Ingham Institute
Applied Medical Research

NSW GOVERNMENT | Health
South Western Sydney
Local Health District

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Investigator Responsibilities

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1. Introduction/Background

ICH GCP states that the PI has overall responsibility for the conduct of a trial at a trial site and must supervise any individual or party to whom they have delegated trial-related duties and functions. These responsibilities are outlined in Section 4 of ICH GCP. To perform this role, the PI must be:

- Qualified by education, training, and experience to take responsibility for the trial at the site.
- Thoroughly familiar with the study protocol and the investigational product(s).
- Aware of, and compliant with GCP and any applicable regulatory requirements relating to clinical trial conduct.

The PI must maintain a list of appropriately qualified persons to whom the PI has delegated trial-related duties known as a Delegation of Responsibilities Log that is kept in the Investigator Site File (ISF). A copy should be provided to the sponsor on request. Delegation Logs should be actively maintained (not constructed retrospectively) so there is evidence of appropriate delegation before any clinical trial activities are undertaken.

2. Objective

To define Investigators' responsibilities and to provide instruction when performing clinical trials under applicable regulatory requirements. Applicable to all phases of clinical trials.

3. Scope

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

4. Ownership and Responsibility

The PI is responsible for the conduct of the clinical trial at the site. This includes the division and allocation of responsibilities and to clarify boundaries of responsibility within the study team, to ensure smooth running of the study under applicable regulatory requirements.

5. Associated Documents

SOP_CTSU_01 Risk assessment for clinical trials

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

SOP_CTSU_04 Clinical trial start-up

SOP_CTSU_05 Budgets and contracts

SOP_CTSU_08 Documentation of training and clinical trial handover

SOP_CTSU_09 Investigator Site File and essential documents

SOP_CTSU_10 Site initiation and activation

SOP_CTSU_11 Monitoring visits

SOP_CTSU_12 Close-out visits

SOP_CTSU_13 Recruiting clinical trial participants

SOP_CTSU_14 Informed consent

SOP_CTSU_15 Managing Investigational Product

SOP_CTSU_16 Managing Medical Devices

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

SOP_CTSU_18 Specimen collection and management

SOP_CTSU_20 Non-Compliance

SOP_CTSU_22 Corrective and preventative action Plans (CAPA)

SOP_CTSU_23 Sponsor audits and Regulatory inspections

FM_007_ Delegation of Responsibilities Log

SWSLHD_PD2018_016 Clinical Trials - Third Party Providers

6. Procedure

6.1 Feasibility

The PI is responsible for assessing whether:

- The clinical trial protocol is feasible and perform the risk assessment. Refer to SOP_CTSU_01 Risk assessments for clinical trials
- To provide feedback or work with the Clinical Trial Support Unit (CTSU) to provide feedback to the Sponsor.

6.2 Study Start Up

The PI's key responsibilities include:

- Ensuing that there are adequate resources to conduct the study which includes but is not limited to eligible participants, staff to conduct the clinical trial and resources and equipment required as per the protocol. For more information please refer to SOP_CTSU_04 Clinical trial start-up.
- Ensuring that there is adequate funding to conduct the protocol requirement activities for the length of the study according to SOP_CTSU_05 Budgets and Contracts.
- Follow Organisational policy when trial-related activities are contracted to external vendors or third-party providers. Refer to SWSLHD_PD2018_016 Clinical Trials - Third Party Providers.
- Have an understanding that the Clinical Trial Notification (CTN) Acknowledgement or Clinical Trial Approval (CTA) schemes form has been received from the Sponsor. The Sponsor is required to provide the forms as part of the initial submission to the RGO. Refer to SOP_CTSU_09 Investigator Site File and Essential Documents for further information.
- As per individual Sponsors requirement, the PI and Sub-investigator must declare any conflicts of interest, financial interests etc. from other parties.

6.3 Study Conduct

PI is responsible for the day-to-day conduct of research taking place. Their key responsibilities include:

- To ensure that clinical trials are carried out according to International Conference on Harmonisation, and Good Clinical Practice (ICH-GCP) and Australian Regulations. Any non-compliance needs to be reported to the CTSU according to SOP_CTSU_20 Non-Compliance.
- Ensuring that mandatory ICH-GCP training is current for all staff involved in Clinical Trials or research involving humans. TransCelerate accredited courses are recommended by the SWSLHD, and required no more than three years prior to the

commencement of a given trial, and every three years thereafter. ICH-GCP courses are available within SWSLHD on a regular basis, please contact the Clinical Trials Support Unit Manager SWSLHD-ClinicalTrialsSupportUnit@health.nsw.gov.au for further details.

