Pre-Study Site Visit Guidance

Updated June 12, 2023

This guidance document sets forth responsibilities for research team members involved in determining feasibility of conducting clinical research studies at the MFA. The Principal Investigator ("PI") retains responsibility for pre-study site visits unless the investigator has expressly delegated this duty to a research team member and the delegation is documented on a study specific *Delegation of Authority* Log. This guidance document applies to research team members responsible for determining the feasibility of conducting clinical research studies at the MFA.

Procedures

1. Verify the sponsors' confidentiality disclosure agreement (CDA) has been signed by MFA and has been returned promptly to the sponsor. The Senior Director of Business Operations should review the CDAs and will obtain institutional signatures, when required. When an institutional signature is required, the PI may not sign off on a CDA.
2. Pre-Study Site Visit Preparation

    a. Review Protocol.

    Upon receipt of a protocol or protocol synopsis, the PI and designee will review the protocol/synopsis to determine feasibility of performing the study at MFA. Items to consider include:

    - Adequate study population;
    - Availability of personnel, e.g., IDS support; GWUH support;
    - Time requirements;
    - Necessary equipment, etc.

    b. Define specific responsibilities/activities for the visit and any follow-up activities that may be required.
    c. Determine if the Sponsor has any areas of special interest that require advance scheduling such as; touring specific site areas (i.e. IDS Pharmacy), seeing special equipment, meeting with ancillary personnel or visiting ancillary facilities (i.e. GWU Hospital).
    d. Review critical study documents such as; the protocol, the investigator brochure, case report forms (CFR's) and if applicable, the sample budget worksheet and draft contract.
    e. Identify key personnel and have current curricula vitae and licensure available for all key personnel as defined by regulations and the Sponsor. This includes GCP and CITI training certificates
    f. Schedule the visit for a date and time agreeable to the PI, other staff (IDS Pharmacy), and Study Sponsor representative.

3. Pre-Study Site Visit

    a. Review the protocol and communication plan with the sponsor's representative.

b. Tour facilities with sponsor's representative to determine that the appropriate space and equipment is available for the proposed study.
c. Discuss with the sponsor's representative the investigator's interest in, and number of potential subjects available for, participating in the study.

Note: At the discretion of the Sponsor, a virtual interview may be done in place of an on-site visit.

4. Complete follow-up communication with the Sponsor (or CRO) after the pre-study site visit clarifying any issues and provide final decision regarding study acceptance/decline.