Policy Directive

Ethics and Research Governance: Monitoring Human Research

Document Number: SWSLHD_PD2017_031
Functional Sub-Group: Research and Ethics Office
Summary: This policy outlines a consolidated framework for monitoring human research projects that are ethically approved by the South Western Sydney Local Health District (SWSLHD) Human Research Ethics Committee (HREC). The policy details responsibilities for the various parties who are involved in monitoring research projects and the procedures to be followed.

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Compliance with this policy directive is mandatory.
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Revision History

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<tr>
<td>October 2017</td>
<td>Policy amended to reflect the current NHMRC and NSW Health policies and guidelines in monitoring human research.</td>
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1. Introduction

This policy provides a consolidated framework for monitoring human research projects that are ethically approved by the South Western Sydney Local Health District (SWSLHD) Human Research Ethics Committee (HREC).

1.1. The risk addressed by this policy:

- Risk of unethical practice during human research trials conducted within and or by staff members of SWSLHD
- Inadequate risk assessment and monitoring of Human Research projects.

2. The Aims / Expected Outcome of this policy:

- Monitoring of human research will be commensurate with the risk, size and complexity of the study.
- Individuals conducting human research comply with the NHMRC National Statement on Ethical Conduct in Human Research and NSW Ministry of Health policies and associated procedures.

3. Policy Statement

This policy outlines responsibilities for the various parties who are involved in monitoring research projects and the procedures to be followed. Reference is made to relevant local Standard Operating Procedures and national guidelines/statutory documents where appropriate.

4. Principles

4.1. Overriding principles

SWSLHD has ultimate responsibility for ensuring, via its research governance arrangements, that all its approved research is monitored. The types of monitoring that SWSLHD employs:

- Reports from researchers of unforeseen events that may affect the continuing acceptability of the project
- Reports from researchers, at least on an annual basis and at the completion of the project
- Reports from sponsors and independent agencies (such as Data and Safety Monitoring Boards).
- Review of adverse event reports.
- Random inspections of research sites, data and consent documentation (discretionary).
Monitoring arrangements will be commensurate with the risk, size and complexity of the study. The degree of risk of each project, as agreed by the HREC, is minuted at the relevant HREC meeting.

For each project:

- There are mechanisms for reporting and reviewing
- Urgent safety related events at any site for which the SWSLHD is responsible are reported and acted upon.
- Serious adverse events (SAEs) and suspected unexpected serious adverse reactions (SUSARs) from any site for which the SWSLHD is responsible are reported and acted upon as appropriate.
- Where the project is a large multi-centre trial, a Data and Safety Monitoring Board (DSMB) is used and there is a mechanism for informing the HREC of any relevant emerging data from the DSMB.
- Where the project is a local trial, there is an identified person/s or committee (initially HREC Executive Committee) with suitable expertise to assist and advise the HREC about reports of serious adverse events.

4.2. Responsibilities

4.2.1. Coordinating/Principal Researcher

Researchers have a significant responsibility in monitoring, as they are in the best position to observe any adverse events or unexpected outcomes. They should report such events or outcomes promptly to the relevant institution/s and ethical review body/ies, and take prompt steps to deal with any unexpected risks. The granting and continuation of ethical approval of clinical research is on the condition that, for any trial site under the HREC’s responsibility, researchers are responsible for the following:

- Notify the reviewing HREC that mechanisms for monitoring are in place, and for satisfying the review body that the mechanisms are appropriate to the research.
- Conduct the research in compliance with the approved protocol.
- Provide reports of the progress of the study to the HREC, at a frequency directed by the HREC in the initial approval notification (but at least annually), and related to the degree of risk to participants.
- Inform the HREC, and seek approval, of amendments to the protocol including amendments that: are proposed or undertaken in order to eliminate immediate risks to participants; may increase the risks to participants; or significantly affect the conduct of the trial.
- Notify the relevant HREC of any serious adverse events at any study sites according to the HREC procedures.
- Inform the HREC as soon as possible of any new safety information from other published or unpublished studies that may have an impact on the continued ethical acceptability of the study or may indicate the need for amendments to the study protocol.
- Inform the HREC, giving reasons, if the study is discontinued before the expected date of completion.
- For studies with implantable medical devices, confirms the existence of, or establishes, a system for: tracking the participant, with consent, for the lifetime of the
device; and reporting any device incidents to the Therapeutic Goods Administration (TGA).

- Report serious adverse events or reactions to trial sponsors to meet the requirements of regulatory agencies, such as the TGA.
- Meet the monitoring responsibilities of the Principal Researcher or research team under any Research Agreement.
- Ensure that SWSLHD, as an institution, meets its monitoring responsibilities under any Research Agreement.

### 4.2.2. Sponsor

Where a Sponsor is designated to a study (Clinical Trial), the sponsor is responsible for:

- Monitoring responsibilities as detailed in the following documents:
  - Note for Guidance on Good Clinical Practice (CPMP/ICH/135/99)
  - Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95)

- The ongoing safety evaluation of the investigational product/s
- Reporting serious adverse events or serious unexpected suspected adverse reactions to: regulatory agencies (such as, Therapeutic Goods Administration) to meet the conditions of approval to conduct a trial: and investigators to enable them to fulfil the conditions of ethical approval by an HREC.

### 4.2.3. Human Research Ethics Committee (HREC)

The responsibility of the Human Research Ethics Committee (HREC), and of the SWSLHD it advises, is to protect the safety of participants in clinical trials. In order to discharge this responsibility, the HREC needs to receive sufficient reliable information about the study to progress and implications of adverse events or reactions.

