1.0 **Purpose:** This rule establishes guidelines for the UMCIRB Quality Improvement Program (QIP). The aim of the UMCIRB QIP is to ensure maximum protection of human participants involved in research activities and promotion of best practices in the conduct of research. This aim will be achieved through quality improvement reviews; education of investigators, research staff and the research community and quality improvement assessment of UMCIRB activities.

2.0 **Research Protocols Affected:**
2.1 Human research reviewed and approved by the UMCIRB (both single site and multi-center).
2.2 Human research in which an ECU or ECU affiliate’s faculty, staff, or student serves on the research team.

3.0 **Rule:** In accordance with federal regulations, the UMCIRB has the responsibility to oversee human research activities and has the authority to observe or authorize a third party to observe ongoing research projects, the consent process and review of research records for the purpose of protecting the rights and welfare of humans participating in research activities.

4.0 **Definitions:**
4.1 **Quality Improvement Review:**
4.1.1 Human Research Activities - Routine, confidential, comprehensive or partial review of IRB approved studies to determine level of compliance with applicable regulations and policies.
4.1.2 Internal UMCIRB Activities - Routine quality improvement assessments of UMCIRB operations conducted to review SOPs, IRB files, database records, actions of the convened IRB or IRB Chair, membership rosters and minutes.

4.2 **Report of Findings:** A summary of quality improvement assessment findings based on standardized evaluation of applied federal regulations, state laws and institutional policies.

5.0 **Responsibilities:**
5.1 **UMCIRB Quality Improvement Assistant Director** (QIAD) is responsible for coordination of QIP activities including but not limited to:
5.1.1 Routine quality review of IRB approved studies; evaluating study conduct, organization, record-keeping and documentation with a focus on proactively identifying areas of risk for non-compliance that compromise participant safety and data integrity such as the consent process, eligibility/ineligibility criteria, data safety monitoring and review of required documentation of approval prior to the commencement of the study. Particular attention may be paid to those studies that are investigator-initiated where the investigator holds the IND/IDE; studies that are not routinely monitored by outside entities; and studies involving vulnerable participants.

5.1.2 Routine quality assessment of UMCIRB activities.
5.1.3 Reporting findings from evaluations and assessments to the appropriate party(ies)
5.1.4 Development of educational and training programs and development and dissemination of study materials such as study tools, templates, and guidance to assist the research community including UMCIRB committee members

5.2 UMCIRB Administrative Director or designee is responsible for ensuring compliance with this policy as well as:
5.2.1 Determining whether findings of serious non-compliance resulting in unanticipated problems involving risks to research subjects or others warrants a for-cause study review and conducting for-cause review if needed
5.2.2 Notification of the IRB of suspected or known serious non-compliance

5.3 Institutional Review Board is responsible for review of research activities involving human participants and ensuring the protection of the rights and welfare of the participants as well as:
5.3.1 Receipt and review of anonymous aggregated reports of findings from routine quality improvement visits and; making recommendations for future initiatives based on the information contained in the reports
5.3.2 Receipt and review of reports of findings that reveal unanticipated problems involving risks to participants or others and determine whether the exposed deficiencies warrant further action by the committee or further follow-up by the Administrative Director or the Quality Improvement Assistant Director

5.4 Investigators are responsible for the conduct of ethical and lawful research as well as;
5.4.1 Fully cooperating with the UMCIRB Quality Improvement Assistant Director in the conduct of quality improvement reviews and other quality improvement activities; and
5.4.2 Providing, in writing, plans for corrective action if any have been recommended.

