SOP 05 Communication with HREC, RGO, Sponsor and Institution's

1.1 Purpose

To describe the procedures relating to communication with the Human Research Ethics Committees (HREC), Research Governance Officer (RGO), Sponsor and Insurer.

1.2 Scope

This Standard Operating Procedure (SOP) applies to all relevant employees including, but not limited to, visiting health professionals, contractors, consultants and volunteers who propose to undertake, administrate, review and/or govern human research involving patients/participants, facilities and or staff. All study personnel involved in the clinical study must operate within their scope of practice. This SOP takes into consideration the single ethical review processes.

1.3 Procedure

The procedure for communication with the HREC and RGO is illustrated in a tabular form in the *National Mutual Acceptance Single Ethical Review of Multi-centre Human Research Projects - Monitoring and Reporting Tables.*

5.1 Communication with Reviewing HREC

When communication regarding key decision points is verbal, the initiating party should follow up verbal communication with written correspondence/e-mail and send to the call recipient. The title of the letter/e-mail should include the term "FILE NOTE" followed by a text string which should include the decision topic. Such documentation must be filed in the Study Master File (SMF) and where applicable in the Satellite Site Study File (SSSF).

Prior to study commencement, the Investigator (CPI/PI/AI) must:

- Choose a reviewing HREC who's approval is acceptable to the Institution/s where the clinical study is being undertaken (or ensure the responsible HREC chosen by the CPI is likewise acceptable). Currently acceptable HRECs are documented in jurisdictional policy for public health organisations, and in local Institutional policy for private health organisations.
- Understand the reviewing HREC requirements, submission processes and be aware of their meeting and submission dates to better liaise with Sponsors.
- Be familiar with the relationships between HREC review and approval, governance authorisation and any other processes/approvals that need to be in place (e.g. does the

HREC have sub-committees), before any study start up activities can commence. This process and approval flow will be required by Sponsors, auditors and inspectors.

- Submit an ethics application as per the reviewing HREC submission process.
- Include in the relevant section of the ethics application that the trial may be undertaken using telehealth with Satellite Sites, if applicable, and that the informed consent process and/or some or all study assessments will be undertaken using telehealth, face to face consultation or a combination of both.
- Submit any other application as per that process found on the relevant website.
- Ensure all documentation and correspondence pertaining to the submission and approval processes is filed in the SMF e.g. correspondence to and from the HREC, RGO or other bodies.

During the study, the Investigator (CPI/PI/AI) must:

- Comply with all conditions and restrictions applied by the RGO or HREC on the conduct or continuation of the trial.
- Submit all documents/reports/summaries according to the requirements and timelines as stipulated on the respective reviewing HREC approval letter, including but not limited to: Sponsor reports of accumulated safety data outcome analyses; proposed changes to the Protocol; major or Serious Breaches; annual progress reports; and unforeseen events that might affect continued ethical acceptability of the trial.
- Comply with the reporting requirements outlined in SOP 12 Safety Data Monitoring and Reporting Requirements for Clinical Trials, noting that individual reports of Adverse Events, Serious Adverse Events, Suspected Unexpected Serious Adverse Reactions, Unanticipated Serious Adverse Device Events and six-monthly line listings should NOT be submitted to the reviewing HREC unless otherwise advised.
- Although all deviations must to be reported to the trial Sponsor, only the sub-set of deviations that have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial must be reported to the HREC. These deviations (also known as 'Serious Breaches') should also be reported by the Principal Investigator (PI) to their Institution, as they may impact on medico-legal risk, the responsible conduct of research, or adherence to contractual obligations.
- Immediately notify the reviewing HREC of any notification received from a participant in a trial that they intend to initiate a claim for compensation against either the Sponsor and/or the Institution.
- File all documentation in the SMF/SSSF.

At the end of the study, the Investigator (CPI/PI/AI) must:

- Submit a trial termination/closeout report according to the requirements and timelines as required by the respective reviewing HREC. This may be stipulated in the approval letter and/or on their website.
- File all documentation in the SMF/SSSF.

5.2 Communication with the Research Governance Office

For the purpose of this SOP, the Clinical Trial Research Agreement (CTRA), other site specific trial related documentation and the Site Specific Assessment (SSA) Form constitute a research

governance application for the Primary Site. Similarly, for the Satellite Site, a Site Specific Assessment/research governance application consists of the Sub-Contract, the SSA Form and other site specific, trial related documentation. This application may be submitted to the RGO in parallel to the HREC submission if all governance related documentation is available and completed correctly. In the majority of cases, the final document to be provided to the RGO is the HREC approval. This has the advantage of enabling an RGO review in parallel to the HREC review and allows a more timely RGO authorisation which may lead to expedited study start up. It is important to note, that HREC approval must be obtained and submitted to the RGO, prior to the final RGO authorisation being granted.

Prior to study commencement, the Investigator (CPI/PI/AI) must:

- Submit the Clinical Trial Research Agreement (CTRA), HREC approval, the SSA Form, evidence of any relevant GCP training, and any other required documentation to the RGO.
- Ensure all documentation and correspondence pertaining to the submission and approval processes is filed in the SMF.
- Ensure each Satellite Site in the cluster (whether in a different Hospital and Health Service (HHS) to the PI or the same HHS) completes a Clinical Trial Sub-Contract and a SSA Form, and submits to their RGO.
- Await site specific RGO authorisation before any study related activity can occur at that site.
- Ensure the Satellite Site files all documentation in the SSSF.

