MERCY HEALTH

INSTITUTIONAL POLICY & PROCEDURE
Date of Original P&P: 09/02/2008
Revision No.: 3
Effective Date 03/01/2015

TITLE: Institutional Review Board Quality Assurance
QA 902 Audits by Regulatory Agencies

ORIGINATOR: Institutional Official

APPROVAL: _____
Institutional Official

POLICY STATEMENT: Mercy Health acknowledges that certain regulatory agencies have the authority to audit the operations of the IRB, and supports such audits as part of its continuing effort to maintain high standards for human research protections.

Entities that may audit the IRB include: FDA, OHRP, JCAHO, and appropriate certified auditors of foreign countries where data from clinical research has been submitted in an application for drug or device approval. Sponsors or funding entities of research may also be authorized to audit specific documents and procedures.

GENERAL PROVISIONS:

Preparing for an Audit

For external audits involving OHRP or FDA, the following must be notified immediately:

- President/CEO
- Executive Director, Office of Research & Innovation
- Institutional Official
- IRB Chairperson
- IRB staff designated to participate in the audit
- Legal Counsel

Participating in an Audit

IRB staff must know and follow the procedures outlined by Mercy Health for the conduct of a regulatory audit.

Prior to being granted access to IRB documentation, inspectors or auditors must exhibit proof of their authority or authorization to conduct the audit and to access IRB documents, and no entity other than those listed on the consent forms may have access to any document that includes subject identifiers.

Auditors will be provided with adequate working area to conduct an audit and IRB staff and members must make every reasonable effort to be available and to accommodate and expedite the requests of such auditors.

The auditor will be asked to give a daily and final exit interview to provide an opportunity for the Office of the IRB staff to answer questions or address problems.

Follow-up after an Audit

Reports of the audit, either verbal or written, should be addressed by the IRB Manager, (with the assistance and support of the Institutional Official and Mercy Health Administration), as soon as possible after the audit.

REFERENCE:
21 CFR 56.115

45 CFR 46.115

FDA Compliance Program Guidance Manual 7348.809, Institutional Review Boards

PROCEDURE:

Responsibility	Action
IRB Manager or designee	1. Upon being notified of an impending audit, notify appropriate individuals. 2. Organize and prepare all requested materials for the auditor such as organizational chart, IRB documents (i.e., membership rosters, policies, procedures, investigator manuals). 3. Prepare and organize IRB study files, agendas and minutes and make available to the auditor upon request. 3. Ensure Senior institutional officials or designees and IRB staff are available for interviews and/or to assist the auditor. 4. Inform IRB staff and members that they are to make every reasonable effort to be available and to accommodate and expedite the requests of the auditors. 4. Provide a brief orientation to the auditor of the IRB office system. 5. Create a file with duplicate copies of all materials provided to the auditor and place on file in the Office of the IRB. 6. Record questions that were asked by the auditor and place on record in an audit file in the Office of the IRB. 7. If the auditor requests interviews with Office of the IRB staff and/or IRB members, contact the individuals and arrange for an interview. The IRB Chairperson will document the names of the interviewees and the time and date of the interview. 8. Address the reports of the audit and findings, either verbal or written, with the assistance and support of the Institutional Official and the Office of the IRB staff during and as soon as possible after the audit.
Office of the IRB Staff	1. Make every reasonable effort to be available and to accommodate and expedite the needs of the IRB Chair and the requests of auditors.
IRB Members	1. Make every reasonable effort to be available and to accommodate and expedite the needs of the IRB Chair and the requests of auditors.

Institutional Official	1. Make every reasonable effort to be available and to accommodate the needs and requests of the auditors as requested by the IRB Chairperson.

CONCURRENT CONSENTS:

Institutional Official