

Alfred Hospital Ethics Committee Update

February 2008

Adverse Event Reporting

The reporting of serious adverse events is undergoing change because of the large amount of uninterpretable information being sent to the Ethics Committee for review.

Guidelines for reporting have been circulated by the NHMRC Australian Health Ethics Committee (HREC Alert No. 1, 18 April 2007) and have been implemented across a number of Australian hospitals. The Alfred Ethics Committee, however, has decided to further refine the reporting requirements and is currently developing a policy.

Until the policy is released, the following interim arrangements will satisfy the Committee and researchers are to notify these to the sponsors of their studies.

Interim Arrangements for Adverse Event Reporting

1. The Alfred Human Research Ethics Committee does not wish to receive any listings (such as quarterly or other line listings) or batched CIOMS reports from sponsors.
2. Researchers are required, however, to report details of any events that impact on the research and require action/changes, whether local, national or international.
3. Serious adverse events 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. All reports must include sufficient information and context. Reports must be accompanied by a comment from the principal researcher on the significance of the event, the possible impact on study participants and action taken or recommended.
4. Researchers are required to forward reports promptly from data safety monitoring boards or other safety monitors for studies approved by Alfred Ethics Committee.
5. Researchers are to notify their study sponsors of these interim arrangements.
6. A more extensive policy on adverse event reporting will be circulated at a later stage.

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Chair, Ethics Committee
28 February 2008