POLICY

1. **Purpose**
   Describes the research Quality Improvement (QI) Program included as part of the University of Rochester’s Human Research Protection Program (UR HRPP), which ensures that the rights, safety, and welfare of subjects are protected during the conduct of research.

2. **Scope**
   This policy applies to all human subject research conducted or supported by employees or agents of the University of Rochester.

3. **Definitions**
   3.1. *Quality Improvement (QI)* – The effort to assess and take measures to improve the level of performance of a program, process, or institution.

   3.2. *Quality Improvement Review* – A comprehensive, systematic, and independent assessment of study-related activities and documents to compare research records to approved documents to evaluate compliance with IRB approved protocols, applicable federal and state regulations, UR policies and guidelines, and OHSP policies and guidelines.

   3.3. *Study Start Up (SSU) Consultation* – A comprehensive, in-person consultation, after IRB approval and before enrollment begins, to evaluate study documentation (e.g. regulatory file, data collection forms, plans for protocol adherence) to assist the study team in their ability to achieve compliance with applicable regulations, policies, and guidelines. The reviewer collaborates with the study team to understand study-specific regulations, policies, and guidelines, providing tools and resources.

   3.4. *Quality Management Plan (QMP) Consultation* – A comprehensive, on-site consultation to provide resources that guide, integrate, and enhance continuous quality improvement for a research site, research program, or department/division. The reviewer focuses on aiding the study team to set-up, implement, evaluate, and/or prioritize areas of potential risk to target within their quality management plan.

   3.5. *Quality Improvement Reviewers* – OHSP staff who conduct QI reviews and consultations.

   3.6. *Types of Quality Improvement Reviews* - The types of QI reviews established by the QI program as defined below:

   3.6.1. *Routine*: A comprehensive on-site QI review to provide a regulatory assessment of study compliance. Routine reviews include a selected sample of human subject
research conducted across the University. The selection of studies is a risk-based approach and may be determined based on such factors as study risk, enrollment of vulnerable populations, and degree of external oversight.

3.6.2. **Directed**: A comprehensive or targeted (i.e. the consent process) on-site QI review requested by the RSRB or the External IRB AdHoc committee to provide an assessment of study compliance.

3.6.3. **Site-Requested**: A comprehensive or targeted QI review requested by an Investigator or study personnel. These reviews are conducted within the limitations of available resources.

3.7. **Review Finding** – A noted deficiency during a QI review.

3.8. **Corrective and Preventative Action (CAPA)** – A plan identified by the Investigator to address any finding noted in the QI report; a straightforward, measurable solution to address the root cause and prevent the issue from occurring again.

3.9. **QI Review Rating** – A summary rating applied to each routine, directed, and some site-requested QI reviews, based upon the severity and quantity of the review findings. The review rating is dependent upon whether or not subjects have been consented in the study:

3.9.1. **QI Review Ratings for research where consent is required by the IRB**:
- 3.9.1.1. Commendable: No deficiencies identified in a study with consent requirements and with enrolled subjects.
- 3.9.1.2. Acceptable: Lesser deficiencies are identified that do not appear to involve risk to subjects.
- 3.9.1.3. Acceptable with follow-up: Multiple lesser deficiencies are identified. Any deficiency in which potential risk to subject needs further consideration. Self-reported deficiencies identified to the IRB and addressed prior to the conclusion of the review.
- 3.9.1.4. Unacceptable: Major deficiencies are identified. A single major deficiency which impacts human subject safety/welfare is identified. One or more missing consent form(s). No response from the Investigator during the review process after a reasonable effort has been made by the reviewer.

3.9.2. **QI Review Ratings for no enrollment or consent not required by IRB**:
- 3.9.2.1. Acceptable: No or lesser deficiencies and no local accrual; however, accrual is possible. Lesser deficiencies are identified that do not appear to involve risk to potential subjects. No deficiencies identified in a study with no enrollment or without consent requirements.
- 3.9.2.2. Acceptable with follow-up: Multiple lesser deficiencies are identified. Any deficiency in which potential risk to subjects needs further consideration.
Self-reported deficiencies identified to the IRB and addressed prior to the conclusion of the review.

