



**SIR CHARLES GAIRDNER GROUP
HUMAN RESEARCH ETHICS COMMITTEE**

MEMO

Effective Date: 5 November 2009

Adverse Event Reporting for Clinical Trials

Please be advised that, consistent with previous statements, the Sir Charles Gairdner Hospital Human Research Ethics Committee does not require sponsors or investigators to submit individual reports of Serious Adverse Events that occur outside of our institution for review. The HREC has adopted the reporting requirements outlined in the NHMRC AHEC Position Statement May 2009

http://www.nhmrc.gov.au/health_ethics/hrecs/reference/files/090609_nhmrc_position_statement.pdf

Summary of Reporting Requirements

Type of Reporting	Event
24 (death) 72 hours (other)	SAEs occurring on site
In a prompt manner	Information which materially impacts the continued ethical acceptability of the trial or Information that requires, or indicated the need for a change to the trial protocol including changed safety monitoring in the view of the investigator or sponsor.
Six monthly	Listing of all SUSARS, Australian and international, occurring with a compound including Sponsor and investigator comments as to whether action is planned for the trial on the basis of the reports. (EU format is acceptable)
Annually	An updated Investigator brochure or An EU ASR (or similar format report) or Current, approved Product Information (PI), if appropriate (eg in a study for a product approved in Australia or where and Investigator Brochure is no longer maintained) Other reports consistent with section 5.5.5 of the National Statement and Good Clinical Practice (GCP) as adopted by the Therapeutic Goods Administration (TGA)

Jenny Westgarth-Taylor
Delegate of the Chair
SCGH Human Research Ethics Committee