INSTITUTIONAL POLICY & PROCEDURE
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TITLE: Institutional Review Board Functions and Operations
QA 903 Quality Improvement Program for Evaluation of Office of the IRB Activities

ORIGINATOR: Institutional Official

APPROVAL: Institutional Official

POLICY STATEMENT: The Office of the IRB has initiated a Quality Improvement (QI) Program designed to evaluate and monitor Office of the IRB (OIRB) activities on a routine basis.

GENERAL PROVISIONS:
The objective of the QI Program is to ensure that Institutional Review Board activities are being completed, recorded and managed according to federal regulations, Mercy Health institutional policies and Mercy Health Institutional Review Board Standard Operating Procedures. The QI program is designed to continually evaluate and improve the Office of the IRB processes, thereby providing a higher degree of review and human subject protection.

Quality review of the daily operations of the IRB ensures effective support of the Board's mandate. Therefore, the QI program consists of three components:

- Regular review and assessment of standard operating procedures (SOP)
- Ensuring the IRB staff have the required education, experience and training to perform their duties appropriately
- Ongoing assessment of IRB operations and outputs

The first component is addressed in detail in SOP GA 101 (Policies and Procedures Maintenance). The second component is addressed in detail in SOP GA 102 (Training and Education) and GA 103 (Management of IRB Personnel). This SOP addresses the third component.

Ongoing assessment of IRB operations and outputs is conducted through QI monitoring. QI monitoring involves periodic, real time checks of specific IRB operations, documents and records. The IRB Manager may assign a designee to perform QI on a routine basis.

Internal auditing is a retrospective assessment of IRB operations through document and record review. Internal audits may be horizontal, where a particular function is assessed across several studies (e.g., minute-taking); or they may be vertical, where a particular study is audited in whole or in part (e.g., high-risk research). An independent auditor performs internal auditing on at least an annual basis.

Sponsors or other responsible agents (e.g., contract research organizations) periodically conduct an audit of their studies reviewed by the IRB. In addition, Food and Drug Administration inspections provide additional assessment of the quality of IRB operations (refer to QA 902, Audits by Regulatory Agencies). These audits are considered external audits.

Office of the IRB staff will discuss the results of the internal/external reviews and regulatory inspections at OIRB team meetings. The consideration of findings derived from these activities results in a determination of the root
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cause(s) of the findings and the development and implementation of a corrective action plan to improve the effectiveness of the IRB human research protection program. The IRB Manager monitors the implementation of the corrective action plans and provides status reports to the Institutional Official as appropriate.

REFERENCE:
21 CFR 56
Institutional Review Boards FDA Compliance Program Guidance Manual 7348.809
Institutional Review Boards FDA's A Self-Evaluation Checklist for IRBs
Applicable DHHS Office of Human Research Protection policy, guidance, and directives (including OHRP Guidebook for Human Subject Protections)

ATTACHMENT:
QA 903-A Self Evaluation Checklist for IRB's
QA 903-B Internal Quality Improvement Checklist-IRB Records
QA 903-C Quality Assurance Review Report
QA 903-D OHRP Self-Assessment Tool

PROCEDURE: All Mercy Health Campuses

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<th>Responsibility</th>
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| IRB Manager    | 1. Determine annual internal auditing plan and assign reviewer.  
|                | 2. Determine root causes and appropriate action plans to address deficiencies found during reviews.  
|                | 3. Monitor implementation of corrective action plans within approved timelines. |
| IRB Chairperson | 1. Remain aware of the OIRB QI activities and provide IRB committee with reports as appropriate. |
| Office of the IRB Team Members | 1. Discuss findings from QI activities at team meetings.  
|                | 2. Implement corrective action plans as directed by the IRB Manager. |

CONCURRENT CONSENTS,

Institutional Official

Signature