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Site Initiation and Activation

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1.0 Introduction / Background

All clinical studies conducted within SWSLHD must undergo a set process for site initiation. This process directly follows Human Research Ethics Committee (HREC), Governance approval and TGA acknowledgement if a CTN/CTX is required. These processes are a mandatory requirement prior to subject recruitment.

The Principal Investigator (PI) may delegate the performing of all clinical trial start up activities to a member of the clinical trial team. This delegation of duties must be formally documented in the Delegation of Responsibility Log.

2.0 Objective

To describe the procedure for site initiation requirements for a clinical trial that is sponsored by a Pharmaceutical Company, Collaborative group or Local Health District.

3.0 Scope

This SOP applies to all staff involved in clinical trials at SWSLHD and the Ingham Institute.

4.0 Ownership and Responsibility

A clinical trial should be initiated at a site only after the PI and Sponsor involved in the clinical trial is satisfied that essential documents, agreements and approvals are all in place.

The site initiation process is designed to ensure that:

- The site has all essential documents in place for the site to conduct the clinical trial in compliance with the approved protocol and applicable regulatory guidelines.
- The site is aware of all the sponsor's procedures and SOPs for study conduct (such as safety recording and reporting, amendments, notification of any urgent safety measures/ non-compliance or serious breaches) and has read and understood each.
- The site is met with all the required regulatory and sponsor requirements.

The procedure outlined below refers to a "sponsored" clinical trial. Where the clinical trial is "Investigator Initiated" and the "Sponsor" is the Institution, the PI should undertake both Investigator and Sponsor roles unless an external contractor has been assigned by the Institution.

5.0 Associate Documents

SOP_CTSU_02 Investigator Responsibilities
SOP_CTSU_08 Documentation of Training and Clinical Trials Handover
SOP_CTSU_09 Investigator Site File and Essential Documents
FM_001_Sourse Data Location Form
FM_006_Protocol Specific Training Log
FM_007_Delegation of Responsibilities Log
FM_010_ Overall Investigator Site File Management for Clinical Trials
FM_017_Protocol Specific Work Instruction
FM_023_Site Initiation Visit Checklist
FM_024_Trial Recruitment Plan

6.0 Procedure

A research study should be initiated at a site only after investigator and Sponsor/CRO involved in the study is satisfied that essential documents, agreements and approvals are all in place. The site initiation process is designed to ensure that;

- The site has all essential documents in place for the site to conduct the study in compliance with the approved protocol and applicable regulatory guidelines.
- The site is aware of all the sponsor's procedures and SOPs for study conduct (such as safety recording and reporting, amendments, notification of any urgent safety measures/ non-compliance reporting) and has read and understood each.
- The site is met with all the required regulatory and sponsor requirements.

6.1 Preparing site for Site Initiation Visit

For preparing the site for initiation the investigator(s) or Clinical Trial Coordinator (CTC) should:

- Confirm the available date and time with the clinical research team including supporting departments such as Pharmacy, must attend the meeting. Ensure that the site and sponsor arrange the most suitable meeting date, time and place.
- Request an agenda for the visit from the sponsor; circulate the same to each team member.
- Confirm that investigator and team has reviewed the Protocol and Investigator's Brochure (IB) and any up-to-date information on investigational product (IP). The Investigator(s) must prepare a list of questions if any to be asked in the SIV.

- Ensure that the procedures stated in the study protocol are applicable at the site and fully understood.
- Confirm that all documents required by Institutional Ethics Committee (HREC) are available.
- Confirm that the Clinical Trial Research Agreement (CTRA) is finalised and signed by all parties (Sponsor, Principal Investigator and SWSLHD Delegate).
- Notify appropriate departments regarding the sponsor/CRO visit (e.g., Laboratories, pharmacy, CT scan, bone scan and x-ray, etc).
- File all essential documents in TMF (or sponsor-supplied Investigator Study File), and compile any outstanding documents to provide to the Clinical Research Associate (CRA) at the initiation meeting.

6.2 During the Site Initiation Visit

During the initiation visit the investigator(s) or Clinical Trial Coordinator (CTC) should ensure that the Investigator Site File contains the following mentioned applicable items and all the required regulatory documents:

- Establish that the Investigator's Site File which contains all the required regulatory documents. (FM_010_ Overall Investigator Site File Management for Clinical Trials)
- Overall Investigator Site File Management for Clinical Trials
- Provide Delegation of Responsibilities Log (FM_007_Delegation of Responsibilities Log) listing research staff and their responsibilities.
- Provide curricula vitae (CV) and current GCP Certificate of all staff listed on the Delegation of Responsibilities Log
- Ensure that the names and contact numbers of the relevant medical and study personnel of the Sponsor are available and documented clearly.
- Check that the procedures and plans for storage, dispensing and return of investigational product have been agreed and finalised with the Sponsor and Pharmacist (if applicable).
- Check that related supplies are available, or are to be shipped to the study site at a later date, and that they are available in sufficient quantities.
- Check that laboratory facilities and arrangements for the dispatch of samples to the laboratory are organised and that any specialised equipment that may be required will be available throughout the period of the trial, e.g. centrifuge freezer, etc.
- Establish who will be responsible for Case Report Form (CRF) completion and clarify the procedure for entering data in the CRF, as well as making changes and corrections.

- Ensure an understanding of the requirements that source documents will need to be available during monitoring visits to enable the monitor to perform source data verification at each monitoring visit.
- Review the arrangements for organising and maintaining the ISF
- Ascertain that the procedures relating to the archiving of study records at the end of the study is agreeable to the Sponsor.
- During the initiation visit the PI or delegate (for investigator initiated study) and Sponsor/CRA (for Sponsor study) will provide a protocol-specific training session to all the members of the research team who will be involved in the research study. The PI or Sponsor/CRA will ensure that the attendance sheets and other training documentation are completed.

The protocol-specific training session will include, but is not limited to, the following:

- Aim and Objective of the protocol
- Time and events schedule for the protocol
- Subject recruitment
- Obtaining informed consent
- Procedure for dispensing the IP
- IP storage and records
- Protocol-specific forms and procedures
- Source documentation
- Adverse event reporting
- Additional information from the Investigator's Meeting (IM)
- Any other relevant information

The Investigator, monitor/CRA and CTC will:

- The PI or Delegate will:
- Develop a Recruitment Plan for how to recruit the participants into the clinical trial. FM_024_Clinical Trial Recruitment Plan
- Identify a back-up to the primary CTC

6.3 Study Activation and Follow-Up

In preparation for study activation:

- Confirm that the Sponsor sends a written summary of key discussions and agreements made during the SIV. Follow-up if necessary.
- Confirm readiness of the site to start the study.

- Confirm the receipt of all study-related materials such as CRFs, laboratory supplies, investigational product(s).
- Distribute protocol summaries and worksheets, if not done previously (the Sponsor may provide study-related worksheets, however the site can prepare one).
- Notify all appropriate departments that the study is ready to enrol participants.
- Initiate study recruitment strategies and begin enrolling participants.

7 References

ICH GCP (E6 R2): Good Clinical Practice Guidelines - Annotated by TGA

National Statement on Ethical Conduct in Human Research (2018)National Statement on Ethical Conduct in Human Research (2018)

Australian Code for the Responsible Conduct of Research (2018)

8 Amendment History

Version	Date	Amended by	Details of Amendment
1.0	1 July 2020	Kelsey Dobell-Brown	Updated to adhere to accreditation requirements

END OF DOCUMENT