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

MONITORING AND REPORTING TABLES

Australian Capital Territory
New South Wales
Queensland
South Australia
Victoria
Western Australia

These tables are designed to assist Investigators, HREC Coordinators and Research Governance Officers. They provide information on reporting requirements for multi-centre human research projects taking place in States and Territories. For further information, contact the jurisdiction.

	Contact	Website	Email	Phone
Australian Capital Territory	Research Ethics and Governance Office	www.health.act.gov.au/datapublications/research/human-research-ethics-committee	acthealth-hrec@act.gov.au	02 6174 5659
New South Wales	Office for Health and Medical Research	www.health.nsw.gov.au/ethics	researchethics@doh.nsw.gov.au	02 9391 9220
Queensland	Research, Ethics and Governance	www.health.qld.gov.au/ohmr/html/regu/regu_home	hiiro_reg@health.qld.gov.au	07 3708 5071
South Australia	Office for Research	www.sahealth.sa.gov.au/researchethics	researchgovernance@health.sa.gov.au	08 8226 7461
Victoria	Coordinating Office for Clinical Trial Research	www2.health.vic.gov.au/about/clinical-trials-and-research	multisite.ethics@dhhs.vic.gov.au	03 9096 7394
Western Australia	Clinical Services and Research	https://rgs.health.wa.gov.au	cmoresearchdevelopment@health.wa.gov.au	08 9222 4332

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Glossary

ACT	Australian Capital Territory
AE	Adverse Event
AU RED	Australian Research Ethics Database
CPI	Coordinating Principal Investigator
DSMB	Data and Safety Monitoring Board
HREC	Human Research Ethics Committee
IB	Investigator Brochure
NSW	New South Wales
PI	Principal Investigator
QLD	Queensland
RGO	Research Governance Officer
RGS	Research Governance Service (Western Australia)
SA	South Australia
SAE	Serious Adverse Event
SSA	Site Specific Assessment
SSI	Significant Safety Issue
SUSAR	Suspected Unexpected Serious Adverse Reaction
USADE	Unanticipated Serious Adverse Device Effect
USM	Urgent Safety Measure
VIC	Victoria
WA	Western Australia

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	Submission
ACT	SAEs no longer required		
NSW	SAEs for all study sites under the responsibility of the HREC. PI's responsibility	No State-wide form, 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	Reviewing HREC by local PI directly
SA	Not required (please refer to PI reporting requirements)		
VIC	Not required		
WA	N/A - refer to: National Health and Medical Research Council (2016) *Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods*		

Drug Research: Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the trial (Significant Safety Issue)

State or Territory	Timeframe	Format	Submission
ACT	Within 72 hours	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	PI directly to HREC with copy to CPI
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	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	Reviewing HREC by local PI directly
SA	Within 24 hours.	Report Significant Safety Issues (SSIs) that are defined as a Urgent Safety Measure (USM) using sponsor template.	CPI to advise Sponsor. Sponsor submits to reviewing HREC.
	Within 15 calendar days.	Report all other SSIs that are not defined as a Urgent Safety Measure (USM) using sponsor template.	
VIC	Within 72 hours (if significant safety issue is an Urgent Safety Measure (USM)) Within 15 calendar days (if significant safety issue is not an USM or Suspected Unexpected Serious Adverse Reaction (SUSAR))	Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI communicates with sponsor. Sponsor submits to reviewing HREC.

WA	Within 72 hours	Report Significant Safety Issues (SSIs) that are defined as a Urgent Safety Measure (USM) using WA Health Safety Report completed by Sponsor and/or CPI (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	From sponsor via CPI to Lead HREC.
	Within 15 calendar days of the sponsor instigating or being aware of the issue	Report all other SSIs that are not defined as a Urgent Safety Measure (USM) using WA Health Safety Report completed by Sponsor and/or CPI (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	

Drug Research: Australian and international SUSARs Industry report or DSMB report (Annual Safety Report and Updated Investigator's Brochure)

	Timeframe	Format	Submission
ACT	SUSARs no longer required. DSMB at least annually.	No template. Letter to HREC or RGO with a copy of the DSMB report.	CPI to lead HREC or local PI to RGO
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.	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.	Reviewing HREC
SA	Annually	As per HREC reporting requirements/template.	CPI to Reviewing HREC
VIC	Annually	Annual Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI communicates with sponsor. Sponsor submits to reviewing HREC.
WA	At least annually	Submit Annual Safety Report, updated Investigator Brochure or where applicable Product Information using WA Health Safety Report completed by Sponsor and/or CPI (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	From sponsor via CPI to Lead 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	Submission
ACT	SAEs no longer required		
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	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	Reviewing HREC by local PI directly
SA	Not required (please refer to PI reporting requirements)		
VIC	Not required		
WA	N/A - refer to: National Health and Medical Research Council (2016) *Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods.*		