The types of monitoring that SWSLHD employs are:

- Reports from researchers of unforeseen events that may affect the continuing acceptability of the study.
- Reports from researchers, at least on an annual basis and at the completion of the study.
- Reports from sponsors and independent agencies (such as Data and Safety Monitoring Boards)
- Review of adverse event reports.
- Random inspections (with two weeks’ notice) of research sites, data and consent documentation (discretionary). Such inspections will consist of meeting with the Coordinating/Principal Investigator at his/her office or other venue where the research is being conducted, and will cover any/all of the following:
  - Compliance with the approved ethics protocol,
  - Inspecting consent forms and other documentation forwarded to participants,
  - Being guided through any physical experiments,
  - Appropriate record keeping,
Storage of electronic and hard copy data,
Provision of contact details of sample of participants.

The HREC will note items related to monitoring on the agenda (in the form of minutes of HREC Executive Meetings or new items for review by the full HREC as agreed by the HREC Executive). HREC members can request additional information or investigation, such as:

- **Clinical Pharmacology Expert**: An individual who has expertise related to clinical pharmacology should be a member of, or available as an expert reviewer to, HREC. This person should be referred to for review of studies involving drugs and the adverse event (AE) reports associated with these studies when the HREC agrees its members do not have the relevant expertise. At a minimum, such an expert will always review Phase I clinical trials.

- **Device expert**: An individual who has expertise related to experimental devices should be a member of, or available as an expert reviewer to, HREC. This member should review studies involving investigational devices and should review the adverse event reports associated with these studies. The device expert would be responsible for reviewing reports to confirm that the report is a reasonable account of the event and verifying that the causality specified by the investigator is accurate.

- **Other relevant experts as required**: Individuals whose expertise is relevant to assist the HREC in its deliberations relating to review of research proposals. Such expertise may relate to the scientific, ethical or other matters before the HREC.

### 4.2.4. Research and Ethics Office

- The Research and Ethics Office (REO) has a prime responsibility to facilitate communication between all parties in a timely and professional manner.
- The REO is to provide advice and assistance to the Coordinating/Principal Researcher and the Human Research Ethics Committees as required. The REO staff will review annual reports, adverse event reports and Institutional audit reports (when/if undertaken) and will report any issues of significance to the Chair or relevant HREC member and/or place the item on the relevant HREC/HREC Executive agenda. All minutes of HREC Executive meetings will be tabled at HREC meetings and members will be able to request further information if necessary.
- The REO will advise Coordinating/Principal investigators in writing of the outcome of review of monitoring documents submitted in accordance with this policy. In some circumstances it may be necessary to also advise the Research Governance Officer(s) and/or Chief Executives of other sites where the research is being undertaken, of such outcomes.
5. Annual Progress Reporting

- A condition of approval for studies approved by the SWSLHD HREC is that a report of project progress is submitted annually. The letter of approval will identify if more frequent progress reports are required.

- Annual reports will include information on:
  - Progress to date, or outcome in the case of completed research.
  - Maintenance and security of records.
  - Compliance with approved protocol.
  - Compliance with conditions of approval.
  - If a researcher fails to complete and return an annual report, approval for the study may be suspended by the HREC.
  - A final report is also due on completion of the study or if the research is discontinued before the expected date of completion. Completion of the study means:
    - For commercially sponsored clinical trials, the study is considered complete once the closeout visit has been completed.
    - For Investigator Initiated clinical trials, the study is considered complete once the last patient has completed follow up and the data has been analysed.
    - For other research projects, the study is considered complete once data collection is complete and there is no further contact with patients or access to medical records or other sources of personal or health information.
  - The Annual or Final Report will be reviewed and acknowledged by the Manager, Ethics and Research Governance Office. Where concerns are raised, the matter will be referred to the HREC Executive Committee for review.

6. Non-compliance

In the event that the HREC determines that a project is not being conducted or cannot be conducted in accordance with the approved protocol, the HREC will action in accordance with the National Statement and local jurisdictional policies and SOPs.

7. Performance Measures

- Review of adverse event reports and annual reports
- Random inspections of research sites, data and consent documentation (discretionary)
- Reports from sponsors and independent agencies (e.g. Data and Safety Monitoring Boards)
8. References and Links

### Related Policy Directives / Guidelines

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<th>Code</th>
<th>Description</th>
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<tr>
<td>MoH GL2010_014</td>
<td>Operations Manual: Human Research Ethics Committee Executive Officers</td>
<td>Link</td>
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<tr>
<td>MoH GL2010_015</td>
<td>Operations Manual: Research Governance Officers</td>
<td>Link</td>
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<tr>
<td>SWSLHD_PD2015_002</td>
<td>South Western Sydney Local Health District Research Code of Conduct</td>
<td>Link</td>
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### Articles / Research / Resources

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<tr>
<td>National Statement on Ethical Conduct in Human Research, 2007.</td>
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<tr>
<td>Australian Code for the Responsible Conduct of Research, 2007.</td>
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<tr>
<td>Australian Health Ethics Committee Position Statement: Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products, May 2009.</td>
<td>Link</td>
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<tr>
<td>Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, 2003.</td>
<td>Link</td>
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<tr>
<td>Keeping Research on Track – a Guide for Aboriginal and Torres Strait Islander Peoples about Health Research Ethics, 2006.</td>
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<td>Therapeutic Goods Act 1989.</td>
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<td>Australian Clinical Trial Handbook, 2006.</td>
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<td>Note for guidance on good clinical practice (CMP/ ICH/135/95) (with TGA notes).</td>
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<td>Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines Regulated by Drug Safety and Evaluation Branch 2005.</td>
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<td>Access to Unapproved Therapeutic Goods – clinical trials in Australia.</td>
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