

# AlfredHealth

## 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. **Local AEs/SAEs/SUSARs**

[Re: PS 2.1] Serious adverse events (including SUSARs) or other significant events concerning patient safety **that occur in sites for which the Ethics Committee is responsible** must be reported to the Ethics Office within 72 hours of knowledge of the event. All reports should be submitted on the [adverse event form](#) and must include sufficient information and context. Reports must be accompanied by a comment from the principal investigator on the significance of the event, the possible impact on study participants and action taken or recommended.

2. **Reports from Safety Monitors**

[Re: PS 2.4] Researchers are required to request reports and forward them promptly 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 Ethics Committee for that project.

**3. Updated Investigator Brochures**

[Re: PS 2.4] Updated Investigator Brochures should be forwarded to the Ethics Unit on receipt from the sponsor, with the following core documents: Full revised IB, a summary of changes (if not included in the revised IB), and an Impact Statement signed by the Principal Investigator advising whether, or not, the changes may have an impact on Alfred Health participants.

**4. Listings**

[Re: PS 2.3]The 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 *and* is 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.

**5. 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 Common Application Form (CAF), Module One, 1.16, Module Two, 2.11; or National Ethics Application Form (NEAF) 5.4.1, 5.4.2)

**6. Notification to Sponsors**

Researchers are to notify their study sponsors of these arrangements.

The [Adverse Event Flowchart](#) depicts the reporting requirements.

**Professor John McNeil**  
**Chair, Ethics Committee**  
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