

**QH Metro South Health Service District  
Human Research Ethics Committee EC00167  
LOCAL PRINCIPAL INVESTIGATORS**

*Directions fro 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	SUBMISSION TO
Commencement of research study	As soon as the study commences <sup>1</sup>	Metro South HREC Commencement of Research Study Form: <a href="http://www.health.qld.gov.au/pahospital/research/docs/msf11.doc">http://www.health.qld.gov.au/pahospital/research/docs/msf11.doc</a>	1	Coordinating Principal Investigator (CPI)
			1	Local RGO
Internal SAE / SADR	<b>All studies - both industry &amp; non-industry sponsored studies:</b> To the Sponsor / reviewing HREC & local RGO within 24 hours of becoming aware of the event.	Sponsor SAE template or Metro South HREC_MS F19: INTERNAL SAE REPORT <a href="http://www.health.qld.gov.au/pahospital/research/docs/msf19.doc">http://www.health.qld.gov.au/pahospital/research/docs/msf19.doc</a>	1	Sponsor
			18	Submission directly to reviewing HREC <sup>2</sup> by local PI Reviewing HREC is to respond directly to submitting PI
			1	CPI
			1	Local RGO
External SUSARs, SAEs	Monthly <sup>3</sup>	DSMB report (if applicable) and Industry report or Metro South HREC MSF20: EXTERNAL SAE REPORT <a href="http://www.health.qld.gov.au/pahospital/research/docs/msf20.doc">http://www.health.qld.gov.au/pahospital/research/docs/msf20.doc</a>  (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.	2	Coordinating Principal Investigator

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> Reference: *NHMRC Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*

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### LOCAL PRINCIPAL INVESTIGATORS

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HREC Annual report	Annually from date of HREC approval (More frequent updates if directed by HREC)	<b>Metro South HREC_ MSF17: ANNUAL PROGRESS REPORT FORM</b> <a href="http://www.health.qld.gov.au/pahospital/research/docs/msf17.doc">http://www.health.qld.gov.au/pahospital/research/docs/msf17.doc</a>	1	<b>Industry Sponsored Research:</b> Submit to CRA who will collate and forward to Coordinating Principal Investigator who will submit to reviewing HREC
			1	RGO
			1	<b>Non industry sponsored studies:</b> Submit to the Coordinating Principal Investigator who will collate and submit to reviewing HREC
			1	RGO
HREC Final report	At study completion or cessation or suspension <sup>4</sup>	<b>Metro South HREC_ MSF18: FINAL REPORT FORM</b> <a href="http://www.health.qld.gov.au/pahospital/research/docs/msf18.doc">http://www.health.qld.gov.au/pahospital/research/docs/msf18.doc</a>	1	<b>Industry Sponsored Research:</b> Submit to CRA who will collate and forward to Coordinating Principal Investigator who will submit to reviewing HREC
			1	RGO
			1	<b>Non industry sponsored studies:</b> Submit to the Coordinating Principal Investigator who will collate and submit to reviewing HREC
			1	RGO

**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.

[http://www.nhmrc.gov.au/files\\_nhmrc/file/health\\_ethics/hrecs/reference/090609\\_nhmrc\\_position\\_statement.pdf](http://www.nhmrc.gov.au/files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf)

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

## QH Metro South Health Service District Human Research Ethics Committee EC00167 COORDINATING 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	Submission to
Commencement of research study	As soon as the study commence <sup>1</sup> s	Metro South HREC Commencement of Research Study Form: <a href="http://www.health.qld.gov.au/pahospital/research/docs/msf11.doc">http://www.health.qld.gov.au/pahospital/research/docs/msf11.doc</a>	1	Reviewing HREC
All SUSARs, SAEs	Monthly <sup>2</sup>	DSMB report (if applicable) and Industry report or Metro South HREC MSF20: EXTERNAL SAE REPORT <a href="http://www.health.qld.gov.au/pahospital/research/docs/msf20.doc">http://www.health.qld.gov.au/pahospital/research/docs/msf20.doc</a>  (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 PIs and CPI have reviewed these events and what changes to the study, if any, have been determined.	2	Reviewing HREC
HREC Annual report	Annually from date of HREC approval (More frequent updates if directed by HREC)	<b>Metro South HREC_ MSF17: ANNUAL PROGRESS REPORT FORM</b> <a href="http://www.health.qld.gov.au/pahospital/research/docs/msf17.doc">http://www.health.qld.gov.au/pahospital/research/docs/msf17.doc</a>	1	Reviewing HREC
HREC Final report	At study completion or cessation or suspension <sup>3</sup>	<b>Metro South HREC_ MSF18: FINAL REPORT FORM</b> <a href="http://www.health.qld.gov.au/pahospital/research/docs/msf18.doc">http://www.health.qld.gov.au/pahospital/research/docs/msf18.doc</a>	1	Reviewing HREC

NOTE: This form is subject to change on SOP review.

<sup>1</sup> 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

<sup>2</sup> Reference: *NHMRC Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products* May 2009  
[http://www.nhmrc.gov.au/files\\_nhmrc/file/health\\_ethics/hrecs/reference/090609\\_nhmrc\\_position\\_statement.pdf](http://www.nhmrc.gov.au/files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf)

<sup>3</sup> Study completion is defined as formal closure of study at site, with all data queries completed.