TITLE: Institutional Review Board Functions and Operations
QA 901 Quality Assurance Program for Evaluation of Research Activities

ORIGINATOR: Institutional Review Board Chairperson

APPROVAL: [signature]

POLICY STATEMENT: The Mercy Health Regional Institutional Review Board (IRB) has initiated a Quality Assurance (QA) Program designed to evaluate and monitor research studies on a routine basis.

GENERAL PROVISIONS:
The objective of the QA Program is to ensure that proper scientific, ethical, and regulatory requirements are being adhered to by evaluating investigators’ documentation, record keeping, data analysis, interactions and interventions with participants, data security measures and all components that constitute sound and responsible conduct of research. The program is designed to continually evaluate and improve the research process, thereby providing a more thorough understanding of regulations and policies by investigators and a higher degree of human subject protection.

Quality assurance monitoring may be employed whenever the IRB deems that it would increase the safety of research participants or ensure federal regulations and Institutional Review Board policies are being met, either as part of a quality assurance program or on a case-by-case basis. For-Cause On-Site Reviews will be performed when concerns regarding research compliance, protocol adherence, or subject safety are brought to the attention of the IRB. Quality assurance monitoring will be focused on but not limited to research involving greater than minimal risk. The studies to be monitored and the frequency of monitoring shall be determined by the IRB Manager in consultation with the IRB Chairperson.

The criteria for selecting Investigators to be reviewed may include:
• Investigators who conduct studies that involve a potential high risk to subjects,
• Studies that involve vulnerable populations,
• Investigators who conduct studies that involve large numbers of subjects,
• Investigators selected at the discretion of the Office of the IRB, and
• Investigators selected at the discretion of the IRB Committee.

Whenever a study is chosen for monitoring the IRB Manager will designate a reviewer. Prior to the audit the designated IRB reviewer will review the complete Office of the IRB study record to familiarize themselves with the study background, documentation and IRB review history. The reviewer will then meet with the IRB Manager to establish a quality assurance review plan.

Quality assurance review may include but is not limited to the auditing of the following items and activities:
• Review of regulatory documents for completeness, accuracy and compliance with protocol and regulatory requirements.
• Informed Consent Form (ICF) has been properly approved by the IRB and if more than one version of the ICF exists, the most recently approved ICF is in use.
• Correct version of the ICF was administered to study participant.
Institutional Policy & Procedure

- Verification that the ICF was signed and dated by the study participant or legally authorized representative and by the Investigator/designee prior to any study related procedures.
- Documentation that potential study participant has had ample time and sufficient information to make a true informed decision and was provided with a signed copy of his/her ICF.
- Documentation of the consenting process in the study participant’s medical and/or research record.
- Documentation in source documents that study participant meets all eligibility criteria.
- Documentation that study procedures follow the study plan as outlined in the protocol.
- Verification that investigational materials are stored in a secure and proper environment, and accountability records are adequate.
- Review of case report forms and/or databases for completeness and clarity in comparison to source documents.
- Documentation that all serious adverse events and major protocol deviations/violations have been reported to the IRB.
- Documentation that all changes in research activity have been approved by the IRB prior to implementation.
- Documentation that any unanticipated problems involving risks to study participants or others have been promptly reported to the IRB, appropriate institutional official(s), study sponsor(s), and any department or agency supporting or regulating the research.
- Assurance that study is being conducted in compliance with applicable federal regulations, Institutional policies and IRB requirements.
- Informed Consent Process observation -observing the informed consent discussion between the person obtaining consent and the potential participant.
- Study visit activity observation-attending study visits to observe the process of source data collection.

Due to the high variability in research projects, it is anticipated that each audit will be tailored to the specific project. While many reviews will require the reviewer to be at the study site, some may require only a review of study documentation which may be accomplished electronically. Investigators may be asked to submit copies of signed informed consent forms or other documents to ensure their compliance with IRB requirements. The designated reviewer may conduct surveys or interviews with screened and/or enrolled subjects as deemed necessary. Sponsors may be asked to submit copies of monitoring reports or documentation.

The Audit Process

Upon receipt of the quality assurance monitoring assignment, the designated reviewer will contact the principal investigator and/or study coordinator to notify them that the study has been chosen for a QA review. A date and time for the review will be determined during the conversation. The designated reviewer will describe the review process and request the materials and space needed for the review. The phone call will be followed by creation of a site visit confirmation letter which is to be provided to the Principal Investigator (PI).

On the initial day of the QA review and prior to start of the review activities, the designated reviewer will meet with the principal investigator and/or study coordinator to provide an overview of the specific items that will be reviewed. The designated reviewer will request that the study coordinator and/or PI be available for questions throughout the quality assurance review process. The designated reviewer will then begin the review process. The designated reviewer may use various quality assurance tools during the review process. At the end of each day of review, the reviewer will provide the principal investigator and/or study coordinator with a broad verbal description of the issues identified that day.

