



REPORTING SERIOUS ADVERSE EVENTS TO THE MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

Method of Reporting Serious Adverse Events to the Mater Health Services HREC

Together with many other Committees in Australia the Mater Health Services HREC has struggled in dealing with the large volume of reports sent each month. The Research Ethics Coordinator receives approximately 6 inches of paperwork per month.

As introduced at many other sites in Australia, templates have been developed to ease the burden to the Committee in assessing how important these events are in relation to the continuation of the study. A number of hospitals have introduced Excel spreadsheets for reporting so there is a constant running tally of events for each trial drug. The Mater has chosen to introduce a Word document which can be printed on letterhead to report local serious adverse events. This Word document is made up of as many tick boxes as possible to assist researchers in completing but more importantly the MHS HREC will be confident that it is taking due responsibility in assessing these reports.

National Statement on Ethical Conduct in Research Involving Humans, Chapter 12, Clinical Trials,

12.8 An institution or organisation and its HREC must require the researcher:

(d) to inform the HREC and the TGA of all serious or unexpected adverse events that occur during the trial and may affect the conduct of the trial or the safety of the participants or their willingness to continue participation in the trial;

12.10 It may be unethical for a researcher to continue a trial if:

(b) side effects of unexpected type, severity, or frequency are encountered;

Chapter 1, Principles of Ethical Conduct, Ethical Review and Conduct of Research

1.17 A research must suspend or modify any research in which the risks to participants are found to be disproportionate to the benefits and stop any involvement of any participant if continuation of the research may be harmful to that person.

2.13 Procedures – Institutions and organisations and their HRECs must establish working procedures concerning:

- Reporting of adverse occurrences;

2.37 Monitoring – An HREC shall, as a condition of approval of each protocol, require that researchers immediately report anything which might warrant review of ethical approval of the protocol, including:

- (a) serious or unexpected adverse effects on participants;

With due consideration to all of these requirements as established by the NHMRC, the Mater Health Services HREC takes its responsibility in protecting participants and promoting good research. The Committee considers it is the responsibility of the Investigators and / or sponsoring companies to advise in relation to adverse occurrences. Please embrace these changes as a continuing quality improvement in assessing, conducting and monitoring high standard research at the Mater.



SAE Pro forma developed by the Mater Health Services HREC

- There are three templates now located on L:\Allusers\ResEthic or www.mater.org.au
- Initial Serious Adverse Event Form
- Follow Up Serious Adverse Event Form
- External SAE Report template
- + Cover letter and receipt pro formae.

All serious adverse events must be submitted using this format. In addition Investigators may also submit Company documentation as an attachment.

The initial SAE form and follow up SAE form templates have been designed so they may be printed on Mater letterhead.

The Principal Investigator at this site is required to sign the form before submission to the HREC.

Timely Notification of a local Serious Adverse Event – for a Fully Sponsored, Pharmaceutical Trial Or Similar

- Notification to the Company as per Company Protocol (this is usually within 24 hours)
- Notification to the MSH HREC – please provide the Committee with a copy of the Company notification as soon as possible – within one month – maximum time lap. It is expected that if the event was serious and unexpected and may affect other participants on the trial at the Mater, that the HREC and Hospital Administration would receive immediate notification (within 24 hours).

Non-Sponsored Trials with only Local Data Safety Monitoring Committees

Immediate notification to the MHS HREC within 24 hours of event. If it is considered that the adverse event is related to the study immediate notification to Hospital Administration is requested.

Method for reporting External Serious Adverse Events to the Mater Health Services HREC

In addition, reporting of Serious Adverse Events external to the organisation are reported to the MHS HREC. These commonly occur from company sponsored multi-centred clinical trials and include full documentation of all serious adverse events which have occurred within the trial both nationally and internationally. Such large amounts of documentation add to the already large volume of reports sent to the HREC. Often the documentation sent cannot be accurately determined with regards to the seriousness of the SAE, its relevance (if any) to the study and if it will or should effect participant information sheets and/or consent procedures. As a result, this compromises the HREC in fulfilling the requirements of the National Statement as quoted above and, most importantly in assessing the benefits and risks of the trial for participants and monitoring needs.

The MHS HREC has proposed that deciphering the impact of external SAE's is more efficiently dealt with by the expertise of the local Principal Investigator. Therefore, the external SAE report template has been implemented to assist both researchers and the MHS HREC to effectively and efficiently report external serious adverse events. Completing this report and submitting to the MHS HREC will enable more accurate and concise reporting allowing the HREC to fulfil NHMRC requirements.

- The spreadsheet is to summarise the external Serious Adverse Event. It includes details of the SAE, date of occurrence, suspected agent, suspected causality (if any), site where the event occurred, initial or follow-up report and the investigators summary and comments. This spreadsheet can be obtained at L:\Allusers\ResEthic\External SAE Report template.xls or <http://www.mater.org.au/educationResearch/researchEthics.asp>.
- A covering letter from the Principle Investigator confirming that the SAE has been noted and has/has not affected the process of the study. This may include changes to the Participant Information Sheet or Consent Form, safety monitoring or changes to the protocol. The letter can be obtained at L:\Allusers\ResEthic\External SAE Covering Letter.doc or <http://www.mater.org.au/educationResearch/researchEthics.asp>.
- A letter addressed to the Principle Investigator or research nurse confirming receipt of the SAE report by the MHS HREC. This can be submitted with the above documents for signing by the HREC Administrator. This will be returned to the Principle Investigator for their own record keeping. Copy of letter obtained from L:\Allusers\ResEthic\External SAE Receipt.doc or <http://www.mater.org.au/educationResearch/researchEthics.asp>.

This is an initiative of the MHS HREC to continue its responsibility in protecting participants, promoting good research and further accommodating Investigators and/or sponsoring companies to expertly advise in relation to SAE reporting. Such changes will assist both the investigators and the MHS HREC to continue improvement in assessing, conducting and monitoring high standard research at the Mater.