Research Site QA/QI Review PREPARATION Overview

HRPP Preamble

All MHC IRB approved human subject research carried out at McLaren and its subsidiaries are to be conducted in compliance with McLaren policies, the Health Insurance Portability and Accountability Act (HIPPA), all applicable federal regulations and Good Clinical Practice (GCP) guidelines, and state and local laws and regulation.

Review Process

The visit will involve an introduction meeting, the review of relevant study procedures/material/storage, and a summary meeting. During the summary meeting, the QA and Education Specialist goes over any findings including any serious or continuing non-compliance events requiring immediate corrective actions. The duration of the site visit will vary from 4 to 8 hours depending on the complexity of the protocol, risk level, and reason for the visit.

Within 10 business days of the site visit, the research team will be provided with a formal written report that outlines the site visit observations, comments, request for clarification, recommendations, and/or required corrective actions. If a response is required from the study team, the response is due within 30 days.

When a response from the study team is received back, the HRPP Corporate Director and QI-Education Specialist will review the response and confirm that all issues either have been resolved, or require additional clarification. Consultation with the IRB Chairman will be sought as necessary. The QI-Education Specialist may schedule a follow-up site visit under certain circumstances.

When the site process is complete, the research team will be provided with a close out letter.

Preparation for the Visit

1. Please send a list of subject IDs and indicate the status if they are screen failures, in screening phase or randomized/enrolled. Do not include subject names or other PHI at this time.

2. Please ensure there will be available space to review study documents during the study review (quiet, private, access to electrical outlets).

3. Please have all study and subject documents, binders, and files available at time of review.

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4. Study material should be maintained in a clear and organized manner, preferably in chronological order. Documents can be provided in hard copy or electronically. Whether a study document is electronic or paper, the reviewer must have access, ensure they exist and are reliable and stored safely. In general, the following should be ready for review (list is not inclusive):

    a. IRB Documentation - All IRB correspondence: Submissions, approval letters, acknowledgement letters, IRB action letters, PI response letters, etc.
        1. Initial Review
        2. Continuing Reviews
        3. Amendments
        4. UPIRSO Events
        5. Significant Deviation Reports and Exception Requests
    b. General Study Documentation
        1. Approved protocol, current, and expired versions
        2. Approved consent and assent forms, current, and expired versions
        3. Standard Operating Procedures
        4. Normal lab value ranges
        5. Subject enrollment and/or screening logs
        6. Recruitment/retention material and/or subject educational tools
        7. Other study tracking logs
        8. Other study materials (e.g. surveys, case report forms, questionnaires)
    c. Complete Subject Study Records for requested subjects IDs
    d. Signed consent/assent forms for <u>all</u> subjects
    e. If applicable, Regulatory Documentation for Drug/Device Trials
    FDA Forms 1571/1572, FDA Financial Disclosure Form, IND/IDE application, study drug or device accountability and shipment logs
    f. If applicable, investigator agreements and/or correspondences with sponsor,
    NIH progress reports, DSMB reports, monitoring visits reports
    g. Research Staff Documentation
    Delegation log, research staff CVs, COI certificate, CITI training certificates, professional license, study-specific training, IATA training, Lab Director CV, CLIA certificate

5. A designated member of the research team that is knowledgeable in all aspects of the project must be available to answer questions and retrieve files during the entire site visit.