National Mutual Acceptance
Single Ethical Review of Multi-centre Human Research Projects

MONITORING AND REPORTING TABLES

New South Wales
Queensland
South Australia
Victoria

The tables included in this document are designed to assist Investigators, HREC Coordinators and Research Governance Officers (RGOs). They provide information on the reporting requirements for multi-centre human research projects taking place in States and Territories.

For further information on multi-centre human research projects:

New South Wales
Office for Medical Research
Website www.health.nsw.gov.au/ethics/research
Email researchethics@doh.nsw.gov.au
Telephone 02 9391 9220

South Australia
Operational Service Policy Unit
Website www.sahealth.sa.gov.au/researchethics
Email researchgovernance@health.sa.gov.au
Telephone 08 8226 7461

Queensland
Health and Medical Research
Website www.health.qld.gov.au/ohmr
Email hmr@health.qld.gov.au
Telephone 07 3328 9503

Victoria
Coordinating Office for Clinical Trial Research
Website www.health.vic.gov.au/clinicaltrials
www.health.vic.gov.au/healthandmedicalresearch
Email multisite.ethics@health.vic.gov.au
Telephone General Enquiries 03 9096 7394
System Information 03 9096 7398

Version: December 2015

PART 1

Coordinating Principal Investigator (CPI)
Reporting for a Multi-centre Human Research Project

SAFETY REPORTING

Drug Research: Adverse and serious adverse event reporting: no material impact on the continued ethical acceptability of the trial

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	SAEs for all study sites under the responsibility of the HREC. PI's responsibility	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	Reviewing HREC by local PI directly and copy of reports to RGO and CPI.
QLD	SAEs for all study sites under the responsibility of the HREC. PI's responsibility	N/A PI responsibility	Specific to HREC	Reviewing HREC by local PI directly
SA	SAEs only - 72 hours, AEs through periodic reports if no material impact	As per HREC reporting requirements/template.	Specific to HREC	Reviewing HREC by local PI directly and copy of reports to local RGO and CPI.
VIC	PI's responsibility	In accordance with the NHMRC Position Statement #2.1 Institutions should seek to keep individual requirements to minimum or utilise such requirements in a highly targeted manner if these are particular safety concerns. www.health.vic.gov.au/clinicaltrials	Not Specified	In accordance with the trial protocol and institutional requirements

Drug Research: Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the trial

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	SAEs for all study sites under the responsibility of the HREC PI's responsibility for reporting purposes. 72 hours unless the PI considers immediate notification is necessary. Where only local DSMB for project (investigator-initiated trial), within 24 hours of the event occurring. Note: CPI's responsibility for communication of change to trial protocol or changed safety monitoring CPI's responsibility for Urgent safety related modifications within 5 working days	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	Reviewing HREC by local PI directly and copy of reports to RGO and CPI. CPI's responsibility for communication of change to trial protocol or changed safety monitoring. CPI's responsibility for Urgent safety related modifications to reviewing HREC.
QLD	SAEs for all study sites under the responsibility of the HREC PI's responsibility	N/A PI responsibility	Specific to HREC	Reviewing HREC by local PI directly
SA	SAE's 72 hours unless the PI considers immediate notification is necessary.	As per HREC reporting requirements/template.	Specific to HREC	Reviewing HREC by local PI directly and copy of reports to local RGO and CPI. CPI's responsibility for communication of change to trial protocol or changed safety monitoring. CPI's responsibility for Urgent safety related modifications to reviewing HREC.
VIC	24 hours	Standard reporting templates – AE and SAE Report, SUSAR/USADE Site Report Standard reporting templates: www.health.vic.gov.au/clinicaltrials	Not specified	PI(s) must notify the CPI or delegate of an AE/SAE report where there is a material impact on the continued ethical acceptability or the AE/SAE indicates the need for a change to the trial protocol. The CPI must submit AE/SAE reports to the reviewing HREC in a prompt manner. Note to avoid delay the PI may contact the CPI and decide to forward the AE/SAE directly to the reviewing HREC. The local site Research Governance Officer and VMIA should also be notified.

Drug Research: Australian and international SUSARs Industry report or DSMB report

State or Territory	Timeframe	Format	Number of Copies	Submission

NSW	At least six-monthly	No State-wide form, as requested by the reviewing HREC, with comments from CPI and sponsor. Submit Industry report or DSMB report or line listings.	No State-wide requirement, as per reviewing HREC requirements	Reviewing HREC
QLD	At least six-monthly**	Industry report or DSMB report or Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/sae_non_local_site.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 letter from the site PIs (including CPI) stating that the PIs have reviewed these events and what changes to the study, if any, have been determined.	Specific to HREC	Reviewing HREC
SA	At least six-monthly	As per HREC reporting requirements/template.	Not specified	CPI to Reviewing HREC CPI to PIs
VIC	At least six-monthly	Standard reporting template – SUSAR/USADE Line Listing Report (CPI to complete and collate). A statement from the sponsor regarding implications for participants and the conduct of the study. Submit Industry report or DSMB report or line listings Standard reporting templates: www.health.vic.gov.au/clinicaltrials	Not specified	Reviewing HREC

Device Research: Adverse and serious adverse event reporting: no material impact on the continued ethical acceptability of the investigation

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	SAEs and SADEs for all study sites under the responsibility of the HREC PI's responsibility for reporting purposes. 72 hours unless the PI considers immediate notification is necessary. Where only local DSMB for project (investigator-initiated trial), within 24 hours of the event occurring. Note: CPI's responsibility for communication of change to trial protocol or changed safety monitoring. CPI's responsibility for Urgent safety related modifications within 5 working days.	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	Reviewing HREC by local PI directly and copy of reports to RGO and CPI.
QLD	SAEs and SADEs for all study sites under the responsibility of the HREC PI's responsibility	N/A PI responsibility	Specific to HREC	Reviewing HREC by local PI directly
SA	SAEs only – 72 hours, AEs through periodic reports if no material impact	As per HREC reporting requirements/template.	Specific to HREC	Reviewing HREC by local PI directly and copy of reports to local RGO and CPI.
VIC	PI's responsibility	In accordance with the NHMRC Position Statement #2. SUSARs should be interpreted as USADEs. Institutions should seek to keep individual requirements to minimum or utilise such requirements in a highly targeted manner if these are particular safety concerns. www.health.vic.gov.au/clinicaltrials	Not specified	In accordance with the trial protocol and institutional requirements

Device Research: Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the investigation

