



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

HRPP Quality Improvement

HRPP Quality Improvement

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Table of Contents

Purpose

Scope

Policy/Procedure

MU HRPP Quality Improvement Plan

Compliance

Quality

Effectiveness

Efficiency

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 Research Protection Program (HRPP).

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board (IRB).

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
- 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 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 being conducted in accordance with Federal, State, and local regulations/laws, MU IRB 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.

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.