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Sponsor Audits and Regulatory Inspections

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Date	23 February 2024	23 February 2024	23 February 2024
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1.0 Introduction / Background

Regulatory Inspections and Sponsor Audits may be scheduled periodically at investigational sites to review protocol compliance and adherence to Good Clinical Practice and Regulatory requirements, during or after the completion of a study. The key is to maintain a culture of inspection readiness.

Human Research Ethics Committees (HREC) may also inspect investigational sites during a clinical trial to ensure participant safety and ethical guidelines are being followed.

2.0 Objective

To describe the roles procedures and activities required to prepare and facilitate a sponsor, audit or Regulatory Inspection.

3.0 Scope

This SOP applies to all staff involved in clinical trials at South Western Sydney Local Health District (SWSLHD) and the Ingham Institute.

4.0 Ownership and Responsibility

The SWSLHD Research and Ethics Office in collaboration with Clinical Trials Support Unit will be involved in the preparation, conduct and follow-up of audits and inspections. This is done in conjunction with the Principal Investigator (PI) and the Clinical Trial Support Unit (CTSU)

5.0 Associate Documents

SOP_CTSU_02 Investigator Responsibilities

SOP_CTSU_03 Communication with Human Research Ethics Committee, Trial Sponsor and Insurer

SOP_CTSU_17 Data Recording - source data, case report forms, record keeping and archiving

SOP_CTSU_19 Safety Assessment, Data Monitoring and Reporting Requirements

6.0 Procedure

6.1 Notification of Audit/inspection

The Sponsor of a clinical trial will be notified by the Regulatory Authority of any proposed Regulatory Inspection dates and asked to confirm availability. The notification will identify the study to be inspected, and if applicable the proposed sites. The Sponsor will then liaise with the site and the Regulator to determine a suitable inspection date.

The PI must notify the SWSLHD Research and Ethics Office and CTSU when notification of an audit or regulatory inspection has been received. The CTSU in collaboration with the PI and or the delegates will establish an inspection file in which all documentation will be stored regarding the inspection/ audit.

The following information may be requested from the Regulatory Inspector/Auditor prior to the inspection:

- Participant status per trial site (number randomised, drop-out rate, and number of serious adverse events reported per site)
- Copies of standard operating procedures e.g. informed consent procedure, serious adverse event reporting procedure, Investigational Product (IP) management procedure etc.
- Trial-specific documents such as a copy of the current protocol and informed consent form, Delegation of Responsibilities Log, source data verification guidelines, product handling instructions, laboratory manual, randomisation code breaking procedure, monitoring plans and reports.
- Qualification documents such as CV and GCP for all involved staff
- Arrangements for direct access to any computerised systems upon which clinical trial data or essential documents are stored
- Any other documentation deemed necessary

In accordance with the regulations, the Investigator Site File (ISF/eISF) comprising the essential documents which enable both the conduct of the trial and the quality of the data produced to be evaluated must be available by direct access and shall provide the basis for the ICH- GCP governed procedure.

6.2 Pre-Inspection Activities

An inspection plan will be provided to the Institution and/or PI by the Regulatory Authority or the Sponsor prior to the inspection. This will outline the facilities to be inspected and the schedule of meetings to be held with the investigator and clinical trial personnel. This may include, but not limited to;

- The appointed person responsible for coordinating actions during the inspection
- All meetings, action items and documents to be collated for inspection

- A nominated person to be contacted when the inspector / auditor arrives.

Appropriate space must be facilitated for the entirety of the inspection/ audit.

6.3 Audit/Inspection Conduct

On arrival, the inspector / auditor must contact the nominated contact and should not be given further access to the Institution or be allowed to commence any activity until the nominated person is present.

All activities should occur in the designated areas.

The Principal Investigator and senior research staff should be present during the opening and closing of the inspection / audit. To meet with the inspector / auditor(s) prior to the audit for a brief introduction to the proposed audit and at the conclusion of the audit to discuss any questions or findings. The inspector / auditor must be accompanied at all times when outside of the designated areas.

During interview of the clinical trials team it is advisable to minute the discussions. If requested the employee's supervisor may be present. The clinical trials team member must only answer the questions that are asked.

Any comments or observations made by the inspector / auditor should be recorded in writing during the audit / inspection and reviewed by the nominated person in a timely manner.

Original documents may be provided on request by the inspector / auditor but may not be retained by the Inspector. All documents provided for review by the Inspector / auditor should be recorded and de-identified to protect patient confidentiality prior to provision. If permitted by audit plan or responsible person, the inspector may be given copies of these documents. These must be stamped as Confidential Copies. A second set of these copies will be retained in the CTSU inspection/audit file and recorded.

The taking of photographs, the use of tape recorders or other electronic equipment, reading and signing of affidavits (sworn statements) by institution personnel, the review of internal audit reports and allowing access to computer databases will not be permitted without legal review or written approval.

An exact duplicate of any approved records, recordings etc. must be retained and filed in the CTSU inspection/audit file.

6.4 Audit/Inspection Close-Out Activities

The close out meeting should be attended by the Principal Investigator, CTSU and representation from the SWSLHD Research and Ethics Office. The meeting is an opportunity to

clarify or discuss any findings during the inspection. Clarification of Inspectors / auditors post-inspection activities should be discussed and timelines for the reports and corrective and preventative action (CAPA) response need to be established.

Following the inspection those present during the inspection/ audit are expected to meet to de-brief, evaluate the inspection / audit and communicate actions to all relevant personnel.

6.5 Follow up action items

An inspection/ audit report will be received by the Sponsor and communicated with the PI and Institution. All actions must be addressed that are found to be findings in the report. Refer to SOP_CTSU_022 Managing Corrective and Preventative Actions (CAPAs).

Prior to any responses being sent to the Sponsor a review should be completed by the SWSLHD Research and Ethics Office and CTSU.

7.0 References

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

National Statement on Ethical Conduct in Human Research (2023)

Australian Code for the Responsible Conduct of Research (2018)

8.0 Amendment History

Version	Date	Amended by	Details of Amendment
2.0	23-Feb-2024	Erfan Jaberiyanfar	• 4.0 – Updated to include CTSU. • Grammatical changes. • Update of reference links.

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