- Has an understanding that when a clinical trial is sponsored by a pharmaceutical or collaborative group, that they are required to follow the study protocol and adhere to the Clinical Trial Research Agreement (CTRA) in order to comply with protocol and contractual obligations. The CTRA should be discussed and agreed upon between the Institution/Investigator and Sponsor during feasibility and start up phase, which occurs prior to the trial commencing at the site. Refer to SOP_CTSU_05 Budgets and Contracts for further information.
- Ensure that they, and their clinical trials team are appropriately qualified and adequately resourced to conduct the trial within their department. Please see SOP_CTSU_08 Documentation of Training and Clinical Trial Handover for further clarification.
- Must maintain a list of any delegated duties on the Delegation of Responsibilities Log with respect to the trial, and those persons to whom the duties are assigned.
- Supervise any individual or party delegated significant trial-related duties and functions.
- Ensure sufficient staff to provide adequate medical cover and appoint a deputy to provide back up when absent. Refer to SOP_CTSU_05 Budgets and Contracts for further information.
- A training log must also be completed and maintained ensuring all staff are adequately trained at site initiation, and thereafter for the duration of the clinical trial. Please see SOP_CTSU_08 Documentation of Training and Clinical Trial Handover for further clarification.
- Informing the participant's primary physician about their participation in the clinical trial, if the participant has a primary physician, and agrees to the primary physician being informed.
- Able to recruit a specific number of participants as agreed upon within the CTRA and provide time and resources to ensure that the conduct the study is in-line with ICH-GCP requirements. Please see SOP_CTSU_05 Budgets and Contracts for further clarification.
- Ensuring that invoice requirements are sent to the CTSU Financial Officer for invoicing. The Financial Officer provides monthly reports to the Director of Research/ Head of Department.
- Ensures medical care to clinical trial participants during routine visits or as a result of any adverse events is performed as per protocol and in reference to ICH_GCP guidelines. Refer to SOP_CTSU_17 Data Recording - source documents, record keeping, case report forms and archiving.

- Additionally, a report for any protocol deviation or serious adverse event that causes immediate harm to the participant requires review by the Sponsor within a 72 hour period of the Investigator or delegate being aware of the incident or as per CTRA if the timelines are specified. Please refer to NHMRC guideline, Safety monitoring and reporting in clinical trials involving therapeutic goods and reporting and SOP_CTSU_20 Non-Compliance for further safety reporting guidelines.
- Prior to commencing the clinical trial activities, must ensure that a favourable Human Research Ethics Committee (HREC) approval and Research Governance Office (RGO) authorisation is received. The process will involve the detailed review of the clinical trial protocol, participant information and consent documents, and any other information relating to the conduct and execution of the clinical trial and CTRA, Indemnity and insurance. Refer to SOP_CTSU_03 Communication with Human Research Ethics Committee, Research Governance Office, Clinical Trial Sponsor and Insurer for further details.
- Must ensure all updated trial related documents such as a protocol amendment, provided by the Sponsor are approved by the HREC and acknowledged by the RGO after initial approval has been provided.
- Must ensure that no deviation from the protocol occurs without HREC endorsement, unless it is required to prevent imminent harm to participants.
- Must ensure the site has the resources to provide adequate storage and accountability of the Investigational Product and Medical Devices in collaboration with the delegated Clinical Trials Pharmacist/ Device Manager. Refer to SOP_CTSU_15 Managing Investigational Product and SOP_CTSU_16 Managing Medical Devices for more details.
- Must ensure that subjects have been provided with the current version of the Participant Information Sheet and Consent Form (PIS/CF) and provided with information relating to all clinical trial procedures and associated risks. All information needs to be adequately explained and the participant allowed to have any questions answered prior to providing written consent. The provision of providing consent needs to be executed within a reasonable timeframe and that the principles and essential elements of Informed consent are complied with under the guidelines provided by ICH-GCP. Documentation of informed consent needs to be provided in the participant's medical record by the consenting Investigator or delegate. Refer to SOP_CTSU_14 Informed consent for more details.
- Must be thoroughly familiar with the appropriate use of the IP or medical device, as described in the protocol, in the current Investigator's Brochure, in the product information and in other information sources provided by the Sponsor.
- Is required to submit written summaries of the clinical trial status to the HREC and/or RGO annually, at completion of the study or more frequently, if requested by the HREC. Refer to SOP_CTSU_03 Communication with Human Research Ethics Committee, Research Governance Office, Clinical Trial Sponsor and Insurer.

- Should promptly inform the clinical trial participants if the clinical trial is prematurely terminated or suspended for any reason as well as the institution and should assure appropriate therapy and follow-up for the participants, and where required by the applicable regulatory requirement(s), inform the regulatory authority (ies).

6.4 Close out

PI is responsible for:

- Ensure close out activities are conducted according to SOP_CTSU_12 Close out.
- Ensure trial related documentation is securely archived for a period of 15 years, and in clinical trials involving a minor 25 years unless otherwise stated within the protocol. Record keeping for NSW Health is regulated by the State Records Authority of NSW. General Retention and Disposal Authority: GDA17 and General Retention and Disposal Authority – Public Health Services: Administrative Records GDA21, both contain a section on research management.

7. References

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

National Statement on Ethical Conduct in Human Research (2018)

Safety monitoring and reporting in clinical trials involving therapeutic goods (2016)

Australian Code for the Responsible Conduct of Research (2018)

State Records Act (1998)

General Retention and Disposal Authority: GDA17
General Retention and Disposal Authority – Public Health Services: Administrative Records GDA21

8. Amendment history

Version	Date	Details of amendment
3.0	16 October 2018	Retired this SOP with new SOP List and local review of all SOPs
1.0	01-Sep-2020	• Update of SOP references • Include reference to NHMRC guideline, Safety

			monitoring and reporting in clinical trials involving therapeutic goods • Update of reference links • Section 6.2, indicating CTN and CTA schemes.

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