Study Start-Up and Close-Out Guidance Document

Updated June 13, 2023

This guidance document applies to activities in preparation for study start-up, the conduct of or attendance at a study site initiation meeting, and study close-out. This guidance document sets forth the responsibilities of research team members involved in study start-up and/or study initiation procedures undertaken at GWU MFA. The Principal Investigator ("PI") retains responsibility for study start-up/initiation and close-out 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.

STUDY START-UP

Regulatory Documents

1. If applicable, once GWU MFA has been selected as a study site, all regulatory documents should be forwarded to the GWU MFA PI from the Sponsor or Sponsor representative;
2. Upon receipt, review all regulatory documents for accuracy;
3. Refer to Essential Documents Checklist at Study Start-Up for complete listing of regulatory documents to be obtained prior to study commencement.
4. PI shall complete and sign forms, as necessary;
5. Submit the required regulatory documents to the appropriate IRB, as applicable, along with other required forms for that IRB, as outlined below:

    a. George Washington University, Institutional Review Board (GWU IRB)

        i. GWU IRB is to be used for all Federally Funded Research and Investigator Initiated research studies.

        ii. Current Study Forms should be completed as applicable per the OHR, IRB website: https://humanresearch.gwu.edu/institutional-review-board- submissions

        iii. Studies being performed at the GWU MFA should have the HRP-200 form signed by the appropriate personnel in the Clinical Research office of the GWU MFA prior to being submitted to the IRB.

    b. Western Institutional Review Board (WIRB)

        i. WIRB is to be used for all legacy industry sponsored research studies or if chosen by the sponsoring company .
        ii. WIRB website: http://www.wirb.com

iii. See Attachments for an example WIRB Submission Checklist
iv. Submit to WIRB after the WIRB Approval Submission Form (MFA Form) has been signed by the appropriate MFA Clinical Research Personnel and the IDS Pharmacy. This form must be submitted to WIRB with initial submission in order for the submission to be reviewed.

c. Advarra (CIRBI)

i. Advarra is to be used for all new industry sponsored research studies
ii. Advarra IRB website: https://www.cirbi.net/CIRBI/sd/Rooms/DisplayPages/LayoutInitial?Container=com.webridge.entity.Entity[OID[AC482809EC03C442A46F2C8EEC4D75D3]]
iii. See Attachments for an example Advarra Reliance Template
iv. Submit to Advarra after the Advarra Reliance Form has been signed by the appropriate MFA Clinical Research Personnel.

6. Review any source documents developed/provided by the Sponsor. If all necessary information can be captured on the sponsor provided source documents, use the documents without change. For additional information refer to SOP 06 - Source Documentation.

Delivery of Study Materials

Review the following materials for completeness:

- A study file notebook (or regulatory binder) - includes all required regulatory documents;
- A complete set of source documents, when provided by the Sponsor;
- All necessary lab supplies and shipping materials; and
- Any other study specific supplies or equipment required by the protocol.

Drug/Device Shipment

Ensure an adequate drug/device supply has been delivered by verifying the following:

- For drug studies, quantity of drug shipped, date of receipt and proper storage. For device studies, type and quantity of device, date of receipt and batch number or code mark; and
- For drug studies, the condition and amount of drug upon receipt. Document condition/amount and file in study file notebook with duplicates to the Sponsor. For additional information refer to SOP 11 – Drug/Device Accountability.
- For more information regarding specific drug delivery procedures please refer to the MFA Investigational Drug Policy and Procedures Manual.

OnCore

Studies will need to entered into OnCore once the site has been selected. Work with the OnCore Project Manager to create the protocol shell in order to have the study visits and costs built into EPIC. The initial IRB Approval Letter will need to be uploaded into OnCore in the IRB Reviews Tab. See Attachments “OnCore Protocol Shell Creation Guide”

Study Initiation Visit

In most cases, before enrolling the first subject, the Sponsor will conduct a study site initiation visit. This visit should involve, at a minimum, the Study Manager, Principal Investigator and study coordinator. It is also suggested that all sub-investigators and other staff involved in the conduct of the study (i.e. x-ray tech, lab tech, pharmacist, etc.) participate in this visit.
During this visit, research team members should:

- Thoroughly review the protocol; and
- Receive training on all aspects of the protocol-required procedures, CRF completion, AE reporting, visit schedule and patient recruitment.