6.0 Procedures:
6.1 Quality Improvement Review
6.1.1 The Quality Improvement Assistant Director will randomly select IRB approved studies from the UMCIRB database for on-site quality improvement review. All IRB approved studies will be eligible for selection; however, there may be occasion when a higher priority may be given to certain types of studies such as investigator initiated studies, studies not regularly monitored by other entities, studies involving vulnerable populations and other high risk studies. Studies that have been reviewed within the last two years will not be selected again for routine review; however, could be chosen again after two years have passed from the last review. Reviews may be deferred to a later date but may not be declined; the investigator’s full cooperation is expected. All evaluations are conducted for quality improvement purposes and should not be viewed as punitive.
6.1.2 Investigators may request a routine review of their study(ies).
6.1.3 The QIAD will notify the Investigator and his/her research staff by email of the selection of their study(ies) for review; the email correspondence will be followed up by a phone call to determine a mutually agreeable time at which to conduct the review; and this will be followed by a letter of confirmation of the scheduled review which will include the following information:
   6.1.3.1 Date, time, and location of the review; visits will typically take 1-4 hours depending on the size and complexity of the study(ies) being reviewed
   6.1.3.2 Notice of which study(ies) will be reviewed
   6.1.3.3 Notice of what documents should be available for review
6.1.3.4 Notice that the investigator and/or his/her designee should be available or accessible to answer questions during the visit.

6.1.3.5 Notice that a brief (+/- 15 minutes) exit interview summarizing review findings will be conducted with the investigator; at the investigator’s discretion, select study personnel may also attend.

6.1.4 Prior to the on-site review the QIAD will review the IRB records for the study(ies) selected to become familiar with the study(ies).

6.1.5 At the time of the review all research/regulatory documents for the selected study(ies) should be available for review. Depending on the study(ies) the list of items to be reviewed consists of, but is not limited to the following:

6.1.5.1 Current IRB approved protocol / research plan and all previous versions
6.1.5.2 Current IRB approved informed consent document(s) and all previous versions
6.1.5.3 All original signed informed consent documents
6.1.5.4 Initial and all continuing review IRB submissions and approval letters
6.1.5.5 Investigator’s Brochure (if applicable)
6.1.5.6 All amendments and/or revisions to the protocol/research plan, consent and investigators and IRB approval of such amendments and revisions
6.1.5.7 If applicable to the study; all FDA required documentation and correspondence
6.1.5.8 If applicable to the study; all sponsor required documentation and correspondence
6.1.5.9 Documentation of any and all unanticipated problems involving risks to participants and others as well as IRB notification of such
6.1.5.10 Documentation of any and all study violations / deviations as well as IRB notification of such
6.1.5.11 Data Safety Monitoring Board reports as well as IRB notification of such
6.1.5.12 All other UMCIRB Correspondence
6.1.5.13 Investigator and research staff training and certification logs
6.1.5.14 Other applicable study logs
6.1.5.15 Grant and contract information

6.1.6 When applicable; the QIAD will ask the investigator in advance to randomly select a set number of participant files/charts and pertinent medical records for review; for the purpose of:

6.1.6.1 Ensuring consent forms used to enroll participants are properly IRB approved and date stamped; have been properly signed and dated and are the correct consent form for the participant’s respective study
6.1.6.2 Ensuring participants met the inclusion/exclusion criteria for their respective study and whether the criteria has been properly recorded and documented
6.1.6.3 Review of the participant’s medical record (if applicable) may be requested to verify this information
6.1.6.4 To maintain confidentiality the QIAD will not record participant’s personal identifiers for purposes of this review

6.1.7 As part of the routine review the QIAD may request the opportunity to observe the consent process using procedures which may include, but are not limited to:

6.1.7.1 Witnessing administration of informed consent to potential participants
6.1.7.2 Surveying research participants enrolled in the study(ies) about the informed consent process and their experiences.

