1.0 **Purpose:** This standard operating practice (SOP) establishes guidelines for the Office of Research Integrity & Compliance Quality Assessment Program (ORIC QAP). The aim of the ORIC QAP is to ensure maximum protection of human participants involved in research activities and promotion of best practices in the conduct of human research. This aim will be achieved through quality assessment reviews of studies and UMCIRB activities as well as education of investigators, research staff and the research community.

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

3.0 **SOP:** 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. In order to ensure the UMCIRB and ECU are meeting their obligations to protect human research participants the ORIC QAP will:
3.1 Evaluate whether investigators implement studies as approved by the UMCIRB;
3.2 Evaluate whether the UMCIRB adequately addressed applicable ethical and compliance issues; and
3.3 Identify issues to be addressed in IRB educational/training incentives;

4.0 **Definitions:**
4.1 **Quality Assessment Review:**
4.1.1 Human Research Activities - Routine, confidential, comprehensive or partial assessment of IRB approved research to determine level of compliance with applicable regulations, policies, and ethical standards as well as adherence to the IRB approved protocol
4.1.2 Internal UMCIRB Activities - Routine assessments of UMCIRB operations including but not limited to; the review of 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 assessment findings based on standardized evaluation of applied federal regulations, state laws and institutional policies.

5.0 **Responsibilities:**
5.1 **ORIC Quality Improvement Assistant Director** (QIAD) is responsible for coordination of ORIC QAP activities including but not limited to:
5.1.1 Routine assessment of IRB approved studies evaluating:
5.1.1.1 Study conduct,
5.1.1.2 Study Organization,
5.1.1.3 Record-keeping and documentation
5.1.1.4 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 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 ORIC 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 participants or others warrants a for-cause study review and conducting for-cause review if needed
5.2.2 Notification to the UMCIRB (and others as warranted) of suspected or known serious non-compliance

5.3 University & Medical Center Institutional Review Board (UMCIRB) 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 reports of aggregated findings from quality assessments 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 assessments 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 Assessment
6.1.1 The Quality Improvement Assistant Director (QAID) will select IRB approved studies from the UMCIRB database for on-site quality assessment. All IRB approved studies will be eligible for selection; however, there may be occasion when priority may be given to investigator initiated studies, studies not regularly monitored by other entities, studies involving vulnerable populations or other high risk studies. Studies that have undergone quality assessment within the last two years will not be selected again for assessment. PIs may request a postponement of a quality assessment but may not decline the assessment; 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 The QIAD will notify the Investigator and his/her research staff by email that their study(ies) has been selected for quality assessment;
6.1.2.1 The email correspondence will be followed up by a phone call to determine a mutually agreeable time at which to conduct the assessment;
6.1.2.2 A letter of confirmation will be sent confirming the date of the scheduled assessment. This letter will include the following information:
6.1.2.2.1 Date, time, and location of the assessment;
6.1.2.2 Notice of which study(ies) will be reviewed
6.1.2.3 Notice of documents to be made available during the review
6.1.2.4 Notice that the investigator and/or his/her designee should be available to answer questions during the visit
6.1.2.5 Notice that a brief (+/- 15 minutes) exit interview summarizing review findings will be conducted with the investigator and any study personnel selected by the PI

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

6.1.4 At the time of the assessment all research/regulatory documents for the selected study(ies) must be available for review. Depending on the study(ies), the list of items to be reviewed includes, but is not limited to:
6.1.4.1 Current IRB approved protocol / research plan and all previous versions
6.1.4.2 Current IRB approved informed consent document(s) and all previous versions
6.1.4.3 All original signed informed consent documents
6.1.4.4 Initial and all continuing review IRB submissions; corresponding requests for revisions/additional information and approval letters
6.1.4.5 All IRB regulatory documents including; Investigator’s Brochure (if applicable)
6.1.4.6 All amendments and/or revisions to the protocol/research plan, consent, study personnel and corresponding approvals
6.1.4.7 If applicable to the study; all FDA required documentation and correspondence
6.1.4.8 If applicable to the study; all sponsor required documentation and correspondence
6.1.4.9 Documentation of any and all unanticipated problems involving risks to participants and others as well as IRB notification of such
6.1.4.10 Documentation of any and all study violations / deviations as well as IRB notification of such
6.1.4.11 Data Safety Monitoring Board reports as well as IRB notification of such
6.1.4.12 All other UMCIRB Correspondence
6.1.4.13 Investigator and research staff training and certification logs
6.1.4.14 Other applicable study logs
6.1.4.15 Grant and contract information

6.1.5 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:
6.1.5.1 Ensuring consent forms used are the documents that were approved for that period and have been properly signed and dated
6.1.5.2 Ensuring participants met the inclusion/exclusion criteria for their respective study and whether the criteria has been properly documented
6.1.5.3 Review of the participant’s medical record (as applicable) will be required to verify this information
6.1.5.4 To maintain confidentiality the QIAD will not record participant personal identifiers for purposes of this review

6.1.6 As part of the assessment the QIAD may request the opportunity to observe the consent process using procedures which may include, but are not limited to:
6.1.6.1 Witnessing administration of informed consent to potential participants
6.1.6.2 Surveying research participants enrolled in the study(ies); the survey will
include, but is not limited to, the following questions:
6.1.6.2.1 The information provided during the informed consent process
6.1.6.2.2 Were they given the opportunity to ask questions
6.1.6.2.3 Were they given sufficient time to make a decision
6.1.6.2.4 Who originally administered the consent process.

6.1.7 At the time of the QI assessment 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

6.1.8 Upon completion of the QI assessment; an exit interview will be conducted with the PI; and at the investigator’s discretion, select study personnel,

6.1.9 The QIAD will generate a report of findings that will be provided to the PI within 2 weeks. The report will be provided in confidence to the PI only; exceptions to this will be when there are findings of serious and/or ongoing non-compliance which results in unanticipated problems involving risks to research participants or others.

6.1.9.1. 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. The report will not be disclosed to entities outside the institution unless otherwise required by state or federal law.

6.1.9.2 The report will address positive findings and identified areas for improvement;

6.1.9.3 The report may include suggestions to facilitate best practices and enhance overall study conduct

6.1.9.4 The report will 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.

6.1.9.5 Findings from assessment 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.

6.1.9.6 Findings from assessment trends will be used for the development of educational initiatives and programs for investigators and research staff.

6.1.10 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 ORIC Administrative Director as well as the PI. The ORIC Administrative Director will then make the determination as to whether;

6.1.10.1 The matter should be referred to the UMCIRB for review
6.1.10.2 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 of UMCIRB activities on a routine basis.

6.2.1.1 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.

6.2.1.2 Assessment activities will include the following:

6.2.1.2.1 Evaluation of convened IRB meetings, including meeting minutes, for
the following;
6.2.1.2.1 Quorum,
6.2.1.2.1.2 Recusals,
6.2.1.2.1.3 Protocol specific findings, and
6.2.1.2.1.4 Appropriate IRB actions;
6.2.1.2.2 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;
6.2.1.2.3 Evaluate items which have been in a pending ePIRATE state for greater
than 6 months to determine the need for “administrative” closure;
6.2.1.2.4 Evaluate required human protections education of UMCIRB members,
researchers and research staff
6.2.1.2.5 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 ORIC
Administrative Director and UMCIRB Chair(s) 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 Trends identified 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
ORIC 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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<tr>
<td>05.16.2014</td>
<td>1</td>
<td>Update</td>
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References
21 CFR 56.109
38 CFR 16.109
45 CFR 46.109