3.9.2.3. Unacceptable: Major deficiencies are identified. A single major deficiency which impacts human subject safety/welfare identified. No response from the Investigator during the review process after a reasonable effort has been made by the reviewer.

3.9.3. Site-requested reviews conducted in preparation for a regulatory inspection do not receive a rating; the QI report is presented as a summary of findings and improvement recommendations.

3.10. QI Findings Index – A central database of review findings maintained by the Director of Quality Improvement.

3.11. Quality Improvement Review Final Report – A written report incorporating a brief description of the study and the results of the QI Review, including detailed findings, Investigator Response and a CAPA plan to each finding, and the review rating.

3.12. Quality Improvement Study Start Up or Quality Management Plan Consultation Summary - A written report incorporating a brief description of the study and a summary of all discussion points from the in-person discussion. The summary is meant to guide the continued actions of the study team as they progress through the conduct of the approved study.

3.13. Quality Improvement RSRB Audits – An internal audit conducted by the reviewer for each review or consultation. Audit content is determined in collaboration with the Ad Hoc RSRB Audit Committee [comprised of the Associate Vice President for Human Subject Protection, the RSRB Executive Director, the Quality Improvement Director, and RSRB Senior Specialist] and is applied consistently to each study. Audit results are discussed bi-annually with the Ad Hoc RSRB Audit Committee.

4. References
4.1. Food and Drug Administration (FDA) 21 CFR parts 50, 56, 312, 812; 36 CFR part 16; HHS 45 CRF 46; Good Clinical Practices (ICH-GCP E6 guidelines as adopted by the FDA)
4.2. Policy 102 University of Rochester’s HRPP
Policy 103 Organizational Structure of HRPP
Policy 301 RSRB Scope and Authority
Policy 302 RSRB Membership and Composition
RSRB Guideline for Institutional and Regulatory Reporting of Suspension, Termination, Non-Compliance, UPIRTSO

5. Responsibilities

Paper copies of the Policy may not be the current version. The current version of this Policy is maintained and available on the OHSP shared network.
5.1. The OHSP Division of Quality Improvement is responsible for the ongoing evaluation of the effectiveness of UR’s HRPP by promoting and ensuring Institutional and Investigator compliance with human subject protection regulations and requirements.

5.1.1. The QI Director is responsible for managing the activities related to the QI program, including but not limited to:

- Prepare, plan, and execute a routine auditing program applying applicable federal regulations and University and OHSP policies and guidelines;
- Prepare, plan, and execute a consultation program applying applicable federal regulations and University and OHSP policies and guidelines;
- Collaborate with Executive RSRB Director and the Research Education Director to enhance educational opportunities as necessary.

5.1.2. The QI team is responsible for conducting routine, directed, and site-requested QI reviews, consultations for compliance with IRB approved protocol, applicable federal and state regulations, UR policies and guidelines, and OHSP policies and guidelines, when applicable.

- During a review, if the QI review team identifies a circumstance that appear to place human subjects at risk, the Associate Vice President for Human Subject Protection, RSRB Executive Director, and RSRB Chair will be notified promptly by QI staff for a further assessment. The RSRB Chair may suspend or terminate approval of research that has been associated with serious events/problems, according to Policy 301 RSRB Scope and Authority.

5.1.3. The QI team is responsible for collaborating with members of the UR’s research community to improve the Institution’s efforts to uphold high ethical standards, to meet regulatory requirements, provide ongoing education, facilitate the sharing of best practices, develop and encourage use of tools for Investigators and research staff that facilitate compliance, and to improve research practices for the protection of human subjects participating in research.

5.2. The Investigator is responsible for providing access to the study regulatory file, research charts, and any other relevant documentation upon request by the QI team.

5.3. The Investigator is responsible for providing timely written responses to each review finding including a CAPA plan during the review process.

5.4. The Associate Vice President for Human Subject Protection, as a representative for the Institution, is responsible for reviewing reports during the QI review process.
5.5. The RSRB or External IRB Ad Hoc committee is responsible for reviewing a QI Review Final Report at a convened meeting to determine if additional action or follow up is required of the Investigator.

6. Requirements
6.1. The QI team will notify the Investigator in advance of a QI review (see Appendix 1 for sample notification letter).

