AlfredHealth

Ethics & Research Governance Update – Safety Monitoring

The NHMRC has released new guidance on safety monitoring and reporting in clinical trials. The guidance replaces the 2009 Position Statement and is in line with global reporting requirements.

The guidance applies to clinical trials involving drugs and devices, although it is frequently used as the gold standard for all clinical trials.

The main points arising from the guidance:

- reinforces the trial sponsor's responsibility for safety monitoring in a trial
- removes the requirement to submit individual SAE and SUSAR/USADE reports to the HREC
- introduces the term SARs (serious adverse reactions) which applies to drug trials
- removes the requirement to submit 6 monthly line (or other periodic) line listing to the HREC or institution
- requires sponsors to provide the HREC with an annual safety report that includes a clear summary of the evolving safety profile of the trial and also evidence that the sponsor is conducting its ongoing safety monitoring appropriately
- states institutions must receive SUSAR/USADE reports that have occurred at their institution and can determine their safety reporting requirements
- states that where an institution is named as the trial sponsor the institution will assume the sponsor responsibilities
- provides timeframes and information on reporting urgent safety measures and significant safety issues.

The implications and changes arising from the guidance are:

The Alfred Hospital Ethics Committee will adopt the guidance as of 1 June 2017. This will be applied prospectively and means all projects submitted for review after 1 June 2017 will report according to the new guidance. Projects reviewed before will report under the old guidance.

The Ethics Committee may decide additional reporting requirements are needed for higher risk trials (i.e. first-in-human) or to accommodate for potentially inadequate safety monitoring.

The Ethics Committee will require the annual safety report to be in line with the NHMRC's document.

Alfred Health as an institution will continue to require all **related** SAEs/SARs and not just SUSARs/USADEs to be reported for medico-legal risk, contractual obligations, ongoing assessment of innovations and clinical governance matters.

Overall there is little change at a site level for reporting individual events as investigators still need to capture adverse events at their site and make an assessment of these. Institution reporting at Alfred Health has always occurred at the same time and on the same form as

HREC reporting. All Alfred Health site **related** SAEs/SARs are to be reported (unrelated events are not reported) to the Institution and those arising from projects prior to June 2017 will be reviewed by the Ethics Committee if the Ethics Committee reviewed the project. The one report form still covers institution and ethics review (if applicable).

Protocols will need to include a detailed safety monitoring plan. This is of particular relevance to investigator initiated research. Monash Partners is currently considering how best to assist researchers and affiliated institutions with the monitoring obligations arising with the monitoring plans.

Forms and templates and Victorian streamlining SOPs will be updated over the coming weeks.

There are no changes to the submission of DSMB/SMC reports, IBs or DSURs.

Further updates will be provided.