Table of Contents

1. Overview

Purpose

The purpose of this guidance document is to describe the activities completed by the study personnel before, during and after site initiation or site initiation visit (SIV) to ensure that all site personnel are properly trained, the study materials and documentation are in place, and the site is ready to start the clinical research study.

Site initiation is completed by the study sponsor or a Contract Research Organization (CRO). Sites may complete additional activation or initiation activities outside of the SIV, e.g., additional personnel training or study preparations. If the study is an investigator-initiated clinical research study, the lead coordinating site Principal Investigator (PI) is considered the Sponsor-Investigator and is typically responsible for both sponsor and investigator obligations, including site initiation, under Good Clinical Practice (GCP) Guidelines. If the investigator-initiated clinical research study is a multisite study, the sponsor-investigator is responsible for completing the site initiation for all participating research sites. Site initiation responsibilities may also be dependent on funding, e.g., SBIR/STTR, management plans, etc.

2. Definitions

Case Report Form (CRF): an electronic or paper document which is used in clinical research to record the protocol required information about each study participant.

Contract Research Organization (CRO): a company that provides research services to other companies or research centers on a contractual basis. CROs are often hired by pharmaceutical, biotechnology, and medical device companies to help with clinical research.

Essential Documents: documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced

Good Clinical Practice (GCP): an international ethical and scientific quality standard for designing, conducting, recording and reporting research studies that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of research participants are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical research data are credible.

Investigator's Brochure: a document that summarizes clinical and non-clinical data about an investigational product (IP) or study drug. It includes the pre-clinical data such as chemical, pharmaceutical, toxicological, pharmacokinetic and pharmacodynamic data in animals and humans as well as the results of earlier research.

Source Documents: original documents, data, and records that document the existence of a research subject and the integrity of the research data collected.

Sponsor-Investigator: an individual who both initiates and conducts, alone or with others, clinical research, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject or under whose immediate direction a behavioral intervention is

administered. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

3. Pre-Visit Preparation

3.1 Scheduling the Visit

Coordinate with the date and time of the SIV with the study sponsor to accommodate all key research personnel (PI, co-Investigators, study coordinator, pharmacists, etc.) as applicable or arrange for alternate protocol training for individuals not present at the SIV. At a minimum the PI and lead coordinator should be present at the SIV.

3.2 Document Preparation and Regulatory Requirements

Ensure the sponsor has provided the most recent study documents, including the protocol, Investigator's Brochure, sample case report forms, relevant operating manuals, etc. These are often available in the regulatory binder provided by the sponsor and should be maintained as essential regulatory documents in the format utilized by the site.

Confirm all required agreements have been executed (e.g., Clinical Trial Agreement) and all approvals obtained as applicable (e.g. IRB, IBC, Radiation Safety, EHS, Third Party Risk Management (TPRM)).

4. Conducting the SIV

The SIV is completed by the study sponsor, CRO, or Sponsor-Investigator. Sites may complete additional activation or initiation activities outside of the SIV, e.g., additional personnel training or study preparations. If the study is an investigator-initiated clinical research study, the SIV should be completed by the PI as the sponsor-investigator or designated personnel.

SIV activities typically include:

4.1 Opening Meeting

Provide an introduction to the meeting and objectives and review of the visit agenda.

4.2 Protocol Training

Provide detailed training on the study protocol, including objectives, study design, and participant population. Discuss study-specific procedures, participant eligibility criteria, randomization procedures, and study visit schedule. Emphasize safety monitoring, adverse event reporting, and compliance with GCP guidelines.

4.3 Study Documents, Supplies, and Facilities Review

Review the essential documents and regulatory files to ensure all required documents are completed and filed. Review the informed consent process and documentation procedures. Review the case report forms, methods for source documentation (e.g., medical records, paper source) and the storage location(s) of the documents. Ensure that all study supplies (e.g., laboratory kits, blood draw supplies, patient diaries) are available. Confirm that the site facilities

(e.g., equipment, space) are adequate to conduct the study and that all sponsor-provided equipment has been received at the site.

4.4 Investigational Product (IP) Management

If applicable, complete any drug or device-specific training procedures. If specialized training is required by the sponsor/CRO, ensure appropriate training is scheduled, completed and documented. Discuss the receipt, storage, accountability, and dispensing of the IP, and review the procedures for temperature monitoring, IP destruction, and return of unused product.