State or Territory	Timeframe	Format	Number of Copies	Submission

NSW	SAEs and SADEs for all study sites under the responsibility of the HREC PI's responsibility for reporting purposes. 72 hours unless the PI considers immediate notification is necessary. Where only local DSMB for project (investigator-initiated trial), within 24 hours of the event occurring. Note: CPI's responsibility for communication of change to trial protocol or changed safety monitoring CPI's responsibility for Urgent safety related modifications within 5 working days	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	Reviewing HREC by local PI directly and copy of reports to RGO and CPI. CPI's responsibility for communication of change to trial protocol or changed safety monitoring. CPI's responsibility for Urgent safety related modifications to reviewing HREC.
QLD	SAEs and SADEs for all study sites under the responsibility of the HREC PI's responsibility	N/A PI responsibility	Specific to HREC	Reviewing HREC by local PI directly
SA	72 hours unless the PI considers immediate notification is necessary.	As per HREC submission requirements.	Specific to HREC	Reviewing HREC by local PI directly and copy of reports to local RGO and CPI. CPI's responsibility for communication of change to trial protocol or changed safety monitoring. CPI's responsibility for Urgent safety related modifications to reviewing HREC.
VIC	24 hours	Standard reporting templates – AE and SAE Report, SUSAR/USADE Site Report Standard reporting templates: www.health.vic.gov.au/clinicaltrials	Not specified	PI(s) must notify the CPI or delegate of an AE/SAE/SADE/DD report where there is a material impact on the continued ethical acceptability or the AE/SAE/SADE/DD indicates the need for a change to the trial protocol. The CPI must submit AE/SAE/SADE/DD reports to the reviewing HREC in a prompt manner. Note to avoid delay the PI may contact the CPI and decide to forward the AE/SAE/SADE/DD directly to the reviewing HREC. The local site Research Governance Officer and VMIA should also be notified.

Device Research: Australian and international USADEs Industry report or DSMB report

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	At least annually	No State-wide form, as requested by the reviewing HREC, with comments from CPI and sponsor. Submit Industry report or DSMB report or line listings.	No State-wide requirement, as per reviewing HREC requirements	Reviewing HREC
QLD	At least annually	Industry report or DSMB report. (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 letter from the site PIs (including CPI) stating that the PIs have reviewed these events and what changes to the study, if any, have been determined.	Specific to HREC	Reviewing HREC
SA	At least annually	As per HREC submission requirements.	Specific to HREC	CPI to Reviewing HREC CPI to Pis
VIC	At least annually	Standard reporting template – SUSAR/USADE Line Listing Report (CPI to complete and collate). A statement from the sponsor regarding implications for participants and the conduct of the study. Submit Industry report or DSMB report or line listings Standard reporting templates: www.health.vic.gov.au/clinicaltrials	Not specified	Reviewing HREC

AMENDMENTS

Amendments

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	As required	No State-wide form, as requested by the reviewing HREC requirements Must provide amended documents in clean and track change, with cover page summarising changes for large documents (IB's and protocols), include revised version numbers and include version dates and page numbers on each page.	No State-wide requirement, as per reviewing HREC requirements	CPI submits to the reviewing HREC. PI submits a copy to RGO
QLD	As required	Not specified – as per Researcher User Guide (RUG) www.health.qld.gov.au/ohmr/documents/regu/resrch_user_guide_v1.pdf	As per RUG	As per RUG. Any submission to HREC will be made by CPI Any RG amendments which do not impact on the ethical acceptability of the study maybe submitted directly to the RGO by the local PI and the CPI notified.
SA	As required	As per HREC reporting requirements/template. Must provide: 1) cover page summarising rationale for amendment and changes to documents (e.g. IB's and protocols); 2) amended document/s with tracked changes; 3) version numbers on all new documents.	Specific to HREC	CPI submits to the reviewing HREC. CPI informs PI when approval obtained. PI submits a copy to local RGO
VIC	As required	Standard template: HREC Amendment form www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Dependent on HREC requirements	CPI or PI prepares HREC amendment request. CPI submits to the reviewing HREC. PI submits a copy to their RGO.

COMPLAINTS

Complaints concerning the conduct of a research project

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	Reviewing HREC
QLD	Not specified	Not specified	1	Reviewing HREC. Local RGO to which the complaint applies.
SA	Not specified	As per HREC submission requirements.	1	Reviewing HREC and CPI. CPI communicates to local PI to whom the complaint applies. PI communicates to Local RGO to which the complaint applies.
VIC	Not specified	Standard reporting template: Complaints report to HREC - Site Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	1	CPI sends to reviewing HREC Copy to RGO

Complaints concerning the HREC's review process including the HREC's rejection of an application

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	To HREC Chair in first instance and can be escalated to Institutional Chief Executive
QLD	Not specified	Not specified	1	Reviewing HREC
SA	Not specified	Must follow SA Health procedure concerning complaints, available in the SA Health Research Ethics Operational Policy.	1	To HREC Chair in first instance and can be escalated to Institutional Chief Executive
VIC	Not specified	CPI responsibility - Process not specified and dependent on HREC's institutional policy	Not specified	Reviewing HREC

Complaints concerning the RGO's review process including authorisation decisions e.g. rejection of an application

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe	No State-wide form, but must be in writing	No State-wide requirement	CPI or PI may submit complaint to Institutional Chief Executive
QLD	N/A – Local PI responsibility			
SA	N/A – Local PI responsibility			
VIC	Not specified	Dependent on PI's institutional policy	Not specified	Institutional governance process

GENERAL REPORTING

Commencement of a clinical trial/investigation

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	To be reported in the first annual progress report	No State-wide form, template stipulated by the reviewing HREC	No State-wide requirement, as per reviewing HREC requirements	Collated progress report to reviewing HREC
QLD	Within 30 calendar days of study commencement	Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/commence_form_hrec.doc	Specific to HREC	Reviewing HREC
SA	To be reported in the first progress report	No State-wide form, template stipulated by the reviewing HREC	Specific to HREC	Reviewing HREC PI submits a Site Report copy to RGO
VIC	To be reported in the first progress report	Standard reporting templates: HREC Progress Report - Site Report HREC Progress Report - CPI Cover Sheet www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Specific to HREC	Reviewing HREC PI submits a Site Report copy to RGO

HREC Annual Report

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	Annually from date of HREC approval (More frequent updates if directed by HREC)	No State-wide form, template stipulated by the reviewing HREC	No State-wide requirement, as per reviewing HREC requirements	Collated progress report to reviewing HREC
QLD	Annually from date of HREC approval (More frequent updates if directed by HREC)	Standard QH Reporting template www.health.qld.gov.au/ohmr/documents/annual_rep_hrec.doc or As received in collated format by Sponsor or CRA	Specific to HREC	Reviewing HREC
SA	Annually from date of HREC approval (More frequent updates if directed by HREC)	No State-wide form, template stipulated by the reviewing HREC	Specific to HREC	Reviewing HREC
VIC	Annually from date of HREC approval (More frequent updates if directed by HREC)	Standard reporting templates: HREC Progress Report - Site Report HREC Progress Report - CPI Cover Sheet www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Specific to HREC	CPI collates progress reports from PIs and submits with a progress report cover sheet to the reviewing HREC. PI submit a copy of the HREC Progress Report Site Report to RGO.