STUDY CLOSE-OUT

The following study close-out procedures take place when all research related activities associated with a study have been completed in accordance with the protocol.

CRF Preparation

Review all CRFs to verify that they have been completed, the PI has reviewed and signed where required and that all queries have been resolved.

Drug/Device Accountability

Review all documents to verify the following: quantity of drug/device shipped, date of arrival, proper storage, quantity of drug/device dispensed to each subject and returned at the end of study participation and quantity of drug/device returned to the Sponsor.

Package any remaining/unused drug/device and dispose according to IDS pharmacy direction or return to the Sponsor as directed.

Regulatory Binder

Ensure that all regulatory documents, staff CVs and trainings, and other correspondence is available, complete and current.

IRB Notification of Closeout

Complete the close out form for the appropriate IRB only when any required criteria for close out per IRB SOPs has been met and the Sponsor has provided confirmation and authorization that the study may be close with the IRB.

OnCore

Upload the IRB Closure Approval Letter into OnCore under the IRB reviews tab and mark the study as “terminated,” select the reason for termination.

Retention of Records

All records pertaining to a clinical trial must be retained until the following have been met (whichever is the greater length must be followed):

- If all participants are adults: at least three years after completion of the research
- If participants are children: until all participants are 18 years of age, or for three years after the completion of the research, whichever is longer
- If the study involves Protected Health Information, research records must be maintained for a minimum of six years after the completion of the research.
- For drug studies conducted under an IND, two years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until two years after the investigation is discontinued and FDA is notified.
- For device studies conducted under an IDE or abbreviated IDE, two years after the latter of the following two dates: The date on which the investigation is terminated or completed, or the date that the records are no longer required for purposes of supporting a premarket approval application or a notice of completion of a product development protocol.
- The retention period required by the sponsor or the Clinical Trial Agreement (CTA); or
- The retention period required by local, state, or international law.

All records must be stored at MFA, or at Iron Mountain, a secure, off-site facility where records may be readily accessed in the event of an audit. Please review SOP 18 for guidance on how to request study pick-up. Alternatively, with IRB approval, the study records may be sent to the Sponsor headquarters for storage on-site or at a secure off-site facility.

Study Termination

Study termination takes place when research related activities are stopped prior to the study's planned completion. A regulatory body, sponsor, PI or IRB may terminate a study.

- For regulatory body termination, follow regulatory body directives for study termination.
- For sponsor termination, follow sponsor directives or if not provided, then follow procedures as outlined in Section 4.1 Study Close-Out.
- For IRB termination, follow IRB directives, which are communicated to the PI in a formal memorandum.

ATTACHMENTS

WIRB Submission Checklist

SPONSOR/CRO: _____

PROTOCOL:_____

PI:_____

STUDY COORDINATOR:_____

- ☐ Regulatory Documents received
  - Send Protocol, CTA (Clinical Trial Agreement), Budget and Consent Template (for subject injury language review) to Proposal Specialist

- ☐ Complete and obtain signatures on:

  - MFA WIRB Submission form
  - ProposalRoutingSheet
  - Complete Hospital questions, if GWUH is involved
  - 1572
  - Conflict of interest form (MFA/GWU) for each Investigator
  - Financial Disclosure forms (Sponsor) for each Investigator

- ☐ Send copy of protocol to IDS pharmacy for review (So they can sign off on MFA WIRB Submission form) IDS@mfa.gwu.edu

- ☐ Send Proposal packet to Proposal Specialist with all forms and required documents

- ☐ Review/Revise Consent form for

- Add site specific information
- Revise Subject injury per Contract
- Put in Subject compensation (if applicable) (from CTA/Budget)

☐ Collect information for WIRB

- Download and complete WIRB Smart Form for initial submission (contact sponsor/CRO for information required to complete form)
- Get documentation to support Billing of WIRB fees (email/letter, etc) (see Contract for who pays WIRB bills)
- Protocols, IBs, Subject materials (ANYTHING TO BE SEEN BY SUBJECTS), Advertisements
- If required (ie. Not already on file at WIRB):

    - CVs (up to date) (PI, Sub-I)
    - Medical Licenses (PI, Sub-I)