HANDLING OF COMPLAINTS REGARDING QA/QI ACTIVITIES

Unit: Human Research Protections Program (HRPP)
Applies to: QA/QI Staff

PURPOSE:
The purpose of this procedure is to identify how complaints or grievances regarding QA/QI activities will be handled if the final QI Routine Review Summary has already been issued to the PI and the MCW/FH IRB.

DEFINITIONS:
Routine Review: A Routine Review is a Quality Improvement Program effort to ensure optimal conduct of human subject research within the framework of institutional policy and regulatory requirements and to provide educational resources to Investigators and members of the study team. Routine review activities may include: interview with member(s) of the study team, review of project related documentation, feedback regarding review findings, and if applicable recommendations and corrective actions.

For Cause Audit: Audit activity is initiated in response to a directive received from a MCW/FH IRB Committee, MCW/FH IRB Chair or Director of Human Research Protection Program. Audit activities are reviewed and authorized by the HRPP Director prior to initiation of audit activities.

Audit activity is based upon the question(s) or concern(s) associated with the request for audit. Audit activities may include interviews with member(s) of study team, review of project related documentation and written report to requestor of audit.

PROCEDURE:
1. After the release of the QI Routine Review Summary for a Routine Review or QI Final Report for an Audit, if the QI Specialist or QI Manager receives a complaint or request for appeal the following steps will be taken.
   - The QI Specialist will forward the complaint or request for appeal to the QI Manager.
   - The QI Manager will review and consider the complaint or request for appeal of the findings, and as applicable notify the HRPP Director of the matter.
   - If the Investigator has requested an appeal of the findings in writing, this information will be forwarded to the IRB Chair or Committee for review and consideration.
   - Responses may vary based on the grievance or complaint and a summary of action may be provided to the HRPP Director.
2. The QI Manager and/or Specialist will keep all documentation and correspondence regarding the grievance or complaint will be maintained in the QI paper file specific to the PI.

REFERENCES:
N/A

SUPPORTING DOCUMENTS:
QI Routine Review Summary
QI Final Report

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Approved By
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