6.2. The QI team will meet with Investigator, and anyone else designated by the Investigator, after the review to review any potential findings.

6.3. The QI team will provide the Investigator a written report of review findings once the review is complete. The review findings report will include a timeframe for providing a written response to each review finding including a CAPA plan, as applicable.

6.4. The QI team will assign a review rating to the review, in consultation with the Associate Vice President for Human Subject Protection.

6.5. The QI team will copy all Quality Improvement Review Final Reports to RSRB staff so that reports may be submitted for convened review. A copy of the QI Review Final Report will also be forwarded to the RSRB Chair, Associate Vice President for Human Subject Protection, the RSRB Executive Director, the Investigator’s Department Chairperson and/or Division Chief, as appropriate, and any other individual as determined by OHSP Leadership (see Appendix 2 for Routine Review Final Report Template).

6.5.1. The reviewer will complete the internal RSRB audit for each conducted review; findings will be added to the REDCap review database.

6.5.2. The QI team will upload the QI Review Memo, QI Review Final Report, and the RSRB audit statement to the RSRB electronic submission system. The IRB Coordinator will upload the RSRB determination memo.

6.5.3. The QI team will copy all Quality Improvement Review Final Reports for studies where the RSRB is the Relying IRB to the external IRB Liaison(s) so reports may be submitted to the Reviewing IRB. A copy of the QI Review Final Report will also be forwarded to the Associate Vice President for Human Subject Protection and the RSRB Executive Director, the Investigator’s Department Chairperson and/or Division Chief, as appropriate, and any other individual as determined by OHSP Leadership.

6.5.3.1. In addition, biannually the OHSP External IRB Ad Hoc Committee [Associate Vice President for Human Subject Protection, RSRB Executive
Director, Quality Improvement Director, and external IRB Liaison(s)] will review summary information on all external IRB QI reports to determine recommendations, as applicable. The Investigator will receive a determination memo only if action is required.

6.5.4. Any final report with a review rating of “Unacceptable” will be forwarded to University Office of Counsel for appropriate risk management.

6.6. The QI team will include review findings in the REDCap database which will allow a quantification of review findings and provide data to identify needed resources to target education programs to the research community.

6.7. The Investigator will be an active participant during the review process.

6.8. The QI team will notify the Investigator in advance of a site-requested SSU or QMP consultation.

6.9. The QI team will meet with any member of the study team during the consultation to address questions and provide education surrounding protocol and regulation adherence.

6.10. The QI team will provide the Investigator a written summary of all discussion points once the consultation is completed.

6.11. The QI team will utilize the QI SSU/QMP templates for standard language which will allow a quantification of consultation needs and provide data to identify needed resources to target education programs to the research community.

6.12. The reviewer will complete the internal RSRB audit for each conducted consultation; audit findings will be added to the REDCap review database.

6.13. The QI team will upload the QI SSU/QMP Memo, the SSU/QMP Final Summary, and the RSRB audit statement to the Click IRB review system.
Originator/Authors:
Kathleen Wessman, Director of Research Quality Improvement

Appendices:
Appendix 1: Principal Investigator Routine Review Letter Template
Appendix 2: Routine Review Final Report Template

Revision History:
11/2016: Added Study Start Up Consultations; editorial changes
10/2019: Added RSRB Audits; Added Quality Management Plan Consultations; editorial changes

Supersedes Date:
11/21/2016
10/28/2014

Approved By:

Richard E. Waugh
Institutional Official, Vice Provost for Research

Kelley A. O'Donoghue
Associate Vice President for Human Subject Protection, OHSP

Kathleen M. Wessman
Director of Research Quality Improvement, OHSP

10/23/19
18 OCT 2019
11 OCT 19

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Appendix 1: Sample Investigator Routine Review Letter Template

MEMORANDUM

TO: XXXXX, MD, PhD
Principal Investigator

FROM: Kelley O'Donoghue, MPH, CIP
Director, Office for Human Subject Protection

DATE: XXXXX

SUBJECT: Routine Internal Quality Improvement Review, RSRB #XXXX

As part of its responsibilities under the University of Rochester's Human Subject Protection Program, the Office for Human Subject Protection (OHSP) has a quality improvement program that conducts routine on-site review of approved research. The intent is to provide an assessment of compliance with applicable regulations and requirements. Your study, RSRB #XXXX: TITLE, has been selected for a routine review.