HREC Final Report

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, template stipulated by the reviewing HREC	No State-wide requirement, as per reviewing HREC requirements	Collated progress report to reviewing HREC
QLD	*** Within 30 calendar days of study completion	Standard QH Reporting template: www.health.qld.gov.au/ohmr/documents/final_rep_form_hrec.doc or as received in collated format by Sponsor or CRA	Specific to HREC	Reviewing HREC
SA	Within 30 calendar days of study completion	No State-wide form, template stipulated by the reviewing HREC	1	Reviewing HREC with copy provided to RGO by PI
VIC	Not specified	Standard reporting template: HREC Final Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Not specified	CPI completes and submits to the reviewing HREC
			1	Copy to the PI
				PI provide a copy to RGO

Research project closure at a site

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	As per submission of HREC Final report

QLD	Within 30 calendar days of study completion ***	Included in HREC Final report Standard QH Reporting template: http://health.qld.gov.au/ohmr/documents/final_rep_form_hrec.doc or as received in collated format by Sponsor or CRA	As per submission of HREC Final report	As per submission of HREC Final report
SA	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	Not specified	CPI to advise HREC PI to forward copy to RGO
VIC	Not specified	Standard reporting template: HREC Final Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Not specified	Specific Site(s) closure only- site(s) PI to complete this form and forward a copy to their CPI.
			1	PI forward a copy to RGO

Protocol deviation or violation report

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	In a timely manner. PI's responsibility.	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	Reviewing HREC by local PI directly and copy of report to RGO
QLD	Not specified	Not specified	Specific to HREC	Reviewing HREC
SA	Not specified	No State-wide form, template stipulated by the reviewing HREC	Specific to HREC	CPI completes and submits to the reviewing HREC on notification by PIs. RGO only advised if further action required.
VIC	Not specified	Standard reporting template: Protocol Deviation or Violation Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Not specified	CPI completes and submits to the reviewing HREC on notification by PIs.
			1	PI sends a copy to 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 Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products* May 2009: www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

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

PART 2

Principal Investigators (PIs)
Site Reporting for a Multi-centre Human Research Project

SAFETY REPORTING

Drug Research: Adverse and serious adverse event reporting: no material impact on the continued ethical acceptability of the trial

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	SAEs for all study sites under the responsibility of the HREC Within 72 hours unless PI considers immediate notification is required. Where there is only a local Data and Safety Monitoring Board (e.g. investigator-initiated trial), reporting within 24 hours. Reporting includes SUSARs occurring at site	No State-wide form, as requested by the reviewing HREC, with comments from PI	No State-wide requirements, as per reviewing HREC requirements	Reviewing HREC
				CPI
				RGO
				(If specified in protocol) sponsor
QLD	SAEs for all study sites under the responsibility of the HREC Within 24 hours of becoming aware of the event.	Sponsor SAE template or Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/sae_local_site.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.	Dependent on HREC requirements	Submission directly to reviewing HREC by local PI Reviewing HREC is to respond directly to submitting PI
			1	Sponsor
				CPI
				Local RGO
SA	SAEs only for all study sites under the responsibility of the HREC Within 72 hours unless PI considers immediate notification is required.	No State-wide form. A covering letter must be included to indicate that the PI has reviewed the events, and to indicate whether any changes to the study are required.	1	Reviewing HREC by local PI directly and copy of reports to local RGO and CPI.
VIC	SAEs for all study sites under the responsibility of the HREC Not specified	In accordance with the NHMRC Position Statement #2.1 Institutions should seek to keep individual requirements to minimum or utilise such requirements in a highly targeted manner if these are particular safety concerns. Standard reporting template: www.health.vic.gov.au/clinicaltrials	Dependent on HREC requirements	Reviewing HREC
			1	CPI
				RGO
				Sponsor

Drug Research: Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the trial

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	SAEs for all study sites under the responsibility of the HREC Within 72 hours unless PI considers immediate notification is required. Where there is only a local Data and Safety Monitoring Board (e.g. investigator-initiated trial), reporting within 24 hours. Reporting includes SUSARs occurring at site. Note: CPI's responsibility for communication of change to trial protocol or changed safety monitoring. CPI's responsibility for Urgent safety related modifications within 5 working days.	No State-wide form, as requested by the reviewing HREC, with comments from PI	No State-wide requirements as per HREC requirements	Reviewing HREC
				RGO
				(If specified in protocol) sponsor
				CPI Note: CPI's responsibility for communication of change to trial protocol or changed safety monitoring CPI's responsibility for Urgent safety related modifications to reviewing HREC.
QLD	SAEs for all study sites under the responsibility of the HREC Within 24 hours of becoming aware of the event	Sponsor SAE template or Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/sae_local_site.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.	Dependent on HREC requirements	Submission directly to reviewing HREC by local PI Reviewing HREC is to respond directly to submitting PI
			1	Sponsor
				CPI
				Local RGO

SA	SAEs only for all study sites under the responsibility of the HREC Within 72 hours unless PI considers immediate notification is required.	No State-wide form. A covering letter must be included to indicate that the PI has reviewed the events, and to indicate whether any changes to the study are required.	1	Reviewing HREC by local PI directly and copy of reports to local RGO and CPI.
VIC	24 hours	Standard reporting templates – AE and SAE Report, SUSAR/USADE Site Report Standard reporting templates: www.health.vic.gov.au/clinicaltrials	Not specified	PIs must notify the CPI or delegate of an AE/SAE report where there is a material impact on the continued ethical acceptability or the AE/SAE indicates the need for a change to the trial protocol. The CPI must submit AE/SAE reports to the reviewing HREC in a prompt manner. Note to avoid delay the PI may contact the CPI and decide to forward the AE/SAE directly to the reviewing HREC. The local site Research Governance Officer and VMIA should also be notified.

Drug Research: Australian and international SUSARs Industry report or DSMB report

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	SUSARs occurring at site are the PI's responsibility	No State-wide form, as per reviewing HREC, with comments from PI	No State-wide requirements, as per reviewing HREC requirements	PI to reviewing HREC
	Other reports – at least six monthly are the CPI's responsibility	No State-wide form, as requested by the reviewing HREC, with comments from CPI and sponsor. Submit Industry report or DSMB report or line listings.		CPI to reviewing HREC
QLD	At least six monthly**	Industry report or DSMB report or Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/sae_non_local_site.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	CPI
SA	Australian & SUSAR Industry Reports are a CPI responsibility.	Please refer to instructions against the CPI section.		
VIC	At least six monthly**	Standard reporting template – SUSAR/USADE Line Listing Report (CPI to complete and collate). A statement from the sponsor regarding implications for participants and the conduct of the study. Submit Industry report or DSMB report or line listings Standard reporting templates: www.health.vic.gov.au/clinicaltrials	Not specified	CPI to forward to the reviewing HREC PI submits a copy to their RGO

Device Research: Adverse and serious adverse event reporting: no material impact on the continued ethical acceptability of the investigation

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	SAEs and SADEs for all study sites under the responsibility of the HREC. Within 72 hours unless PI considers immediate notification is required. Where there is only a local Data and Safety Monitoring Board (e.g. investigator-initiated trial), reporting within 24 hours. Reporting includes SUSARs occurring at site	No State-wide form, as requested by the reviewing HREC, with comments from PI	No State-wide requirements, as per reviewing HREC requirements	Reviewing HREC CPI RGO (If specified in protocol) sponsor
QLD	SAEs and SADEs for all study sites under the responsibility of the HREC	Sponsor SAE template or Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/sae_local_site.doc Include a cover letter to state that the local PI has reviewed these	Dependent on HREC requirements	Submission directly to reviewing HREC by local PI Reviewing HREC is to respond directly to submitting PI Sponsor