4.5 Behavioral Intervention or Assessment Training

If applicable, provide a detailed description and training of the behavioral intervention or assessment(s), its goals, scoring, and its theoretical framework. If a validated instrument is being used, provide instruction on how to ensure the instruments are used within their specificity and scope and are scored consistently. Explain the specific techniques and approaches used in the intervention, how to engage with participants, delivery of intervention, monitoring and escalation to mitigate risk to participants.

4.6 Data Management

Provide training on data entry procedures (e.g., training on the specific electronic data capture (EDC) system used) and review timelines for data entry, query resolution, and monitoring visit expectations. Ensure only appropriately delegated and IRB-approved individuals have access to EDC systems.

4.7 Safety Reporting

Review the identified study and IP risks and any expected adverse events (AEs) or AEs of special interest as defined by the protocol. Review the process for recording and reporting AEs and serious adverse events (SAEs). Discuss the timelines for reporting and the appropriate reporting mechanisms to record and report events. As AE and SAE reporting requirements may differ for the sponsor and IRB, ensure sponsor and IRB reporting requirements are reviewed.

5. Post-Visit Activities

5.1 Documentation

The sponsor, CRO, or sponsor-investigator should document the SIV activities in a report summarizing the visit, attendees, training provided, and readiness of the site, including any outstanding issues or action items to be completed prior to fully activating the site.

SIV records should also include a list of all personnel who attended the SIV and received protocol training.

The regulatory files should be updated to reflect completion of the SIV, including updating any documents provided during the SIV, the SIV report, and the SIV training log.

5.2 Additional Actions

Review the SIV report and complete any outstanding action items. Review all study files (e.g., regulatory files, procedure manuals) and ensure equipment and supplies are available on-site.

Review and compare the case report forms to the protocol and ensure there are no discrepancies in data collection versus the approved protocol.

5.3 Site Activation

Following the SIV and resolution of any action items, the study sponsor should provide documentation of the site activation and approval to begin study procedures. Study activities should only begin after all applicable approvals have been obtained (e.g., IRB, IBC, Radiation Safety, EHS, Drexel's Third-Party Risk Management (TPRM), clinical trial agreements, regulatory authority approval, etc.) and site activation by the sponsor.

Please note, if new study personnel are added after site initiation or did not attend the SIV, please ensure the personnel receive the applicable training as referenced above with the current document versions.

6. Responsibilities

6.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, and monitoring. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

6.2 Principal Investigator Responsibilities

The Principal Investigator retains overall responsibility for the study, including participation in the SIV and training activities. The PI must ensure all study personnel are adequately trained to perform their research-related responsibilities. If the PI is conducting an investigator-initiated clinical research study, the PI is responsible for following the investigator and sponsor responsibilities under GCP.

6.3 Study Personnel Responsibilities, as delegated by the PI

Study personnel, as delegated by the PI, are responsible for attending the SIV and completing pre-visit and post-visit activities. Study personnel should ensure their role and responsibilities are well understood prior to engaging in study activities.

7. Resources

- ICH E6 R2 Guidance for Industry Good Clinical Practice
- ORI-613 Supplement Site Initiation Checklist
- ORI-615 Maintenance of Regulatory Files

8. Revision and Advisory Members

8.1 Revision

Version 001/Effective Date 1/24/2025 – Original Document: Site Initiation

8.2 Workgroup & Advisory Members

The Office for Research and Innovation appreciates the following individuals who served as Workgroup and Advisory Members:

Workgroup & Advisory Members	
Taish Bruton Executive Administrator College of Medicine	**Janet Matthews, MSN RN** Senior Director, Research Program Development College of Medicine
Marisa Corbett, BA, CCRC Executive Director, Research Quality Assurance Office of Research & Innovation	**Carissa Miller** Research Compliance Coordinator Office of Research & Innovation
Honora Cutler, BSN, RN Clinical Research Operations Manager College of Medicine	**Cassandra Myers, BS** Associate Vice Provost, Research Compliance and Regulatory Affairs Office of Research & Innovation
Rose Ann DiMaria-Ghalili, PhD, RN, FASPEN, FAAN, FGSA Senior Associate Dean for Research Professor College of Nursing and Health Professions	**Jacqueline Stults, MBA, BS** Research Quality Assurance/Quality Improvement Office of Research & Innovation