included in all full board reviews. Board representation includes at least one non-affiliated community member as well as additional representation by community members that serve on various advisory councils within the UM/MU community. Additional board representation enables the protection of the rights and provides perspective for veteran and prisoner research studies. Faculty membership on the MU IRB board includes individuals with research and teaching experience related to the local community, children, as well as to national efforts focused on marginalized populations.

HRPP/IRB staff provide education to community boards and groups as well as provide education and feedback to investigators on study design and recruitment. Recent efforts have focused on utilization of online tools and resources to reach prospective participants through collaborative, remote recruitment efforts.

HRPP/IRB Collaboration and Activities to Support Researchers:

A. Engagement and Recruitment Support available through collaboration with:
    a. MU Center for Patient-Centered Outcomes Research (MU PCOR)
    b. Greater Plains Collaborative (GPC)
    c. Thompson Center Autism Research Core (ARC)
    d. ResearchMatch
    e. OnCore supported export for ClinicalTrials.gov
    f. PatientIQ

B. Educational Resources
    a. Study specific support from HRPP/IRB staff during study design and dissemination
    b. Seminar sessions, Webinars, and recorded workshops
    c. Research faculty, including IRB members, with success dealing with challenges to recruitment or working with hard-to-reach populations

C. Dissemination of Research Results and Research Demographics
    a. Oversight and support for required ClinicalTrials.gov reporting and dissemination
    b. OnCore supported export for ClinicalTrials.gov as well as integration with participant demographic data
    c. REDCap, PatientIQ, and other UM/MU supported platforms for demographic evaluation

Participation in regional and national conferences and workshops including those provided by OHRP and GPC focused on alternative methods to engage community members and provide research results in a meaningful manner

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