MELBOURNE HEALTH	OFFICE FOR RESEARCH		
	STANDARD OPERATING PROCEDURE: SOP003		
	Communication with HREC, Trial Sponsor and Insurer		
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1. AIM

To describe the procedures related to communication with the HREC, trial sponsor and insurer.

2. SCOPE

Applicable to all clinical research projects undertaken at Melbourne Health, including investigator initiated research, collaborative research and all phases of clinical investigation of medicinal products, devices and diagnostics.

3. APPLICABILITY

Principal Investigator/Investigator, Sub-Investigator(s) and delegate(s) and other staff involved in research-related duties at, or under the auspices of Melbourne Health, or which involves Melbourne Health staff, resources, patients, their tissue samples, test results or medical records.

4. PROCEDURE

4.1 Communication with HREC (all HREC approved research projects)

The investigator(s) should:

- Understand the HREC requirements and processes of review for HREC applications. For sponsored studies, communicate the information to the sponsors – e.g. application process, documents, understanding legal requirements, understanding specific institutional site specifications on wording in consent forms etc.

- Be aware of how often the HREC meets, what documents are required in an initial application and when (time period prior to an ethics committee meeting), what is the approval documentation and how to issue safety alerts.

- Ensuring they are familiar with this process (e.g. does the HREC have subcommittees) (for sponsored projects this may be required to be described to sponsors, auditors, inspectors).

- Ensure the HREC is registered with NHMRC and is constituted in accordance with the National Statement.

- Obtain written and dated approval from the HREC for the research/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 research/trial. This is normally in the form of an ethics approval letter which should state the version number and dates of documentation submitted.

- As part of the written application to the HREC, provide the HREC with a current copy of the Investigator's Brochure and if updated during the trial, the investigator/institution should supply a copy of the updated IB to the HREC.

- 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.

- Provide to the HREC all documents participant to review during the research/trial, including any serious or unexpected adverse events, proposed changes in the protocol and unforseen events that might affect continued ethical acceptability of the project.

- Submit written summaries of the research/trial status to the HREC annually, or more frequently, if requested by the HREC. They should understand the reporting requirements for their ethics committee including protocol deviations and safety reporting.

- In addition, the Investigator must report to the HREC any serious, adverse drug/device effect that is experienced during the research/trial by any participant in accordance with MH guidelines Guidelines for Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products and Other Clinical Research.

4.2 Communication with the Trial Sponsor

The investigator(s) should:

- Notify the sponsor within 24 hours of any serious or unexpected adverse events involving trial participants.

- 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.

- Notify the sponsor within 24 hours of any significant deviation from the protocol (this is individually defined by the sponsor).

- Notify the sponsor promptly of any adverse effect that may reasonably be regarded as caused by, or probably caused by, the investigational product.

- Be available during the study to meet with sponsor delegates to discuss study progress, issues and safety.

The Research Governance Officer should:

- Communicate with a research sponsor when the relevant investigator is unable to reach a resolution with the sponsor regarding legal documents or other governance matters associated with a trial (e.g. Clinical Trial Research Agreement, Insurance, Indemnity, etc.).

4.3 Communication with the Insurer

The investigator(s) should:

- Familiarise themselves with and comply in full with MH insurance policies to ensure that MH meets its insurance obligations
- Communicate with any issues that may affect the institutions insurance obligations to a research governance officer.
- Refer to the MH legal services webpage for further information.

Obligation of the Institution:

- Comply in full with its insurance requirements.
- Report serious adverse events, [or events 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.

5. GLOSSARY

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.

Investigator

An individual responsible for the conduct of a research projects including clinical trials at a research/trial site and ensures that it complies with GCP guidelines. If a research/trial is conducted by a team of individuals at a research/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.

Serious Adverse Device Event (SADE)

A device-related serious adverse event. (See Serious Adverse Event (SAE) – device).

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

e. 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.

Sub Investigator

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

6. REFERENCES

1. MH Research Policy MH18
2. Note for guidance on Good Clinical Practice (CPMP/ICH/135/96) annotated with TGA comments DSEB, July 2000.
3. Victorian Managed Insurance Authority Guidelines for Clinical Trials for Victorian Public Hospitals (CTN guidelines), 2006.

7. APPENDICES

Appendix 1: SOP Change Log

DOCUMENT END

APPENDIX 1 : SOP CHANGE LOG

Version No.	*Reason for Issue*
1	First issue
2	26/9/2013 Further specifies when PI must report SAE to HREC / add insurance certificate review by VMIA to section 4.3
3	5/9/2017 Review and minor edits. • Updated scope to include clinical research projects including investigator initiated research, collaborative research • Updated Applicability to include "and other staff involved in research-related duties at, or under the auspices of Melbourne Health, or which involves Melbourne Health staff, resources, patients, their tissue samples, test results or medical records". • 4.1 dot point 1 – minor edits for clarity. • 4.1 dot point 4 - added full name of AHEC. • 4.1 dot point 6 – deleted 5th word (institution's), "the updated IB". • 4.1 dot point 10 – replaced "for within 24 hours of him or her becoming aware of same." With "in accordance with MH guidelines Guidelines for Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products and Other Clinical Research". • 4.2 add section for contact by The Research Governance Officer to sponsor • 4.3 – replace entire section with updated wording