6.1.8 At the time of the review the QIAD may also request a tour of the facility to
verify/confirm security of documents/records; verify/confirm control of storage and accountability of investigational products

6.1.9 Upon completion of the review; an exit interview will be conducted with the PI; at the investigator's discretion, select study personnel may also attend

6.1.10 The QIAD will generate a report of findings;

6.1.10.1 This report, as well as a cover letter, will be provided in confidence to the PI only, except in the case of findings of serious and/or ongoing non-compliance which results in unanticipated problems involving risks to research participants or others. In the case of serious and/or ongoing non-compliance the results will be immediately reported to the UMCIRB Administrative Director for determination of course of action. Otherwise, the report will address positive findings and identified areas for improvement; the report may include suggestions to facilitate best practices and enhance overall study conduct as well as outline any corrective actions required and the time frame within which these actions are expected to be completed. This correspondence will be provided to the PI within two weeks of the completion of the review. This report will not be disclosed to entities outside the institution, unless otherwise required by state or federal law.

6.1.10.2 Findings from routine review visits will be de-identified and reported in aggregate to the UMCIRB Administrative Director and the IRB on a quarterly basis with an emphasis on evaluation of the overall effectiveness of the UMCIRB program.

6.1.10.3 Findings from routine review visits will be used for the development of educational initiatives and programs for investigators and research staff.

6.11 In the case of findings that could lead to increased risk(s) and/or unanticipated problems involving risks to participants or others the report will be provided to the UMCIRB Administrative Director as well as the PI. The UMCIRB Administrative Director will then make the determination as to whether;

6.11.1 The matter should be referred to the IRB for review

6.11.2 The matter is of sufficient concern that immediate action on the part of the UMCIRB is warranted such as a for-cause study review visit or suspension or termination of the study.

6.2 Quality Improvement Assessment of Internal UMCIRB Activities

6.2.1 The Quality Improvement Assistant Director will perform QI assessments on a routine basis. The purpose of these assessments is to determine the level of compliance with the Belmont Report, federal regulations, institutional policy and UMCIRB policy. Outcomes of assessment activities will used to determine the need for education and training opportunities. Assessment activities will include the following:

6.2.1.1 Evaluate convened IRB meetings, including meeting minutes, for the following; quorum, recusals, protocol specific findings and appropriate IRB actions;

6.2.1.2 Review of IRB database to determine accuracy of data entry;

6.2.1.3 Review of a random selection of Exempt and Expedited Studies to determine accuracy of category selection; use of checklists by staff and reviewers; accuracy and completeness of correspondence; actions are appropriately posted to an agenda;

6.2.1.4 Evaluate pending items to close out and to identify areas of deficiency;

6.2.1.5 Evaluate file room to ensure the file system is organized and maintained in a
functional manner;
6.2.1.6 Evaluate Progress Report Reviews – Notice of Expirations to ensure prompt
notification of the investigator of upcoming study expiration dates
6.2.1.7 Evaluate required human protections education of UMCIRB members,
researchers and research staff
6.2.1.8 Evaluate UMCIRB member knowledge and application of regulations and policies
and procedures
6.2.1.9 Periodic review of UMCIRB Rules/SOPs

6.2.2 The QIAD will generate a report of findings:
6.2.2.1 The formal report of findings will be provided to and discussed with the UMCIRB
Administrative Director at the conclusion of the assessment activity;
6.2.2.2 Reports of findings will be kept on file for review for a period of 36 months.
6.2.2.3 Findings from routine QI assessments will be used for the development of
educational initiatives and improvement programs for UMCIRB Committee
members and staff.

6.2.3 Improvement initiatives will be monitored and measured to determine effectiveness
and if necessary additional improvements will be implemented.
6.2.4 In the case of a report of findings of non-compliance of the UMCIRB in the role of and
with responsibility for the protection of humans involved in research activities; the QIAD
will provide the Director of Research Compliance with a summary of findings. A copy of
the summary of findings will be provided to the Director and Associate Director of the
UMCIRB as well.

7.0 Revision History:

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<th>Date</th>
<th>Revision #</th>
<th>Change</th>
<th>Reference Section(s)</th>
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<tr>
<td>04.29.2010</td>
<td>New Rule</td>
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References
21 CFR 56.109
38 CFR 16.109
45 CFR 46.109