

Reporting timeframes for events (local principal investigators) — multi-centre studies

Type of event	Timeframe for reporting	Format required	# of copies required	Local Principal Investigator submits to
Commencement of research study	Within 5 working days of study commencement ¹	Standard QH Reporting Template: <u>Commencement of research study</u>	1	Coordinating Principal Investigator (CPI)
			1	Local RGO
Internal SAE / SADR	All studies - both industry & non-industry sponsored studies: To the Sponsor / reviewing HREC & local RGO within 24 hours of becoming aware of the event.	Sponsor SAE reporting template or <u>Metro North HHS SAE reporting template</u> Cover letter stating that the local PI has reviewed these events and what changes to the study, if any, have been determined.	1	Sponsor
			1	Reviewing QH HREC ² Reviewing HREC responds directly to local PI
			1	Coordinating Principal Investigator
			1	Local RGO
External SUSARs, SAEs	At least six monthly ³	DSMB report (if applicable) and Industry report or <u>Standard QH Reporting Template</u> : (Do not submit individual line listings if submitting an industry or DSMB report. However, these must be available to the HREC if requested) Include a cover letter to state that the local PI has reviewed these events and what changes to the study, if any, have been determined.	1	Coordinating Principal Investigator

¹ Study commencement refers to the first point of recruitment i.e. the date when the advertising or screening for participants begins or commencement of data collection for studies which are not recruiting participants.

² For multi-centre studies, the reviewing HREC is the NHMRC certified QH HREC which, under the single ethical review process, has reviewed and ethically approved the study and has assumed responsibility for monitoring the conduct of the research being conducted at QH sites.

³ Reference: [NHMRC Australian Health Ethics Committee \(AHEC\) Position Statement](#): Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009

Type of event	Timeframe for reporting	Format required	# of copies required	Local Principal Investigator submits to
HREC Annual report	Annually from date of HREC approval (More frequent updates if directed by HREC)	Standard QH Reporting Template: HREC Annual report	1	Industry Sponsored Research: Submit to CRA who will collate and forward to Coordinating Principal Investigator who will submit to reviewing HREC
			1	Local RGO
			1	Non industry sponsored studies: Submit to the Coordinating Principal Investigator who will collate and submit to reviewing HREC
			1	RGO
HREC Final report	Within 30 days of study completion ⁴	Standard QH Reporting Template: HREC Final report	1	Industry Sponsored Research: Submit to CRA who will collate and forward to Coordinating Principal Investigator who will submit to reviewing HREC
			1	RGO
			1	Non industry sponsored studies: Submit to the Coordinating Principal Investigator who will collate and submit to reviewing HREC
			1	RGO

Note: The Coordinating Principal Investigator may also be a Local Principal Investigator for a site, and therefore must follow the local Principal Investigator reporting requirements for their own site.

⁴ Study completion is defined as formal closure of study at site, with all data queries completed.

Reporting timeframes for events (coordinating principal investigators) — multi-centre studies

Type of event	Timeframe for reporting	Format required	# of copies required	Coordinating Principal Investigator submits to
Commencement of research study	Within 5 working days of study commencement ⁵	Standard QH Reporting Template: <u>Commencement of research study</u>	1	Reviewing HREC
All SUSARs, SAEs	At least six monthly ⁶	DSMB report (if applicable) and Industry report or <u>Standard QH Reporting Template</u> : (Do not submit individual line listings if submitting an industry or DSMB report. However, these must be available to the HREC if requested) Cover letters from the local PIs (including the CPI) stating that the investigators have reviewed these events and what changes to the study, if any, have been determined.	1	Reviewing HREC
HREC Annual report	Annually from date of HREC approval (More frequent updates if directed by HREC)	Standard QH Reporting template as received from local Principal Investigators: <u>HREC Annual report</u> or as received in collated format by Sponsor or CRA	1	Reviewing HREC
HREC Final report	Within 30 days of study completion ⁷	Standard QH Reporting Template as received from local Principal Investigators: <u>HREC Final report</u> or as received in collated format by Sponsor or CRA	1	Reviewing HREC

⁵ Study commencement refers to the first point of recruitment i.e. the date when the advertising or screening for participants begins or commencement of data collection for studies which are not recruiting participants.

⁶ Reference: [NHMRC Australian Health Ethics Committee \(AHEC\) Position Statement](#): Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009

⁷ Study completion is defined as formal closure of study at site, with all data queries completed.