Western Health

STANDARD OPERATING PROCEDURE

Communication with HREC, Trial Sponsor and Insurer

Standard Operating Procedure

Western Health

SOP reference	003
Version:	3.0 June 2019
Effective Date	June 2019
Next Review Date	June 2024
Approved by	Mr Bill Karanatsios, Research Program Director
Signature and date	

Amendment History

VERSION	DATE	AMENDMENT DETAILS
2.0	04 Dec 2015	
3.0	June 2019	Updated to align with MACH SOPs

1. AIM

To describe the procedures related to communication with the Human Research Ethics Committee (HREC), trial sponsor and insurer

2. SCOPE

Applicable to all clinical research projects undertaken at Western Health (WH), including Investigator initiated research, collaborative research and all phases of clinical investigation for medicinal products, medical devices and diagnostics for which WH is responsible for the conduct of the trials as a site study.

3. APPLICABILITY

Principal Investigator, Associate Investigator(s), delegate(s) and other staff delegated to research-related duties at, or under the auspices of WH, or which involves WH staff, resources, patients, their tissue samples, test results or medical records.

4. PROCEDURE

For investigator initiated trials where WH is also the sponsor, obligations owed to or emanating from sponsor should be interpreted to mean WH.

4.1. Communication with HREC

The investigator(s) should:

STEPS	ACTION
4.1.1	Understand the HREC requirements and processes to better liaise with Sponsors – e.g. on application process, documents, understanding legal requirements, understanding specific institutional site specifications on wording in consent forms etc.
4.1.2	Be aware of how often the HREC meets, what documents are required in an initial application and when documents need to be submitted (i.e. time period prior to an ethics committee meeting), what is the approval documentation required and how to issue safety alerts.
4.1.3	Ensure staff are familiar with this process (e.g. does the HREC have subcommittees) since this may be required to be described to sponsors, auditors, inspectors.
4.1.4	Ensure the institutional ethics committee is registered with the Australian Health Ethics Committee (AHEC) and is constituted in accordance with the National Statement (2007).
4.1.5	Obtain and file in Trial Master File (TMF) (See WH GCP SOP 002) written and dated approval/favourable opinion from the HREC for the trial protocol, written informed consent form, consent form updates, participant recruitment procedures (e.g. advertisements), and any other written information to be provided to participants prior to the commencement of the trial. This is normally in the form of an ethics approval letter which must state the version number and dates of documentation approved for use. **ICH GCP 8.2.7**
4.1.6	As part of the institution's written application to the HREC, provide the HREC with a current copy of the Investigator's Brochure (IB), and if updated during the

	trial, the investigator/sponsor should supply a copy to the HREC when available.
4.1.7	Be familiar with the procedure for submitting protocol amendments and changes to the informed consent form and understand the time periods associated to obtain approval following submission of amendments.
4.1.8	Provide to the HREC all documents subject to review during the trial, including any Significant Safety Issues (SSI), Suspected Unexpected Serious Adverse Reaction (SUSAR) or Unanticipated Serious Adverse Device Effect (USADE), proposed changes in the protocol and unforeseen events that might affect continued ethical acceptability of the project**. ICH GCP 3.1.2**
4.1.9	Submit written summaries of the trial status to the HREC annually, or more frequently, if requested by the HREC. The Investigator should understand the reporting requirements for the reviewing ethics committee, including protocol deviations and safety reporting. **ICH GCP 8.3.19**
4.1.10	In addition, the Investigator must report to the HREC any drug/device SAE, SSI, SUSAR, USADE effect that is experienced during the project by any participant within 24 hours of him or her becoming aware of same.

4.2. Communication with the Trial Sponsor

The investigator(s) should:

STEP	ACTION
4.2.1	Notify the sponsor within 24 hours of the Investigator becoming aware of any SAE, SSI, SUSAR, USADE involving trial participants **ICH GCP 4.11; 8.3.16**
4.2.2	Provide written reports promptly to the sponsor, the HREC and, where applicable, the institution on any changes significantly affecting the conduct of the trial, and/or increasing the risk to participants. **ICH GCP 5.16.2; 5.17; 4.11.1**
4.2.3	Notify the sponsor or their delegate within 24 hours of any significant deviation from the protocol (this is individually defined by the sponsor) **ICH GCP 4.5; 8.3.11**
4.2.4	Notify the sponsor promptly of any adverse effect that may reasonably be regarded as caused by, or probably caused by, the investigational product.
4.2.5	Be available during the study to meet with sponsor delegates to discuss study progress, issues and safety.
4.2.6	Provide the Sponsor with copies of all correspondence from the reviewing HREC **ICH GCP 5.11. ICH GCP Section 8**
4.2.7	As soon as practicable, notify the site Governance Officer or equivalent of any notification received from a research participant that they intend to initiate a claim against either the Sponsor and/or the Institution. In addition, the Trial Sponsor, Insurer and the reviewing HREC must also be notified as soon as possible.