Studies are randomly selected from a sampling of research across the University. The studies selected may involve use of novel techniques, research without external monitoring systems, high subject enrollment or risk-based research or vulnerable populations. The intent of the review is to be cooperative and educational.

The study will be reviewed under the following regulations and/or guidelines:
- RSRB approved protocol/amendment(s),
- RSRB requirements,
- Good Clinical Practice,
- UR Policy,
- in accordance with applicable federal regulations, the Food and Drug Administration (FDA), and under the University's Federal-wide Assurance (45 CFR 46).

Kathleen Wessman and/or Jennifer Dolan will conduct this review and will contact you in the near future by email to schedule. You do not need to be present during the records review; you may delegate an individual (e.g., study coordinator or assistant) to provide access to the study documentation. However, if you do delegate this task, please note that as PI of the study, you must ensure that any and all necessary information and documents are provided in a timely fashion. If you have any questions, please contact Kathleen at 273-2118/Jennifer at 276-5709.

The intent of this on-site review is to replicate, in part, the types of reviews that could be conducted by a federal regulator or a study sponsor. Many of our investigators have found the process to be quite informative, either to confirm that appropriate study practices and procedures are being followed or to allow for the early detection and correction of problems or concerns when necessary.

Saunders Research Building - 265 Crittenden Boulevard, Suite 1.250 - CU 420628 - Rochester, NY 14642-0628
585.273.4127 - 585.273.1174 fax
We urge you to participate fully in this review, and to promptly implement any recommendations contained in the final report when approved by the Board. The results of the review are treated by OHSP as confidential and, unless a report to internal/external offices is required, they are shared only with the parties listed below. You will be notified if others who may have a need to know receive copies.

Thank you in advance for your cooperation and support of the University's program for human subject protection. For a description of the OHSP Internal Quality Improvement program, visit the website link: http://www.rochester.edu/ohsp/quality/index.html

**Investigator rights and responsibilities during the QI process:** You have the right to be present during the review and to transparency during the review process. You are encouraged to contact the reviewer with any questions you may have during the process. After reviewing the study documentation, a meeting with the reviewer is held at your convenience. During this meeting, study-specific processes at your site will be discussed and all potential findings will be shared. In addition, options to address any findings can be discussed. Shortly after this meeting, draft findings will be provided to you. Your written response and, if applicable, preventative action plan will be requested within a stated time frame.

You are responsible to provide timely written responses during the review process. Failure to do so may result in an unsatisfactory review. Because all QI Reports are reviewed by the RSRB, unsatisfactory site reviews may lead to actions on the part of the RSRB and/or the University. Per federal guidelines, some of these actions may require mandated reporting to federal agencies and study sponsors.

In the unlikely event that circumstances are identified that appear to put human subjects at risk, you will be notified promptly. I will also be notified immediately for a further assessment of risk. Immediate notification to and action by the RSRB may be required to prevent risk to human subjects.

cc: Kathleen Wessman, RN, MPA, RQAP-GCP, CCRC - Director, Quality Improvement, OHSP
    Jennifer Dolan, MS, LMT, CCRC - Associate, Quality Improvement, OHSP
    Nicole Mason, MS, CIP - Executive Director, IRB
    XXXXX - RSRB Chair
    XXXXX - RSRB Specialist
Appendix 2: Sample Routine Review Final Report Template

OFFICE FOR HUMAN SUBJECT PROTECTION

Research Quality Improvement

Report Finalized and sent to RSRB On: XXXX

Final Quality Improvement Review Report

CONFIDENTIAL

Review of: RSRB #XXXX
Protocol Title: XXXX
Issued to: XXXX, MD, PhD (Principal Investigator)

Notification of Review Sent On: XXXX
Review Conducted On: XXXX
Investigator Exit Discussion: XXXX
Draft Findings to Investigator: XXXX
Investigator Response Received On: XXXX

Research Site Staff Physically Present During Review: XXXX
XXXX
XXX
Review Conducted By:

Kathleen Wessman, RN, MPA, RQAP-GCP, CCRC
Director, Research Quality Improvement
Office for Human Subject Protection

Jennifer Dolan, MS, LMT, CCRC
Associate, Research Quality Improvement
Office for Human Subject Protection

Saunders Research Building • 265 Crittenden Blvd • Box C420628 • Rochester NY, 14642 • 585.275.2388

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Final Quality Improvement Report - RSRB #XXXXX

This report is confidential. Please do not copy. If copies are required, please provide requests in writing. Controlled copies will be provided and then subsequently recovered at the end of their useful period for secured archival.

