Updated 15 Jun 2018

Adventist HealthCare Limited

Monitoring and reporting of safety for clinical trials involving therapeutic goods

Reference: NHMRC AHEC Position Statement May 2009

Type of Monitoring	**AHCL Human Research Ethics Committee and Research Governance Office reporting requirements**	
	Single-centre research, approved by the AHCL HREC, involving an AHCL research participant at an AHCL site, for review by the AHCL HREC	Multi-centre research, approved by a Lead HREC, involving an AHCL research participant at an AHCL site, for review by the AHCL RGO
Expected Adverse **E**vent (**AE)** Definition: Reactions / events both serious and non-serious as defined in the Investigator's Brochure	Not required unless the Principal Investigator considers the event will impact on ethical acceptability and action is planned e.g. amendment to Investigators Brochure, PIS&C or other approved document	Not required
Serious **A**dverse **E**vent (**SAE**) Definition: Any untoward medical occurrence that results in death; is life-threatening at the time it occurred; requires inpatient hospitalisation or prolonged hospitalisation; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect; medically important event or reaction	The Principal Investigator will provide a report of each event, in the required format *, within 15 days of occurrence	The Principal Investigator will provide a copy of the report submitted to the Lead HREC and a copy of the Lead HREC acknowledgement letter #
Suspected **U**nexpected **S**erious **A**dverse **R**eactions (**SUSAR**) Definition: A serious adverse event (SAE) for which there is a degree of probability that the event is an adverse reaction to the administered drug and the reaction is unexpected	The Principal Investigator will provide a report of each event, in the required format *, within 15 days of occurrence.	The Principal Investigator will provide a copy of the report submitted to the Lead HREC and a copy of the Lead HREC acknowledgement letter #
Suspected **U**nexpected **S**erious **A**dverse **R**eactions (**SUSAR**) occurring at <u>all</u> sites Definition: A serious adverse event (SAE) for which there is a degree of probability that the event is an adverse reaction to the administered drug and the reaction is unexpected	The Principal Investigator will provide a report in the required format * attaching the **six monthly line-listings of SUSAR occurring at all sites**. The report must include the Sponsor and Co-ordinating Investigator's comment regarding any planned action e.g. amendment to IB, Clinical Protocol and/or PICF. Quarterly line-listings are not required.	The Principal Investigator will provide a copy of the report submitted to the Lead HREC and a copy of the Lead HREC acknowledgement letter #
Progress Report	The Principal Investigator will provide an **Annual** (or as specified in conditions of approval) **Progress Report**, in the required format * on the anniversary of site authorisation of the study. The Principal Investigator will provide a **Final Progress Report**, in the required format * at conclusion of the study.	The Principal Investigator will provide a copy of the report submitted to the Lead HREC and the Lead HREC acknowledgement letter
Safety Report For example: Data Safety Monitoring Reports	The Principal Investigator will provide safety reports, as available.	The Principal Investigator will provide a copy of the report submitted to the Lead HREC and a copy of the Lead HREC acknowledgement letter #
Protocol Violation Definition: Serious departures from the protocol requirements and/or regulatory guidelines	The Principal Investigator will provide a report in a timely manner.	The Principal Investigator will provide a copy of the report submitted to the Lead HREC and a copy of the Lead HREC acknowledgement letter

* Form is available at Ethics Committee Forms & Guidelines

If the Lead HREC has adopted the *NHMRC Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods – NHMRC - Nov 2016* <u>and/or</u> *Safety Monitoring and Reporting for Clinical Trials Conducted in NSW Public Health Organisations – NSW Health Policy Directive PD2017_039 published 27 Oct 2017,* reporting to the Lead HREC is not required. However, if the Lead HREC requires reports to be submitted then the above process of secondary submission to the AHCL RGO must be followed.