**Alfred Hospital Ethics Committee**

**SAFETY MONITORING AND REPORTING REQUIREMENTS**

**It is the responsibility of Principal Investigators to review all adverse events coming to their notice and assess whether these contain information that should be drawn to the attention of the Ethics Committee**

The NHMRC Australian Health Ethics Committee (AHEC) Position Statement on Monitoring and Reporting of Safety for Clinical Trials Involving Therapeutic Products (May 2009) has been widely adopted by Australian hospitals. The Alfred Hospital Ethics Committee adopts the requirements set out in the Position Statement (PS) with the following refinements:

1. **Adverse Events (AEs)**

**Serious Adverse Events (SAEs)**

**Serious Unexpected Suspected Adverse Reactions (SUSARs)**

**Unanticipated Serious Adverse Device Effects (USADEs)**

Serious adverse events (including SUSARs and USADEs) that have a material impact on the continued ethical acceptability of the research or which require an amendment **and occur in sites for which the Ethics Committee is responsible** must be reported to the Alfred Ethics & Research Governance Office within 72 hours of knowledge of the event. All reports should be submitted on an appropriate adverse event form and must include sufficient information and context.

The Adverse Event Flowchart depicts the reporting requirements.

2. **Reports from Safety Monitors**

Researchers are required to request reports from data and safety monitoring boards or other safety monitors for studies approved by the Alfred Hospital Ethics Committee. The timing of these reports should be in accordance with any monitoring and reporting arrangements requested/approved by the Alfred Hospital Ethics Committee for that project. The reports should be forwarded promptly to the Alfred Health Ethics and Research Governance Office.

3. **Updated Investigator Brochures (IBs)**

Updated IBs (if not part of an amendment) should be forwarded to the Alfred Health Ethics and Research Governance Office on receipt from the sponsor, with the following core documents:

1. Full revised IB and a summary of changes (if not included in the revised IB)
2. An Impact Statement signed by the Principal Investigator (advising whether, or not, the changes may have an impact on study participants).

4. **Development Safety Update Reports (DSURs)**

DSURs should be forwarded to the Alfred Health Ethics and Research Governance Office on receipt from the sponsor. The reports should be accompanied by a statement from the Principal Investigator advising whether, or not, there may be any impact on study participants.

5. **Listings**

The Alfred Hospital Ethics Committee does not wish to receive any listings (such as quarterly or other line listings) from sponsors *unless* the listing has been assessed by the Principal Investigator as containing significant safety information that should be drawn to the attention of the Ethics Committee. In this instance, the listing should be sent to the Alfred Health Ethics And Research Governance Office and accompanied by a comment from the Principal Investigator on the significance of the information, the possible impact on study participants and action taken or recommended.

6. **Adherence to approved procedures**

Researchers must ensure that the action they take to manage, monitor and report adverse or unforeseen events accords with the procedures detailed in the approved ethics submission for that project.

For example, as set out in the following application templates:

* National Ethics Application Form (NEAF) Online Forms

Section 5 Q17 and Q18;

* National Ethics Application Form (NEAF) National

Section 5.4 5.4.1 and 5.4.2;

* Common Application Form (CAF)

Module One, 1.16, Module Two, 2.11).

7. **Notification to Sponsors**

Researchers are to notify their study sponsors of these reporting arrangements.

**Professor John McNeil**

**Chair, Alfred Hospital Ethics Committee**

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