Executive Summary:
This greater than minimal/minimal risk study was selected for routine review under the Office for Human Subject Protection (OHSP) policy and guidelines. Funding is provided through the XXXXX via grant XXXXX. Vulnerable Populations included: XXX.

In accordance with OHSP Policy 1001, "Quality Improvement Program," the review findings for this site result in a rating of:
[Utilize Ratings as defined by Policy 1001, as appropriate; remove this text]
- [ ] Commendable
- [ ] Acceptable
- [ ] Acceptable with Follow-Up
- [ ] Unacceptable

Findings are shared with the RSRB, who may take further action.

Brief Protocol Summary:
The purpose of this study is to evaluate XXXXX. This is a randomized controlled study involving XXXXX. Subjects are assigned randomly to XXXX and participate for XX months/years.

Scope:
The study was reviewed under the following regulations or guidelines:
- [ ] RSRB approved protocol/amendment(s),
- [ ] RSRB requirements,
- [ ] Good Clinical Practice,
- [ ] UR Policy,
- [ ] In accordance with applicable federal regulations, the Food and Drug Administration (FDA), and under the University's Federal Wide Assurance (45 CFR 46).

During the post-review meeting with the Principal Investigator (Investigator), the following topics were discussed:
1. OHSP Department structure, the selection and review process, and OI goals
2. Identification, reporting, and management of potential conflicts of interest
3. Investigator oversight of study activities
4. Documentation of compliance to the protocol and consent process
5. RSRB requirements of documentation of written consent
6. OHSP educational resources to support research
Final Quality Improvement Report - Study #XXXXX

Review Findings:
Below is a list of findings identified during the review, and the investigator’s responses and planned preventative actions.

[INSERT INVESTIGATOR’S COMPLETED FINDINGS/RESPONSES.]

Follow-up:
This review determined the findings noted above which did not reveal an increased risk to human subjects. The Investigator’s responses are adequate/acceptable and no further follow-up is planned for quality improvement purposes.

The Investigator is responsible for implementation of corrective and preventative action plans for the findings as stated. The Investigator is also responsible for continued adherence to protocol, regulations, and good clinical practice.

Upon review of this report, the RSRB will make the final determination regarding any corrective measures.

Attachments: Appendix A - XXXX

cc: Kelley O'Donoghue, MPH, CIP - Associate Vice President for Human Subject Protection, OHSP
Nicole Mason, MS, CIP - Executive Director, IRB
Kathleen Wessman, RN, MPA, ROAP-GCP, CCRC - Director, Quality Improvement, OHSP
Jennifer Dolan, MS, LMT, CCRC - Associate, Quality Improvement, OHSP
XXXXX - RSRB Chair
XXXXX – RSRB Specialist

<table>
<thead>
<tr>
<th>Commentable</th>
<th>• No deficiencies identified in a study with consent requirements and with enrolled subjects.</th>
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| Acceptable  | • Lesser deficiencies are identified that do not appear to involve risk to subjects.  
|             | • No deficiencies and no local accrual however, accrual is possible.  
|             | • No deficiencies identified in a study without consent requirements.  
|             | • A review not encompassing all aspects of a standard review (i.e. consents only)  
|             | • CAPA re-review with no enrollment since prior review.                          |
| Acceptable with follow-up | • Multiple lesser deficiencies are identified.  
|                               | • Any deficiency in which potential risk to subjects needs further consideration.  
|                               | • Self-reported deficiencies identified to the RSRB and being addressed prior to the conclusion of the review. |
| Unacceptable | • No response from the investigator during the review process after a reasonable effort has been made by the reviewer.  
|              | • Major deficiencies are identified.  
|              | • A single major deficiency which impacts human subject safety/welfare is identified.  
|              | • One or more missing consent form(s). |