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Communication with Human Research Ethics Committee, Trial Sponsor and Insurer

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1.0 Introduction/Background

International Council for Harmonisation (ICH) Good Clinical Practice (GCP) guidelines clearly outline the documentation required between the Sponsor, Principal Investigator (PI)/ Institution and Human Research Ethics Committee (HREC).

A sponsor may delegate responsibility to a Contract Research Organisation (CRO) for tasks in conducting the clinical trial. For the purposes of this SOP, the Sponsor could also refer to CRO.

The SWSLHD HREC and Research Governance Office (RGO) processes are available: https://www.swslhd.health.nsw.gov.au/ethics/default.html

There are a variety of forms of clinical trial insurance depending on the nature of the clinical trial. The NSW Health Policy Directive provides information on Clinical Trial Insurance and Indemnity and the RGO can provide support if the PI is unsure what the requirements are. For Industry-Sponsored clinical trials, the Sponsor must provide clinical trial insurance in accordance with the Medicines Australia Indemnity Form. For Collaborative Group and Investigator-Initiated Clinical Trials, a risk assessment will be completed to determine the clinical trial insurance requirements.

2.0 Objective

To describe the procedures related to communication with the HREC, RGO, Clinical Trial Sponsors and Insurers.

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 PI is responsible for communicating with the HREC, RGO and Sponsor as described in ICH GCP. The PI can delegate responsibilities to clinical trial team members. All personnel involved in clinical trials must operate according to the protocol and within the scope of their role, as per the delegation of responsibilities.
The Sponsor will provide instructions for communications with the Insurer. When SWSLHD is the Sponsor the Research Directorate will communicate with the Insurer.

5.0 Associated Documents

SOP_CTSU_20 Non-Compliance

SOP_CTSU_05 Budgets and Contracts

FM_001_Source data Location Form

FM_002_Contact Report

FM_003_Subject Identification Log

FM_005_Record Management Form

6.0 Procedure

6.1 Communication with HREC

The PI and delegates are required to:

- Understand the Institutional HREC requirements and processes to better liaise with sponsors to facilitate efficient processing. If SWSLHD HREC is the Lead HREC under the National Mutual Acceptance scheme, please submit the HREC application via REGIS: https://regis.health.nsw.gov.au/
- Obtain written and dated approval from the HREC for the trial protocol, Participant Information Sheet and Consent Form and any other written information required before commencement of the trial. This is normally in the form of an ethics approval letter which should state the version number and dates of documentation submitted.
- Be familiar with the procedure for submitting protocol amendments which may include changes to the Participant Information Sheet and Consent Form.
- Submit written summaries of the trial status to the HREC annually, or more frequently, if requested by the HREC.
- Report non-compliance as per SOP_CTSU_20 Non-Compliance.

6.2 Communication with the RGO

The PI and delegates are required to:

- Submit any Confidentiality Agreements, Clinical Trial Research Agreements and Indemnity Forms to the RGO for review and signature.

  NB: the Director of Research and the Chief Executive are the only signatories on these agreements.

- Complete the Site Specific Assessment (SSA) application via REGIS
- Submit any amendments to the SSA via REGIS

6.3 Communication with the Clinical Trial Sponsor

The PI or delegate must ensure significant communication is documented. FM_002_Contact Report can be used as required.

6.3.1 Pre-study Communication

The PI or delegate is responsible for

- Sending the signed Confidentiality Agreement to the Sponsor once reviewed and signed by SWSLHD or the Ingham Institute.
- Completing the feasibility information in conjunction with the Clinical Trial Support Unit (CTSU) and notifying the Sponsor of whether the clinical trial is feasible.
- Reviewing the protocol and submitting feedback to the Sponsor in writing and filing a copy in the Investigator Site File/electronic Investigator Site File (ISF or e-ISF).
- Prepare questions to clarify protocol procedures, subject eligibility criteria, and other clinical trial-related issues in writing and file the reply in the ISF or e_ISF.
- Accept or decline participation in the clinical trial

6.3.2 During the clinical trial

The PI or delegate will:

