QH Gold Coast Hospital and Health Service Human Research Ethics Committee EC00160

Local Principal Investigators

Directions re reporting timeframes and no. of copies required for reporting events related to a multi-centre research study

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*	Standard QH Reporting Template: https://www.health.qld.gov.au/__data/assets/word_doc/0026/152675/commence_form_hrec_Mar18.doc	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 template or Standard QH Reporting Template: https://www.health.qld.gov.au/__data/assets/word_doc/0026/146915/sae_local_site_Mar18.doc 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	Sponsor
			13	Reviewing QH HREC**** Reviewing HREC responds directly to local PI
			1	Coordinating Principal Investigator
			1	Local RGO
External SUSARs, SAEs	At least six monthly**	DSMB report (if applicable) **and** Industry report or Standard QH Reporting Template: https://www.health.qld.gov.au/__data/assets/word_doc/0012/152202/sae_non_local_site_Mar18.doc (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
HREC Annual report	Annually from date of HREC approval (More frequent updates if directed by HREC)	Standard QH Reporting Template: https://www.health.qld.gov.au/__data/assets/word_doc/0020/150392/annual_rep_hrec_Mar18.doc	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

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			1	RGO
HREC Final report	Within 30 days of study completion***	Standard QH Reporting Template: https://www.health.qld.gov.au/__data/assets/word_doc/0011/151400/final_rep_form_hrec_Mar18.doc	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

* 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.
** Reference: NHMRC*, Safety Monitoring and reporting in clinical trials involving therapeutic goods,* November 2016
https://nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods
*** Study completion is defined as formal closure of study at site, with all data queries completed.
****The reviewing HREC is the QH HREC which has reviewed and ethically approved the study and has assumed responsibility for monitoring the conduct of the research being conducted at QH sites.

Please 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.

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Coordinating Principal Investigators

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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*	Standard QH Reporting Template: https://www.health.qld.gov.au/__data/assets/word_doc/0026/152675/commence_form_hrec_Mar18.doc	1	Reviewing HREC
All SUSARs, SAEs	At least six monthly**	DSMB report (if applicable) **and** Industry report or Standard QH Reporting Template: https://www.health.qld.gov.au/__data/assets/word_doc/0012/152202/sae_non_local_site_Mar18.doc (Do not submit individual line listings if submitting an industry or DSMB report. However, these must be available to the HREC if requested) Include the 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 full original plus 12 copies of summary	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: https://www.health.qld.gov.au/__data/assets/word_doc/0020/150392/annual_rep_hrec_Mar18.doc **or** as received in collated format by Sponsor or CRA	13	Reviewing HREC
HREC Final report	Within 30 days of study completion ***	Standard QH Reporting Template as received from local Principal Investigators: https://www.health.qld.gov.au/__data/assets/word_doc/0011/151400/final_rep_form_hrec_Mar18.doc **or** as received in collated format by Sponsor or CRA	13	Reviewing HREC

* 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.
** Reference: NHMRC, *Safety Monitoring and reporting in clinical trials involving therapeutic goods,* November 2016
https://nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

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