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Site Close-out

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1.0 Introduction / Background

The International Council for Harmonisation (ICH) Good Clinical Practice (GCP) Guidelines outline processes and documentation that need to be in place prior to closing a clinical trial.

All clinical studies conducted within South Western Sydney Local Health District (SWSLHD) and the Ingham Institute must undergo a set process for study closure and archiving. This process directly follows Human Research Ethics Committee (HREC), Governance approval and TGA acknowledgement if a Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) requirements.
These processes are a mandatory requirement prior to archiving.

The Principal Investigator (PI) may delegate the performing of all clinical trial close out activities to a member of the clinical trial team. This delegation of duties must be formally documented in the Delegation of Responsibility Log (FM_007_Delegation of Responsibilities Log).

2.0 Objective

To describe the procedure for closing out a clinical trial is conducted at SWSLHD or the Ingham Institute.

3.0 Scope

This Standard Operating Procedure (SOP) applies to all staff involved in clinical trials at SWSLHD and the Ingham Institute.

4.0 Ownership and Responsibility

During close out procedures, the Principal Investigator in conjunction with the Sponsor are responsible for implementing close out activities which includes but not limited to reporting to the HREC and the Research Governance Office (RGO).

5.0 Associate Documents

SOP_CTSU_02 Investigator Responsibilities

6.0 Procedure

Close-out is defined as the act of ensuring that all clinical trial related activities are appropriately reconciled, recorded, and reported at the end of a trial in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s). The site close out process is designed to ensure that;

- The site has reconciled all data queries raised by the Sponsor
- The site has ensured all final payments as per the Clinical trials Research Agreement (CTRA) have been processed and received
- The site has all essential documents prepared for archiving
- The site has organised appropriate archiving arrangement either electronic or paper with the Sponsor and/or external provider

6.1 Site close-out

6.1.1 Preparing the site for study close-out visits:

- Once the last patient has completed all scheduled visits associated with the study and all data has been cleaned, arrange a mutually convenient date and time with the Sponsors representative Clinical Research Associate (CRA) to conduct the study close-out visit.
- Request the CRA for the visit agenda so key research personnel such as PI, Sub-Investigator (SI), Clinical Trials Coordinator (CTC), research nurse and other team members including supporting departments will be available or as appropriate.
- Ensure all regulatory documentation, and case report forms (CRFs) are complete and available for review and finalisation.
- Ensure all data queries received to date have been resolved.

- Inventory IPs supply and complete final accountability records. If previously instructed to return or destroy IP, ensure all required documentation is filed in the Investigator Site File (ISF) for CRA review.
- Arrange CRA meeting with the PI and/or SI and CTC to discuss any outstanding issues.
- PI and/delegate is required to discuss with the CRA regarding finalisation of all outstanding payments to the site, as per CTRA.

6.1.2 Managing the study close-out visit:

- Ensure all documentation (e.g. regulatory correspondence) is filed appropriately and ready for the CRA to review during the close-out visit.
- Discuss all open study-related issues and what steps will be taken to resolve them in order to satisfy the regulatory and Sponsors requirement(s).
- Review with the CRA the list of outstanding issues related to regulatory documents, source data verification, IP reconciliation, and any requirements for data retention and storage.
- Discuss any concerns regarding the possibility of a quality assurance audit and/or inspection by HREC or external regulatory bodies.
- If the study involved electronic data capture, determine when copies of all CRFs will be provided to the site as applicable.
- The PI is responsible for ensuring the appropriate follow-up, per the protocol, for any participant experiencing an ongoing unanticipated problem (e.g., serious adverse event) at study end and providing this information to the Sponsor, assuring all requirements have been met.
- Arrange meeting of the PI and Sponsor to discuss any future considerations (e.g., publication of study data or future studies).

6.1.3 Follow-up after the study close-out visit

- For any remaining IP(s), ensure the item(s) is returned to the Sponsor per their requirements.
- If the randomization code for any IP was broken for any reason, ensure complete documentation has been filed.
- Ensure return or destruction of all other study-related materials, such as unused lab kits and CRFs.
- Ensure any equipment on loan from the sponsor is returned or if mutually agreed by both the parties can be retained at the site.
- After all data queries have been resolved, check ISF/eISF, subject files and other study files for completeness.
- Arrange for transfer of study documents to secure storage for archiving.

- Submit the Final Closure Report to the HREC, in accordance with HREC SOP for Study Completion or Closure.
- Provide the Sponsor a copy of the HREC closure letter.
- Ensure the Closure letter has been provided to the site RGO for acknowledgement.
- The PI should maintain documents as specified in the ISF list and take measures to prevent accidental or premature destruction. Perform a reconciliation of the ISF/eISF to ensure all documents are filed prior to archiving. Refer to SOP_CTSU_09 Investigator Site File and Essential Documents for more information.
- Verify participant reimbursement or compensation are up to date, as outlined in the Informed Consent and CTRA.
- If the informed consent and CTRA, protocol or contract state subjects will be informed of their treatment arm, ascertain from the Sponsor how and when will this occur.

6.1.4 Premature Termination or Suspension of a Study

If the clinical trial is prematurely terminated or suspended for any reason, the Investigator/ Institution should:

- Immediately inform the HREC and RGO respectively regarding the premature termination of the study
- Promptly inform the clinical trial participants and include, where appropriate, the reason for suspension or early termination of the study.
- Assure appropriate therapy and follow-up for the participants.
- Inform the applicable regulatory authorities where required of the suspension or termination.
- Inform all supporting departments and service providers involved with site.
- If the PI terminates or suspends a clinical trial without prior agreement of the sponsor, the PI should promptly inform the Sponsor and the HREC regarding the suspension or termination and provide a detailed written explanation of the termination or suspension.
- In case the Sponsor terminates prematurely or suspends the clinical trial, then the Sponsor should notify the investigator(s) and Institution(s) in writing.

8.0 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)

9.0 Amendment History

Version	Date	Amended by	Details of Amendment
2.0	22-Feb-2024	Erfan Jaberiyanfar	• 1.0 – Updated CTN and CTA schemes • Updated list of associated documents. • 6.1.3 – Updates to include eISF • 6.1.4 – Update to indicate requirement for notification to supporting departments and service providers • Grammatical changes • Update of reference links

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