- Submit the updated screening and/or enrolment logs to the Sponsor by the preferred mode of communication.
- Notify the Sponsor about unanticipated issues, including Adverse Events (AEs) and Serious Adverse Events (SAEs), per the sponsor's definitions and timelines, as defined in the protocol or SOP.
- Communicate protocol deviations, as they occur, according to the sponsor requirements.
- Submit completed CRFs (paper-based or e-CRF) to the sponsor in accordance with the Clinical Trial Research Agreement (CTRA).
- Respond promptly to data queries as requested via fax, e-mail, and/or direct electronic data capture resolution, per the Sponsor's requirements and document the same in the specified ISF or e-ISF.
- Communicate significant regulatory changes as per the Sponsor's requirements (e.g., HREC acknowledgement of unanticipated issues or

protocol deviation, HREC approval of a revised consent document, etc.). Typically these documents are reviewed during monitoring visits however specific Sponsors may require prompt notification in specific circumstances.

- Submit Sponsor-generated protocol amendments to the HREC. Once approval is obtained, PI will train the clinical trial team regarding the changes before implementation and will be documented to inform the Sponsor.
- Notify the Sponsor within 72 hours of being aware of any Significant Safety Issue (SSI) as defined in the protocol.
- Provide written reports promptly to the Sponsor and where applicable, the Institution on any changes significantly affecting the conduct of the trial and/or increasing the risk to subjects. Refer to SOP_CTSU_20 Non-Compliance for further guidance.
- Be available during the study to meet with Sponsor delegates to discuss study progress, issues and safety in accordance with GCP.
- Retain all correspondence in the ISF or e-ISF

6.3.3 After the clinical trial is complete

The PI or delegate will:

- Communicate with the sponsor and confirm the close-out date.
- Provide the Sponsor with any HREC-required correspondence (e.g information required in the HREC study closure letter) related to the study close out.
- Ensure that all close-out activities are performed and all Sponsor requirements are met ensuring that all payments have been made.
- Determine with the Sponsor the process for dissemination of clinical trial results for the HREC and participants.
- File all the communication in the appropriate section of the ISF or e-ISF.

6.4 Communication with Insurer

6.4.1 Claims when there is a Medicines Australia Indemnity in place

- The Sponsor will be the main point of contact with the Insurer.
- The Claims pursuant should be made by the Subject to the Sponsor, preferably via the PI setting out details of the nature and background of the claim.
- The Subject will be asked to provide on request authority for the Sponsor to review any medical records relevant to the claim for the Sponsor to make an expedited assessment and communicate with the insurer.

6.4.2 Claims when there are Public Liability and Medical Indemnity Policies

The institution must report the following to the relevant insurer:

- Reports of Significant Safety Issues [or which relate to a claim made against the Hospital/ Institution (or member of its staff) and/or the occurrence of circumstances which may subsequently give rise to a claim against a Hospital/Institution], must be reported to the relevant insurer in accordance with the provisions of the Institutions' Public Liability and Medical Indemnity Policies.
- In addition to the requirements of the NHMRC National Statement, all Significant Safety Issues (SSI) that occur within the hospital or Institution which are possibly or likely to be related to any trial conducted by that hospital or Institution.
- It is usually sufficient to fax or email a copy of a Significant Safety Issue (SSI) report with a cover letter/email. Notification to the insurer should occur as promptly as possible upon becoming aware of the SSI.
- Note: Failure to give proper, prompt notification of any circumstance likely to give rise to a claim or the making of a claim may compromise insurance coverage for both the Hospital/Institution and/or a member of its staff.

7.0 References

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

PD2011_06_Clinical Trial Insurance and Indemnity

Medicines Australia Clinical Trial Compensation Guidelines (2010)

8.0 Amendment History

Version	Date	Details of amendment
1.0	1 July 2020	Due to operational changes and accreditation requirements, inclusive of changing the naming convention of GCP to SOP_CTSU
2.0	30 September 2022	Review of V1.0 to update any superseded links and processes

DOCUMENT END