	Within 24 hours of becoming aware of the event.	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	CPI
				Local RGO
SA	SAEs only for all study sites under the responsibility of the HREC Within 72 hours unless PI considers immediate notification is required.	No State-wide form. A covering letter must be included to indicate that the PI has reviewed the events, and to indicate whether any changes to the study are required.	1	Reviewing HREC by local PI directly and copy of reports to local RGO and CPI.
VIC	SAEs and SADEs for all study sites under the responsibility of the HREC Not specified	In accordance with the NHMRC Position Statement #2.1 Institutions should seek to keep individual requirements to minimum or utilise such requirements in a highly targeted manner if these are particular safety concerns. Standard reporting template: www.health.vic.gov.au/clinicaltrials	Dependent on HREC requirements	Reviewing HREC
			1	CPI
				RGO
				Sponsor

Device Research: Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the investigation

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	SAEs and SADEs for all study sites under the responsibility of the HREC Within 72 hours unless PI considers immediate notification is required. Where there is only a local Data and Safety Monitoring Board (e.g. investigator-initiated trial), reporting within 24 hours. Reporting includes USADEs occurring at site. Note: CPI's responsibility for communication of change to trial protocol or changed safety monitoring. CPI's responsibility for Urgent safety related modifications within 5 working days.	No State-wide form, as requested by the reviewing HREC, with comments from PI	No State-wide requirements as per HREC requirements	Reviewing HREC
				RGO
				(If specified in protocol) sponsor
				CPI Note: CPI's responsibility for communication of change to trial protocol or changed safety monitoring. CPI's responsibility for Urgent safety related modifications to reviewing HREC.
QLD	SAEs and SADEs for all study sites under the responsibility of the HREC Within 24 hours of becoming aware of the event.	Sponsor SAE template or Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/sae_local_site.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.	Dependent on HREC requirements	Submission directly to reviewing HREC by local PI Reviewing HREC is to respond directly to submitting PI
			1	Sponsor
				CPI
				Local RGO
SA	SAEs only for all study sites under the responsibility of the HREC Within 72 hours unless PI considers immediate notification is required.	No State-wide form. A covering letter must be included to indicate that the PI has reviewed the events, and to indicate whether any changes to the study are required.	1	Reviewing HREC by local PI directly and copy of reports to local RGO and CPI
VIC	24 hours	Standard reporting templates – AE and SAE Report, SUSAR/USADE Site Report Standard reporting templates: www.health.vic.gov.au/clinicaltrials	Not specified	PIs must notify the CPI or delegate of an AE/SAE report where there is a material impact on the continued ethical acceptability or the AE/SAE indicates the need for a change to the trial protocol. The CPI must submit AE/SAE reports to the reviewing HREC in a prompt manner. Note to avoid delay the PI may contact the CPI and decide to forward the AE/SAE directly to the reviewing HREC. The local site Research Governance Officer and VMIA should also be notified.

Device Research: Australian and international USADEs Industry report or DSMB report

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	USADEs occurring at site are the PI's responsibility	No State-wide form, as per reviewing HREC, with comments from PI	No State-wide requirements, as per reviewing HREC requirements	PI to reviewing HREC
	Other reports – at least annually are the CPI's responsibility	No State-wide form, as requested by the reviewing HREC, with comments from CPI and sponsor. Submit Industry report or DSMB report for the listings.		CPI to reviewing HREC

QLD	At least annually	Industry report or DSMB report or Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/sae_non_local_site.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	CPI
SA	Australian & USADE Industry Reports or DSMB reports are a CPI responsibility.	Please refer to instructions against the CPI section.		
VIC	At least annually**	Standard reporting template – SUSAR/USADE Line Listing Report (CPI to complete and collate). A statement from the sponsor regarding implications for participants and the conduct of the study. Submit Industry report or DSMB report or line listings Standard reporting templates: www.health.vic.gov.au/clinicaltrials	Not specified	CPI to forward to the reviewing HREC PI submits a copy to their RGO

AMENDMENTS

Amendments

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	As required	No State-wide form, as requested by the reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	CPI submits to the reviewing HREC. PI submits a copy to their RGO.
QLD	As required	Not specified – as per Researcher User Guide (RUG) www.health.qld.gov.au/ohmr/documents/regu/resrch_user_guide_v1.pdf	As per HREC requirements	As per RUG: Any submission to HREC will be made by CPI Any RG amendments which do not impact on the ethical acceptability of the study maybe submitted directly to the RGO by the local PI and the CPI notified.
SA	As required. Note: amendments will be submitted by the CPI to the reviewing HREC for approval. Notification will be sent to the RGO post-approval by the PI.	No State-wide form, as per reviewing HREC requirements. Must include as a minimum: 1. Covering letter summarising changes for documents (e.g. IBs and protocols) and rationale for amendment/s; 2. Amended document/s with tracked changes OR changes clearly highlighted; 3. Version numbers on all new documents.	Dependent on HREC requirements	CPI submits to the reviewing HREC. CPI informs PI when approval obtained. PI submits a copy to local RGO
VIC	As required - not specified	Standard template: HREC Amendment form www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Dependent on HREC requirements	CPI or PI prepares HREC amendment request. CPI submits to the reviewing HREC. PI submits a copy to their RGO.

COMPLAINTS

Complaints concerning the conduct of a research project

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	No State-wide requirements, as per reviewing HREC requirements	PI sends to CPI who reports to reviewing HREC PI sends report to RGO
QLD	Not specified	Not specified	1	CPI Local RGO
SA	Not specified	If complaints are received by the PI, it is considered appropriate that these are referred to the CPI with notification to the RGO. No specific format for submitting such complaints, although the RGO may seek further information as required.	Not specified	PI sends to CPI who reports to reviewing HREC PI sends report to RGO
VIC	Not specified	Standard template: Complaints report to HREC - Site Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Dependent on HREC requirements	PI send to CPI who reports to reviewing HREC. PI forward a copy to RGO

Complaints concerning the HREC's review process including the HREC's rejection of an application

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	Either PI or CPI will submit to HREC Chair in first instance. Can be escalated to Institutional Chief Executive.
QLD	N/A – CPI responsibility			
SA	N/A – CPI responsibility			
VIC	Not specified	Process not specified and dependent on HRECs institutional policy	Not specified	Reviewing HREC or institution executive

Complaints concerning the RGO's review process including authorisation decisions e.g. rejection of an application

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	No State-wide requirements, as per reviewing HREC requirements	To Institutional Chief Executive
QLD	Not specified	Not specified	1	CPI Local RGO
SA	As required	Must follow SA Health procedure concerning research governance complaints, available in the SA Health Research Governance Policy.	1	RGO
VIC	Not specified	Dependent on PI's institutional policy	Not specified	Institutional governance process

