

Monitoring Requirements for Research Studies at Austin Health

Minimum requirement is an annual report on the Austin Health template and a final report at the completion of the study on the Austin Health template.

The HREC may require more frequent reporting – this will be noted in the original approval letter and maybe dependent on the risk, size and complexity of the study.

Should the conduct of the study raise concerns with the HREC, they may increase reporting requirements during the running of the study.

Serious Adverse Event (SAE) Reporting

- All internal Serious Adverse Events must be reported to the HREC as soon as the event is known. These SAEs will also be reviewed by a scientific sub-committee.
- For trials involving therapeutic goods, the HREC have adopted the NHMRC Australian Health Ethics Committee (AHEC) Position Statement 'Monitoring and reporting of safety for clinical trials involving therapeutic products' May 09.

Data Safety Monitoring Boards

- When a Data Safety Monitoring Board is utilised by a study:
 - The names and affiliations of the members of the DSMB must be made known to the HREC
 - The DSMB meeting conclusions must be reported to the HREC without being filtered by the Sponsor eg should not be submitted on Sponsor letterhead. Must be accompanied by a letter from the site PI.

Device Trials

- For implantable device trials, approval is dependent on the researchers tracking the participant for the lifetime of the device and reporting any device incidents to the TGA and the HREC. Evidence that this will be done must be provided.

Auditing and inspections

- The HREC have authority to carry out random inspections of study sites, study data or study consent documentation. These are most likely to be carried out in investigator driven studies since sponsored studies should have external monitors. One flag for a random inspection is non-submission of an annual report after an appropriate reminder.
- The HREC may choose to hold interviews with research participants or gain feedback from them via questionnaires.

Self-Auditing

- The Research Ethics Unit has a self-auditing tool published on its website that investigators can use to audit their studies. This is recommended.