4.3. Communication with the Insurer

Obligation of the Institution:

The institution must report the following to the Victorian Managed Insurance Authority (VMIA) (usually through the ethics office or nominated site personnel):

STEP	ACTION
4.3.1	Reports of SAE/SSI/SUSAR/USADE, [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 VMIA in accordance with the provisions of the VMIA Public Liability and Medical Indemnity Policies. VMIA recommends the use of the Safety Report Form**.**
4.3.2	In addition to the requirements of the NHMRC National Statement, all SAE/SSI/SUSAR/USADE that occur within the hospital or institution, that are possibly or likely to be related to any trial conducted by that hospital or institution.
4.3.3	It is usually sufficient to fax or email a copy of the Safety Report with a cover letter/email. Notification to the VMIA should occur as promptly as possible upon becoming aware of the safety event to miclaims@vmia.vic.gov.au

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.

5. GLOSSARY

Associate Investigator

Any individual member of the clinical trial team designated and supervised by the investigator at a study site to perform critical study-related procedures and/or to make important study-related decisions (e.g., associates, residents, research fellows). Also referred to as “Sub-Investigator”

Delegate

A person delegated specific but appropriate tasks in relation to the conduct of a clinical trial. Delegation must be evidenced in writing.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Human Research Ethics Committee (HREC)

A body which reviews research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

The National Statement requires that all research proposals involving human participants be reviewed and approved by an HREC and sets out the requirements for the composition of an HREC.

International Conference on Harmonisation (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Insurer

The entity that underwrites an insurance risk; the party in an insurance contract undertaking to pay compensation

Investigator Brochure (IB)

The document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product that are relevant to the study of the product in humans.

Investigator initiated trial

A clinical trial that is undertaken by the investigator whereby the investigator and/or their institution takes on the role of the sponsor in addition to their role as investigator.

Principal Investigator (PI)

An individual responsible for the conduct of a clinical trial at a trial site and ensures that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Research Governance Office (RGO)

Site/institutional office that are accountable for the research activities conducted at their site to ensure that research is conducted according to established ethical principles, guidelines for responsible research conduct, relevant legislation and regulations and institutional policy.

Serious Adverse Event (SAE) – drug

Any untoward medical occurrence that, at any dose:

a) results in death;

b) is life-threatening; *NOTE: The term 'life-threatening' in the definition of 'serious' refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event, which hypothetically might have caused death if it were more severe.*

c) requires in-patient hospitalisation or prolongation of existing hospitalisation;

d) results in persistent or significant disability/incapacity; or is a congenital anomaly/birth defect; and fits the SAE criteria as specified in the relevant clinical trial protocol.

Medical or scientific judgment should be exercised in deciding whether reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the participant or may require medical or surgical intervention to prevent one of the other outcomes listed in the above definition. These should also usually be considered serious. Examples of such events are intensive treatment in an emergency room or at home for allergic bronchospasm; blood dyscrasias or convulsions that do not result in hospitalisation; or development of drug dependency or drug abuse.

Serious Adverse Event (SAE) – device

Serious Adverse Event for *medical devices*: any adverse medical occurrence that:

a) lead to a death;

b) lead to a serious deterioration in health of a patient user or other. This would include:

- a life threatening illness or injury
- a permanent impairment of body function or permanent damage to a body structure
- a condition requiring hospitalisation or increased length of existing hospitalisation
- a condition requiring unnecessary medical or surgical intervention e) foetal distress, foetal death or a congenital abnormality/birth defect

c) might have led to a death or a serious deterioration in health had suitable action or intervention not taken place.

This includes:

- a malfunction of a device such that it has to be modified or temporarily/permanently taken out of service
- a factor (a deterioration in characteristics or performance) found on examination of the device.

Significant Safety Issue (SSI)

A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

Sponsor

An individual, company, institution or organisation which takes responsibility for the initiation, management, and/or financing of a clinical trial.

Suspected Unexpected Serious Adverse Reactions (SUSAR)

A SAE for which there is a degree of probability that the event is an adverse reaction to the administered drug, and the adverse reaction is unexpected.

Trial Master File (TMF)

A file that contains all the applicable essential documents that demonstrate that the study/trial has been conducted in accordance with regulatory requirements and ICH GCP, enabling both the conduct of a project and the quality of the data produced to be evaluated. The preparation and maintenance of the Study File resides with the Site Investigator and set up at the start of a trial and is archived at the end of the trial. This may also be called the “Study Site Master File” or “Investigator Site File”.

Unanticipated Serious Adverse Device Effects (USADE)

A SAE for which there is a degree of probability that the event is an adverse effect attributed to the device, and the adverse effect is unanticipated.

Victorian Managed Insurance Authority (VMIA)

Victorian statutory authority for the provision of insurance and risk advice and cover for Vic State entities.

6. REFERENCES

1. Based on VMIA GCP SOP No.003 Version 1.0 Dated 17 September 2007
2. Based on MACH GCP SOP No.003 Version 1.0
3. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000.
4. NHMRC Safety monitoring and reporting in clinical trials involving therapeutic goods (2016)
5. National Statement on Ethical Conduct in Human Research (2007)
6. VMIA Clinical Trials Risk and Insurance Guide December 2018

7. AUTHORS/CONTRIBUTORS

Bill Karanatsios, Research Program Director, Western Health

Virginia Ma, Research Governance Officer, Western Health

Kerrie Russell, Ethics Administration Officer, Western Health

Noelle Gubatanga, Research Ethics and Governance Administration Officer, Western Health

Meera Senthuren, Ethics and Governance Administration Officer, Western Health

8. PRIMARY PERSON/DEPARTMENT RESPONSBLE FOR DOCUMENT

Western Health Office for Research