During the trial, the Investigator (CPI/PI/AI) must:

- Submit all governance related documents/reports/summaries to the relevant RGO according to the requirements and timelines as stipulated by the respective RGO including but not limited to:
  - changes to the CTRA/Sub-Contract;
  - changes to the budget;
  - any change that might affect continued financial acceptability of the trial;
  - any change that may increase Institutional risk.

- Serious Breaches (those deviations that may have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial) should be reported by the PI to their Institution, as they may impact on medico-legal risk, the responsible conduct of research, or adherence to contractual obligations.
- Immediately notify the RGO of any notification received from a participant in a trial that they intend to initiate a claim against either the Sponsor and/or the Institution.
- Ensure all training and accreditation remains current.
- Ensure the Satellite Site files all documentation in the SSSF.

At the end of the trial, the Investigator (CPI/PI/AI) must:

- Notify the RGO the trial has terminated/closed.
- File all documentation in the SMF/SSSF.Poor compliance with the Protocol or Good Clinical Practice (GCP) can lead to data being rejected by regulatory authorities, can compromise

participant safety and can nullify a trials insurance/indemnity. ICH GCP requires that the PI (or delegate) document and explain any deviation from the Protocol and requires that non-compliance with the Protocol, SOPs, GCP, and/or applicable regulatory requirement(s) lead to prompt action to secure compliance.

In the majority of instances, non-compliances are deviations that do not result in harm to trial participants or significantly affect the scientific value of the reported results of the trial. Some of these deviations are unavoidable (e.g. a participant misses a visit) or permitted (e.g. a deviation from the Protocol to protect a participant from an immediate hazard known as an Urgent Safety Measure). ICH GCP requires all non-compliances (both minor and major) to be reported to the trial Sponsor. The NHMRC Guideline: *Reporting of Serious Breaches of GCP or the Protocol for Trials Involving Therapeutic Goods*, categorises certain instances of noncompliance as a Serious Breach, defined as: A breach that is likely to affect to a significant degree: the safety or rights of the trial participant, and/or the reliability and robustness of the data generated in the clinical trial.

Deviations that may (depending on their nature) meet the definition of a Serious Breach include:

- Intentional or accidental loss of blinding of study medication.
- Failure to control Investigational Medicinal Product(s) such that participants are put at significant risk or the scientific value of the trial is compromised.
- Deviations from eligibility criteria related to the diagnosis of patients/participants.
- Non-compliance relating to evaluation of important efficacy endpoints.
- Missing Source Data which are extensive or which concern diagnosis, primary efficacy assessments, and important safety information.
- Persistent or systematic non-compliance with GCP or the Protocol that has a significant impact (e.g. systematic underreporting of serious adverse events leading to an inappropriate dose escalation in a phase I study).

Glossary

TERM	DESCRIPTION
ADE	Adverse Device Effect
ADR	Adverse Drug Reaction
AE	Adverse Event
AHPRA	Australian Health Practitioner Regulation Agency
AI	Associate Investigator
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
ARPANSA Code of Practice	ARPANSA Code of Practice for the Exposure of Humans to Ionizing Radiation for Research

CAPA	Corrective and Preventative Actions
CASA	Civil Aviation Safety Authority
CIOMS	Council for International Organizations of Medical Sciences
CPI	Coordinating Principal Investigator
CRA	Clinical Research Associate
CRC	Clinical Research Coordinator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Approval scheme (previously Clinical Trials Exemption (CTX) scheme)
CTN	Clinical Trial Notification scheme
CTPRG	Clinical Trials Project Reference Group
CTRA	Clinical Trial Research Agreement
CV	Curriculum Vitae
DSMB	Data and Safety Monitoring Board
EMR	Electronic Medical Record
GCP	Good Clinical Practice
HHS	Hospital and Health Service
HREC	Human Research Ethics Committee
IATA	International Air Transport Association
ICH	International Council for Harmonisation of Technical Requirements of Pharmaceuticals for Human Use
IP	Investigational Product
IMD	Investigational Medicinal Device
IMP	Investigational Medicinal Product
IVRS	Interactive Voice Response System
IWRS	Interactive Web Response System
National Statement	National Statement on Ethical Conduct in Human Research (NHMRC)
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
PI	Principal Investigator
PICF	Participant Information and Consent Form

PMS	Post Registration or Marketing Surveillance Study
RGO	Research Governance Officer
SADE	Serious Adverse Device Effect
SAE	Serious Adverse Event
SMF	Study Master File
SSA Form	Site Specific Assessment Form
SSI	Significant Safety Issue
SSSF	Satellite Site Study File
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
UR	Unit Record
USADE	Unanticipated Serious Adverse Device Event
USM	Urgent Safety Measure

○ Revision Chronology

Document History			
Version	**Effective Date**	**Summary of Changes**	**Author**
1.0	*13/11/2025*	Initial Version	Katie Ozdowska