GENERAL REPORTING

Commencement of a clinical trial/investigation

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	To be reported in the first annual progress report	No State-wide form, as per reviewing HREC requirements	No State-wide requirements, as per reviewing HREC requirements	Site progress report to CPI and RGO
QLD	Within 30 working days of study commencement*	Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/commence_form_hrec.doc	1	CPI Site RGO
SA	To be reported in the first progress report	No State-wide form, as per reviewing HREC requirements	1	PI to CPI PI to RGO
VIC	To be reported in the first progress report	Standard reporting template: HREC Progress Report - Site Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	1	PI submits to site RGO when the HREC Progress Report Site Report is completed PI completes the HREC Progress Report Site Report, CPI collates and submits to the reviewing HREC

HREC Annual Report

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	Annually from date of HREC approval (More frequent updates if directed by HREC)	No State-wide form, template stipulated by the reviewing HREC	No State-wide requirement, as per reviewing HREC requirements	Site progress report to CPI and RGO
QLD	Annually from date of HREC approval (More frequent updates if directed by HREC)	Standard QH Reporting template www.health.qld.gov.au/ohmr/documents/annual_rep_hrec.doc	1	Industry Sponsored Research: Submit to CRA who will collate and forward to CPI who will submit to reviewing HREC Local RGO Non industry sponsored studies: Submit to the CPI who will collate and submit to reviewing HREC Local RGO
SA	Please refer to CPI requirements regarding annual HREC reporting.			
VIC	Annually from date of HREC approval (More frequent updates if directed by HREC)	Standard reporting template: HREC Progress Report - Site Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Not specified	PI submits site progress report CPI collates and submits to the reviewing HREC PI submits a copy of the site progress report to their RGO

HREC Final Report

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, template stipulated by the reviewing HREC	No State-wide requirement, as per reviewing HREC requirements	Site progress report to CPI and RGO
QLD	Within 30 days of study completion***	Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/final_rep_form_hrec.doc	1	Industry Sponsored Research: Submit to CRA who will collate and forward to CPI who will submit to reviewing HREC Local RGO Non industry sponsored studies: Submit to the CPI who will collate and submit to reviewing HREC Local RGO
SA	Please refer to CPI requirements regarding annual reporting.			
VIC	Not specified	Standard reporting template: HREC Final Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Not specified	CPI completes and submits to the reviewing HREC PI to forward a copy to their RGO

Research project closure at a site

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	As per submission of HREC Final report
QLD	Within 30 days of study completion***	Included in HREC Final Report Standard QH Reporting Template: www.health.qld.gov.au/ohmr/documents/final_rep_form_hrec.doc	As per submission of HREC Final report	As per submission of HREC Final report
SA	Not specified	No State-wide form, as per reviewing HREC/RGO requirements	Not specified	HREC PI to CPI PI to local RGO
VIC	Not specified	Standard reporting template: HREC Final Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Not specified	Specific Site(s) closure only- site(s) PI to complete form and forward a copy to the CPI PI forward a copy to their RGO

Protocol deviation or violation report

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	"In a timely manner"	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	PI or CPI may submit report to Reviewing HREC
				RGO
QLD	Not specified	Not specified – as per Protocol or HREC request.	1	Local RGO
				CPI
SA	Not specified	No State-wide form, as per reviewing HREC requirements	No State-wide requirement, as per reviewing HREC requirements	PI reports to the CPI CPI submits to the reviewing HREC. PI reports to local RGO (if requested)
VIC	Not specified	Standard reporting template: Protocol Deviation or Violation Report www.health.vic.gov.au/clinicaltrials or www.health.vic.gov.au/healthandmedicalresearch	Not specified	PI reports to the CPI CPI submits to the 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 Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products* May 2009:
www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

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

PART 3

Reviewing HREC Correspondence Regarding
HREC Review & Post-approval Monitoring of a Multi-centre Human Research Project

PROCESSING AN HREC APPLICATION

Receipt of an HREC application

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Valid applications acknowledged within 5 working days of receipt.	Acknowledgement may be by written letter or email. EO may contact CPI to request provision of missing information prior to issuing the acknowledgement. Recommended Standard letters: Acknowledgement of receipt of a valid application	1	CPI
	No timeframe specified for notification of invalid applications.	Recommended Standard letters: Acknowledgement of receipt of invalid application		
QLD	On receipt of a HREC application and within 7 calendar days of the HREC closing date.	Recommended standard letters: Initial notification may be electronic SL1: Acknowledgement of receipt of a valid application SL2: Acknowledgement of receipt of invalid application SL4: Acknowledgement of Application and Invitation to Meeting	1	CPI
SA	Acknowledgement of applications as soon as possible after receipt (no timeframe specified).	Format of acknowledgement dependent on HREC and their Standard Operating Procedures.	1	CPI
VIC	On receipt of a HREC application notify, within 3 working days, the valid status.	Initial notification may be electronic Recommended standard letters: Acknowledgement of a valid application Acknowledgement of an invalid application	1	CPI

HREC Decision

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Within 10 working days after the HREC meeting date	Application requiring further information requested Initial notification may be electronic but must be in writing Recommended standard letter: Request for modification/further information. Advise the CPI to submit a response within 3 months or 2 HREC meetings (whichever occurs sooner).	1	CPI
	Within 60 calendar days of 'clock start' – HREC closing date	Application approved. Recommended standard letter: HREC Approval letter Approval letter should include: List of sites for which approval applies List of documentation approved with version numbers and dates Duration of HREC approval		CPI (CPI to provide copies to the RGO at each site where study is to be conducted).
	Within 10 working days after the HREC meeting date	Application not approved Recommended standard letter: HREC application not approved Letter to include: Decision of HREC Explanation of reasons with reference to N.S or relevant legislation Advice regarding available options for further review.		CPI
		Application not requiring HREC review Initial notification may be electronic Recommended standard letter: SL5 Not requiring review by HREC		
		Application requiring further information requested Initial notification may be electronic Recommended standard letter: SL7: Request for further information or clarification in order to reach a final opinion Notification should: Link request for further information with the National Statement on Ethical Conduct in Human Research where applicable. Notify CPI that response must be submitted to HREC within 3 months of notification.		

QLD	Within 60 calendar days of 'clock start' – HREC closing date	Application approved Initial notification may be electronic Recommended standard letters: SL6: Approval of Protocol Notification should include: List of sites application to approval List of documentation reviewed and approved Length of HREC approval (usually 3 years from date of approval letter)	1	CPI
		Application not approved Initial notification may be electronic Recommended standard letter: SL11: Unfavourable Decision on Protocol given by HREC following advice from Scientific Sub Committee/ Expert Reviewer SL12: Request for further information - response not approved Notification should link reasons for non approval with the National Statement on Ethical Conduct in Human Research where applicable.		
SA	Within 60 calendar days of 'clock start' – HREC closing date	Application will be either approved or not approved. If approved, HREC letter to include: List of sites for which ethics approval applies List of documentation approved with version numbers and dates Duration of HREC approval Conditions of HREC approval. If not approved, HREC letter to include: Decision of HREC Explanation of reasons for non-approval with reference to N.S or relevant legislation, where applicable Advice regarding available options for further review.	1	CPI If approved, CPI to provide copies to the PI for attachment/submission as part of the SSA process at each site where study is to be conducted.
VIC	Within 5 working days after the HREC meeting date	Request for further information Recommended standard letters: Provisional opinion with a request for further information No opinion pending consultation with referee Advise the CPI to submit a timely response as soon as possible	1	CPI
	Within 5 working days after the HREC meeting decision date. A 30 working day benchmark for HREC decision applies.	Application approved Recommended standard letter: Approval of research project Notification should include: List of sites approved List of documentation reviewed and approved with version date Duration of HREC approval		
	Within 5 working days after the HREC meeting decision date. A 30 working day benchmark for HREC decision applies.	Application not approved Recommended standard letter: Research project not approved		