At the conclusion of the quality assurance review an exit interview will be scheduled with the PI and/or study coordinator to review the findings from the audit. If no significant findings or areas of concern are identified during the review, the PI designee may represent the PI at the exit interview. If there are significant findings, the QI reviewer will ask the PI to be available during the discussion of these findings. The reviewer will inform the PI that they will be provided with a written report indicating any areas of concern.

The audit observations will be categorized as follows:

**Critical:** Significant departure from standard operating procedures, protocols, or governing regulations and guidelines which negatively affect data integrity and/or patient safety.

**Major:** Departure from standard operating procedures, protocols, or governing regulations and guidelines, which if uncorrected, could negatively affect data integrity and/or patient safety.

**Minor:** Departure from standard operating procedures, protocols, or governing regulations and guidelines, which if uncorrected, would not negatively affect data integrity and/or patient safety.
The reviewer shall submit a QA Site Visit Review Summary Report to the IRB Manager. The IRB Manager will review the report and discuss findings with the designated reviewer. The IRB Manager may also discuss the findings with the IRB Chairperson. Based on these activities the IRB designated reviewer will draft a Site Visit Report which shall consist of the following elements:

- Statement describing the type of review, the date, location and procedure followed, who was in attendance;
- Description of the PI's overall compliance;
- Description of any noncompliance, (policies, regulatory or legal) or other deficiencies (as in documentation, etc.). If serious or ongoing noncompliance is observed, the IRB Chairperson will initiate action by the IRB.
- Recommendations of the IRB designated reviewer concerning education for PI and/or research assistants, record keeping, etc;
- PI corrective action plan when necessary;
- Request for written PI response within a designated timeframe.

The Site Visit Report is provided to the PI and study coordinator. When indicated, the PI will be invited to create a corrective action plan. The summary report, the observation report, and any corrective action materials shall be included in the protocol file. The IRB Manager and designated reviewer shall review each report, evaluate the need for follow-up, and verify that any issues raised have been resolved and that all corrective actions have been taken.

**The IRB Manager Response to the audit report and the Investigator response will be classified as follows:**

1. Acceptable
2. Acceptable – Needs follow-up
3. Unacceptable (Any indication that study participant safety is at risk)

The IRB Manager may consult with the IRB Chairperson and/or the IRB Committee to decide on action to be taken for unresolved findings.

**Failure to Respond to Audit Report**

If no response within 60 days, the IRB may suspend the research study in accordance with the noncompliance policy.

**Noncompliance**

Noncompliance with the protocol, SOP's, and/or applicable regulatory requirement(s) by an investigator or by member(s) of the investigators staff should lead to prompt action by Mercy Health's IRB to secure compliance.

If the monitoring and/or auditing identify serious and/or persistent noncompliance on the part of an investigator, the IRB may consider terminating the investigator's participation in the trial. When an investigator's participation is terminated because of noncompliance, the IRB should promptly notify the Institutional Official, the study sponsor and the appropriate regulatory authority(ies).

The IRB Committee will also be provided with a summary of appropriate modifications to IRB policies and procedures, quality assurance and improvement initiatives and IRB and research training developments based on quality assurance program findings.

**REFERENCE:**

45 CFR 46, Protection of Human Subjects
21 CFR 50, Protection of Human Subjects
21 CFR 56, Institutional Review Boards
21 CFR 11, Electronic Records
21 CFR 54, Financial Disclosure by Clinical Investigators

Applicable DHHS Office of Human Research Protection policy, guidance, and directives (including OHRP Guidebook for Human Subject Protections)

**ATTACHMENTS:**

QA 901-A Checklist Participant Chart Review
QA 901-B Essential Documentation Checklist
QA 901-C Regulatory Compliance Monitoring Tool
QA 901-D Regulatory Documentation Checklist
QA 901-E Site Visit Confirmation Letter
QA 901-F Quality Assurance Site Visit Review Summary
**Responsibility** | **Action**
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IRB Chairperson/IRB Manager | 1. Determine which investigators and/or protocols warrant monitoring.  
2. Assign reviewer to conduct quality assurance review.  
3. Establish a quality assurance review plan with the reviewer.  
4. Review all review reports, corrective action materials, education plans and investigator replies.  
5. Inform IRE Committee of quality assurance review outcomes and provide noncompliance findings for review and voting action when appropriate.  
6. Issue correspondence related to IRE Committee actions as necessary.

Designated Reviewer | 1. Conduct quality assurance monitoring activities as directed by the IRB Manager and/or IRB Chairperson.  
2. Create appropriate correspondence to be issued to investigator related to site visit arrangements and reporting.  
3. Complete appropriate checklists and provide to IRB Manager.  
4. Complete appropriate reports and provide to investigator once finalized.

IRB Coordinator/IRB Specialist | 1. Assist in creating and organizing quality assurance correspondence and documentation as advised by the IRB Manager.  
2. Add quality assurance review items to the agenda as advised by the IRB Manager.

IRB Committee | 1. Review reports of unanticipated problems and non-compliance in the conduct of research as outlined in the IRB SOP RR 405 and CO 602.  
2. Request quality assurance reviews in a routine or for-cause manner for issues that have been previously identified by the IRB.