POST-APPROVAL

Amendments

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	No timeframe specified	Request for modification/further information for review of amendment to be in writing (may be electronic). Recommended standard letter: Amendment requiring further information requested Correspondence to clearly articulate reasons for determination and refer to *National Statement*.	1	CPI
		Approval of amendment to be in writing (may be electronic) Recommended standard letter: Amendment approved		
		Notification to be in writing (may be electronic). Recommended standard letter: Amendment not approved. Where the amendment alters the nature of the research and the extent of the involvement of, or risk to, existing and/or potential participants, the HREC has the discretion to reject and amendment and request the submission of a new application.		
QLD	On receipt of a HREC application and within 7 calendar days of the HREC closing date.	Recommended standard letters: SL20: Acknowledgement of receipt of a valid HREC amendment application SL21: Acknowledgement of receipt of invalid HREC amendment application	1	CPI
	Within 60 calendar days of 'clock start' – HREC closing date	Application requiring further information requested Initial notification may be electronic No recommended standard letter Notification should: Link request for further information with the National Statement on Ethical Conduct in Human Research where applicable. Notify CPI that response must be submitted to HREC within 3 months of notification.		
		Amendment approved Initial notification may be electronic Recommended standard letter: SL13: Favourable Opinion of Post Authorisation Amendments		
		Application not approved Initial notification may be electronic Recommended standard letter: SL14: Unfavourable Opinion of Post Authorisation Amendments with options for Further Review Notification should link reasons for non approval with the National Statement on Ethical Conduct in Human Research where applicable.		
SA	No timeframe specified, however, timely consideration is required	Communication issued will be HREC dependent, however, will clearly indicate decision; and if approved, will include the nature of the Amendment, including approved documents and version dates.	1	CPI
VIC	For substantial amendments Within 5 working days of the HREC submission closing date.	Validation of amendment Recommended standard letters: Acknowledgement of a valid amendment Acknowledgement of an invalid amendment	1	CPI
	Within 5 working days after the HREC meeting date.	Amendment requiring further information Recommended standard letter: Conditional approval of an amendment		
	Within 5 working days after the HREC meeting decision date	Amendment approved Recommended standard letter: Approval of an amendment		
		Amendment not approved Recommended standard letter: Non-approval of an amendment		

Withdrawal/Suspension of Ethical Approval

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	3 working days after HREC decision (unless immediate notification required for urgent safety reasons)	Notification will be in writing. No State-wide standard letter; as specified by reviewing HREC	1	CPI Copy to: RGO at each site.
QLD	Within 24 hours of HREC decision	Recommended standard letter: SL19: Suspension/Withdrawal of HREC Approval for a research project. Notification must include: Reasons for withdrawal of approval Conditions that may restore HREC approval for the Research to proceed Recommended actions for participants currently enrolled in the trial.	1	CPI
SA	Within 3 working days of HREC decision (unless immediate notification required for urgent safety reasons)	Notification will be in writing. No SA standard letter; as specified by reviewing HREC	1	CPI CPI to provide copies to the PI and RGO at each site where study is being conducted.
VIC	HREC immediately notifies CPI of the decision	No standard letter	1	CPI Copy to: PI(s), RGO, sponsor, trial coordinator

SAFETY REPORTING

Adverse and serious adverse event reporting: no material impact on the continued ethical acceptability of the trial

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	SAEs for all study sites under the responsibility of the HREC Notification of HREC review outcome within 10 working days of the meeting. Notification of HREC review outcome may be immediate if required for urgent safety reasons.	Format of notification of HREC review outcome not specified, but should be in writing. (May be electronic). No State-wide standard letter; as specified by reviewing HREC	1	CPI HREC has discretion to notify RGOs and PI(s) directly for safety reasons.
QLD	SAEs for all study sites under the responsibility of the HREC Notification within 7 calendar days of being reviewed by HREC	Receipt notification (may be electronic) and HREC decision re continued ethical acceptability of the trial. Recommended standard letter: SL27: Acknowledgement of Adverse event report	1	CPI
SA	For HREC responsible for SAEs at all study sites: notification within 10 working days after the HREC meeting decision date	Acknowledgement only where deemed no material impact on the ethical acceptability of the trial	1	CPI
VIC	HREC responsible for SAEs at all study sites Within 5 working days after the HREC meeting decision date	Notification of HREC decision re continued ethical acceptability of the trial No standard letter	1	CPI

Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the trial

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	SAEs for all study sites under the responsibility of the HREC Notification of HREC review outcome within 10 working days of the meeting. Notification of HREC review outcome may be immediate if required for urgent safety reasons.	Format of notification of HREC review outcome not specified, but should be in writing. (May be electronic). No State-wide standard letter; as specified by reviewing HREC	1	CPI HREC has discretion to notify RGOs and PI(s) directly for safety reasons.
QLD	SAEs for all study sites under the responsibility of the HREC. Notification within 7 calendar days of being reviewed by HREC.	Receipt notification (may be electronic) and HREC decision re continued ethical acceptability of the trial Recommended standard letter: SL27: Acknowledgement of Adverse event report	1	CPI
SA	For HREC responsible for SAEs at all study sites: notification of review outcomes as soon as possible if material impact on the trial.	Notification of HREC decision re continued ethical acceptability of the trial No standard letter	1	CPI
VIC	HREC responsible for SAEs at all study sites Within 5 working days after the HREC meeting decision date	Notification of HREC decision re continued ethical acceptability of the trial No standard letter	1	CPI

Australian and international SUSARs Industry report or DSMB report

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Notification of HREC review outcome within 10 working days of the meeting. Notification of HREC review outcome may be immediate if required for urgent safety reasons.	Format of notification of HREC review outcome not specified, but should be in writing. (May be electronic). No State-wide standard letter; as specified by reviewing HREC	1	CPI HREC has discretion to notify RGOs and PI(s) directly for safety reasons
QLD	Notification within 14 calendar days of being reviewed by HREC	Receipt notification (may be electronic) and HREC decision re continued ethical acceptability of the trial. Recommended standard letter: SL27: Acknowledgement of Adverse event report	1	CPI
SA	Notification within 14 calendar days of being reviewed by HREC	Acknowledgement only unless the HREC deems further action is necessary to ensure ethical acceptability of the trial	1	CPI
VIC	Time not specified after the HREC meeting decision date	Notification of HREC acknowledgement / decision re continued ethical acceptability of the trial No standard letter Notification according to reviewing HREC policy	1	CPI

COMPLAINTS

Complaints concerning the conduct of a project

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	No timeframe specified.	Acknowledgement in writing to be sent to complainant, where possible. No State-wide standard letter.	1	Complainant
QLD	Notification within 7 calendar days of being received by HREC	Recommended standard letter: SL25: Acknowledgement of receipt of complaint	1	CPI
		No standard letter		Local site RGO to which the complaint applies
SA	No timeframe specified.	Acknowledgement and outcomes of HREC consideration to be sent in writing to complainant.	1	Complainant Discretion to notify CPI
VIC	Time not specified after the HREC meeting decision date	Receipt notification and HREC decision re continued ethical acceptability of the trial No standard letter	1	CPI

Complaints concerning the HREC's review process including the HREC's rejection of an application

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Appeals regarding HREC rejection Recommendation within two weeks from time appeal is lodged	HREC Chair to provide recommendation to HREC on appropriate course of action following investigation of appeal in writing. No State-wide standard letter.	1	HREC Chair to HREC
	Appeals regarding HREC rejection Notification to appellant in a timely manner	HREC to notify appellant of the course of action and determination in writing. No State-wide standard letter.		Appellant
	Appeals regarding HREC approval by any party No timeframe specified for HREC Chair response	HREC Chair to demonstrate due consideration by addressing each issue in writing. No State-wide standard letter.		Appellant
QLD	Notification within 7 calendar days of being received by HREC	Receipt notification (may be electronic) Recommended standard letter: SL25: Acknowledgement of receipt of complaint	1	CPI
	Notification within 30 calendar days of being received by HREC	Notification of HREC decision re the outcome of the complaint review Recommended standard letter: SL26: Acknowledgement of resolution of complaint		
SA	No timeframe specified (please refer to SA Health Research Ethics Operational Policy)	HREC to provide recommendation / advice on appropriate course of action following investigation of appeal in writing. No State-wide standard letter. Process to follow requirements outlined in SA Health Research Ethics Operational Policy.	1	CPI
VIC	Time not specified after the HREC meeting decision date	Receipt notification and explanation of HREC decision No standard letter	1	CPI

Complaints concerning the RGO's review process including authorisation decisions e.g. rejection of an application

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	N/A – local RGO responsibility			
QLD	N/A – local RGO responsibility			
SA	N/A – local RGO responsibility			
VIC	N/A – local RGO responsibility			

GENERAL REPORTING

HREC Annual Report

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Non receipt of annual report from CPI by due date	HREC annual report not received by due date Recommended standard letter: Reminder for an annual progress report/final report	1	CPI
	One month post non receipt of annual report from CPI	HREC annual report not received by due date, second reminder Recommended standard letter: Reminder for an annual progress report/final report Where no report rec'd, Chair to consider further action.		
	Within 10 working days of the meeting	Acknowledgement of annual report provided in writing (may be electronic). HREC annual report received by due date. Recommended standard letter: Acknowledgement of an annual progress report		CPI Copy to: PI(s). Each PI to forward to site RGO.
QLD	One month post non receipt of annual report from CPI	HREC annual report not received by due date Recommended standard letter: SL15: Reminder for Progress Report	1	CPI
	Within 10 calendar days of the HREC review of the annual report	HREC annual report received by due date Recommended standard letter: SL16: Acknowledgement of Progress Report		
SA	Within 10 working days of the HREC meeting	Acknowledgement provided in writing (may be electronic).	1	CPI
VIC	Non receipt of annual report from CPI by due date	HREC annual report not received by due date Recommended standard letter: Reminder for an annual progress report/final report	1	CPI
	By submission closing date for the HREC meeting to review the annual report	HREC annual report received by due date Recommended standard letter: Acknowledgement of an annual progress report		

HREC Final Report

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	No timeframe specified	Acknowledgement of final report provided in writing (may be electronic). HREC final report received by due date. Recommended standard letter: Acknowledgement of a final report	1	CPI
QLD	Within 10 calendar days of the HREC review of the final report	Recommended standard letter: SL17: Acknowledgement of Final Report without Results SL18: Acknowledgement of Final Results	1	CPI
SA	Within 10 working days of the HREC meeting	Acknowledgement provided in writing (may be electronic).	1	CPI Copy to: PI(s). Each PI to forward to site RGO.
VIC	By submission closing date for HREC meeting to review the final report	HREC final report received. Recommended standard letter: Acknowledgement of a final report	1	CPI

Protocol deviation or violation report

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	No timeframe specified	Format of HREC acknowledgement not specified, but should be in writing. (May be electronic). No State-wide standard letter.	1	PI Copy to: RGO
QLD	Within 10 calendar days of the HREC review of the report	No standard letter Letter should include any recommendations from the HREC to the CPI as applicable.	1	CPI
SA	Within 10 working days of the HREC meeting	No standard letter Acknowledgement provided in writing (may be electronic).	1	CPI

VIC	By submission closing date for HREC meeting	HREC acknowledgement not specified No standard letter	1	CPI

* 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 Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products* May 2009: www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

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

PART 4

RGO Correspondence Regarding a Multi-centre Human Research Project

RESEARCH GOVERNANCE APPLICATIONS

Receipt of an initial SSA application

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Not specified	Acknowledgement may be by letter or email Recommended standard letters: SSA Acknowledgement Invalid SSA Notification.	1	PI
		Access Request Review: Acknowledgement may be by letter or email No standard letter		CPI
QLD	Within 5 business days of receipt of the application	Recommended standard letters: SL1: SSA Acknowledgement and validation. SL2: Invalid SSA Notification.	1	PI
SA	Not specified	Acknowledgement may be be letter or electronic (email). If SSA is deemed invalid, PI to be notified with request to resubmit / amend SSA.	1	PI
VIC	Within 5 working days of the receipt of the SSA application	Recommended standard letters: Valid SSA form Invalid SSA form	1	PI

Research Governance decisions – authorisation process

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Timeframe not specified but must be conducted in an efficient and timely manner.	Application requiring further information requested Initial notification may be electronic No standard letter	1	PI
		Application approved Initial notification may be electronic Recommended standard letter SSA authorised.		
		Application not approved Initial notification may be electronic Recommended standard letter SSA not authorised.		
		Access Request Review outcome Will provide outcome advice in writing. Format to be determined by RGO.		CPI
QLD	Within 25 calendar days of receipt of a valid SSA form & all supporting documentation	Application requiring further information requested Initial notification may be electronic No standard letter	1	PI
		Application approved Initial notification may be electronic Recommended standard letter: SL4: Research Authorisation		
		Application not approved Initial notification may be electronic Recommended standard letter: SL5: Research not Authorised		
SA	Timeframe not specified but must be conducted in an efficient and timely manner.	Authorisation notification may be be letter or electronic (email). RGO will issue either: 1) SSA authorisation letter 2) SSA not authorised letter	1	PI
VIC	'Early action' before HREC approves ethics	SSA application requiring further information No standard letter, according to site policy	1	PI
	Written notification of SSA authorisation within 1 working day of decision (post-HREC approval)	SSA approved Recommended standard letter: SSA authorised		
	Written notification of SSA non-authorisation within 1 working day of decision (post-HREC approval)	SSA not approved Recommended standard letter: SSA not authorised		

AFTER SSA AUTHORISATION

Amendments

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Timeframe not specified but must be conducted in an efficient and timely manner.	Amendment requiring further information requested Initial notification may be electronic No standard letter	1	PI
		Amendment approved Authorisation to implement the changes must be in writing. No standard letter		
		Amendment not approved Authorisation refusal must be in writing. No standard letter		
QLD	Within 25 calendar days of receipt of a valid SSA form & all supporting documentation	Amendment requiring further information requested Initial notification may be electronic No standard letter	1	PI
		Amendment approved Initial notification may be electronic Recommended standard letter: SL8: Favourable Opinion of Post Authorisation SSA Amendment.		
		Application not approved Initial notification may be electronic Recommended standard letter: SL9: Unfavourable Opinion of post authorisation SSA amendments (with options for further review)		
SA	Timeframe not specified but must be conducted in an efficient and timely manner.	Correspondence issued may be either by letter or electronic (email). RGO will issue either: 1) SSA amendment approval letter 2) SSA amendment not approved letter	1	PI
VIC	Timely action	SSA Amendment requiring further information No standard letter. By email or letter	1	PI
		SSA Amendment validated Recommended standard letter: SSA acknowledgement and validation of an amendment		
	Within 1 working day of the authorisation decision	SSA Amendment approved Recommended standard letter: Authorisation of an SSA amendment		
		SSA Amendment not approved Recommended standard letter: Unfavourable opinion of a SSA amendment		

Withdrawal/suspension of SSA authorisation for research at a site

State or Territory	Timeframe	Format	Number of Copies	Submission
NSW	Notification is to be immediate.	Notification of suspension or withdrawal should be verbal.	1	Reviewing HREC & PI
	Course of action to be communicated within 3 working days	Following consultation with Reviewing HREC re safety issues, course of action to be documented in writing.		
QLD	Within 24 hours of decision	Recommended standard letter: SL10: Suspension/Withdrawal of District Authorisation to conduct research. Notification must include: Reasons for withdrawal of authorisation Conditions that may restore authorisation for the research to proceed Recommended actions for participants currently enrolled in the trial.	1	PI
SA	Within 24 hours of decision (where possible)	Communication should be issued by RGO in writing and verbally, where possible, clearly stating grounds for withdrawal or suspension of authorisation at the site.	1	PI

VIC	Within 24 hours of decision	No standard letter Notification must include: Reasons for withdrawal of authorisation Conditions that may restore authorisation Recommended actions for participants currently enrolled in the trial	1	PI

SAFETY REPORTING

Adverse event and serious adverse event reporting for local site

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	SAEs for all study sites under the responsibility of the RGO Timeframe not specified but must be conducted in an efficient and timely manner.	Initial notification by email No standard letter	1	PI
QLD	SAEs for all study sites under the responsibility of the RGO Notification within 5 business days of being reviewed by RGO	Notification of receipt No standard letter	1	PI
		Notification of recommendations No standard letter		Local clinical governance committee (or equivalent) if applicable
				PI
SA	SAEs for all study sites under the responsibility of the RGO, as required. If AE/SAE impacts research governance authorisation of the study at the local site, the RGO must issue advice to the PI in an efficient and timely manner.	Not specified, dependent on RGO processes and SOP's	1	PI
VIC	SAEs for all campus sites under the responsibility of the institution's RGO Notification within 5 working days of review and decision by the RGO/institution governance	RGO may have institution governance involvement according to site policy No standard letter	1	PI

Australian and international SUSARs Industry report or DSMB report

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	N/A – reports are sent to the Reviewing HREC by the CPI			
QLD	N/A – reports are sent to the Reviewing HREC by the CPI			
SA	N/A – reports are sent to the Reviewing HREC by the CPI			
VIC	N/A – reports are sent to the Reviewing HREC by the CPI			

COMPLAINTS

Complaints concerning the conduct of a project

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Timeframe not specified.	Complaints to PHO should be sent to RGO Complainant to receive acknowledgement in writing, where possible. No standard format	1	Designated person at the institution to review complaints regarding conduct of research Copy to: PI & Reviewing HREC (if applicable)
		Final outcome of investigation to be in writing. No standard format		PHO to notify final outcome to: Complainant PI / other investigators Reviewing HREC
QLD	Within 5 business days of being received by RGO	Recommended standard letter: SL25: Acknowledgement of receipt of complaint	1	PI
	Within 5 business days of being received by RGO	No standard format		The 'designated person' (as described in the *Australian Code for the responsible conduct of research*) assigned to review complaints & research misconduct.
	Notification within 5 business days of decision by Designated Person			PI Clinical governance unit if applicable Reviewing HREC
SA	Timeframe not specified	Complaints should be submitted in writing to the RGO. Complainant to receive acknowledgement in writing. No standard format	1	PI Reviewing HREC (if applicable)
VIC	Timely action	Designated person at the institution to review complaints regarding conduct of research. According to site policy. No standard format	1	PI and reviewing HREC (if applicable)

Complaints concerning the HREC's review process including the HREC's rejection of an application

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	N/A – reviewing HREC responsibility			
QLD	N/A – reviewing HREC responsibility			
SA	N/A – reviewing HREC responsibility			
VIC	N/A – reviewing HREC responsibility			

Complaints concerning the RGO's review process including authorisation decisions e.g. rejection of an application

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	No timeframe specified	Appeals on authorisation decisions to be in writing. Management of complaint to be determined by Chief Executive	1	Chief Executive (CE) Response determined by CE
QLD	Within 5 business days of being received by RGO	Receipt notification (may be electronic) No standard format	1	PI
	Within 5 calendar days of being reviewed by RGO and a decision made	Notification (initial notification may be electronic) of decision re the outcome of the complaint review No standard format		
SA	No timeframe specified, however, timely action and consideration required.	All complaints and concerns to be made in writing. The SA Health SSA Complaints and Appeals process should be followed (refer to SA Health Research Governance Policy).	1	PI
VIC	Timely action	Designated person at the institution to review complaints regarding RGO review process and decisions. According to site policy. No standard format	1	Institution's executive PI

GENERAL REPORTING

Study Annual Report

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Timeframe not specified	No standard format	1	PI (if required at site)
QLD	Within 5 calendar days of being received by RGO	Receipt notification No standard format	1	PI
SA	Timeframe not specified	Receipt notification No standard format	1	PI
VIC	Notification of receipt not specified	No standard format	1	PI (if required at site)

Study Final Report

State or Territory	Timeframe	Format	Number of Copies	Recipient(s)
NSW	Timeframe not specified	No standard format	1	PI (if required at site)
QLD	Within 5 calendar days of being received by RGO	Receipt notification No standard format	1	PI
SA	Timeframe not specified	Receipt notification No standard format	1	PI
VIC	Notification of receipt not specified	No standard format	1	PI (if required at site)

* 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 Australian Health Ethics Committee (AHEC) Position Statement: Monitoring and reporting of safety for clinical trials involving therapeutic products* May 2009: www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

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