Device Research: Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the investigation (Significant Safety Issue)

State or Territory	Timeframe	Format	Submission
ACT	Within 72 hours	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	CPI to lead HREC. Local PI or CPI to RGO.
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	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	Reviewing HREC by local PI directly
SA	Within 24 hours.	Report Significant Safety Issues (SSIs) that are defined as a Urgent Safety Measure (USM) in appropriate format.	CPI to advise Sponsor; Sponsor submits to reviewing HREC.
	Within 15 calendar days.	Report all other SSIs that are not defined as a Urgent Safety Measure (USM) in appropriate format	

VIC	Within 72 hours (if significant safety issue is an Urgent Safety Measure (USM)) Within 15 calendar days (if significant safety issue is not an USM or Suspected Unexpected Serious Adverse Reaction (SUSAR))	Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI communicates with sponsor. Sponsor submits to reviewing HREC.
WA	Within 72 hours.	Report Significant Safety Issues (SSIs) that are defined as a Urgent Safety Measure (USM) using WA Health Safety Report completed by Sponsor and/or CPI (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	From sponsor via CPI to Lead HREC.
	Within 15 calendar days of the sponsor instigating or being aware of the issue.	Report all other SSIs that are not defined as a Urgent Safety Measure (USM) using WA Health Safety Report completed by Sponsor and/or CPI (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	

Device Research: Australian and international USADEs Industry report or DSMB report (Annual Safety Report and Updated Investigator's Brochure)

State or Territory	Timeframe	Format	Submission
ACT	USADEs no longer required. DSMB at least annually.	No template. Letter to HREC or RGO with a copy of the DSMB report.	CPI to lead HREC or local PI to RGO
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.	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.	Reviewing HREC
SA	Annually	As per HREC submission requirements.	CPI to Reviewing HREC CPI to PIs
VIC	Annually	Annual Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI communicates with sponsor. Sponsor submits to reviewing HREC.
WA	At least annually.	Submit Annual Safety Report, updated Investigator Brochure or where applicable Instructions for Use using WA Health Safety Report completed by Sponsor and/or CPI (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	From sponsor via CPI to Lead HREC.

AMENDMENTS

Amendments

State or Territory	Timeframe	Format	Submission
ACT	As required	No standard template. PI to submit letter detailing amendments and supporting documents as required. All documents to be provided in both clean and track changes versions with version numbers, dates and summary of changes for large documents (protocol/IB)	CPI or PI to reviewing HREC. Local PI to RGO with a copy of the lead HREC approval letter.
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.	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. 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.	CPI submits to the reviewing HREC. CPI informs PI when approval obtained. PI submits a copy to local RGO
VIC	For Significant Safety Issue (SSI) requiring amendment: submitted without undue delay. Other amendment: as required.	Amendment Request Form available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI communicates with sponsor. Sponsor submits to reviewing HREC.
WA	As required, for amendments that may affect the ongoing ethical/scientific acceptability of the project.	WA Health Amendment Form (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	CPI to Lead HREC.

COMPLAINTS

Complaints concerning the conduct of a research project

State or Territory	Timeframe	Format	Submission
ACT	Not specified	No standard template. Complaints received in writing or via phone	Complainant directly to Head of Research Ethics and Governance
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	Reviewing HREC
QLD	Not specified	Not specified	Reviewing HREC. Local RGO to which the complaint applies.
SA	Not specified	As per HREC submission requirements.	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	Complaint Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI submits to site RGO in first instance. If advised by RGO, site PI provides a copy to CPI for submission to reviewing HREC, and copy to sponsor.
WA	As required, complainant responsibility (not CPI).	Complaint related to the overall conduct of the project or the protocol using the WA Health Research Complaint Form (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	Complainant to Lead HREC. The form can be completed by someone other than the complainant (e.g. the HREC on behalf of a participant) if the complaint is provided verbally. All complaints must be documented in writing.

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

State or Territory	Timeframe	Format	Submission
ACT	Not specified	No standard template. Complaints received in writing or via phone	Complainant directly to Head of Research Ethics and Governance
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	To HREC Chair in first instance and can be escalated to Institutional Chief Executive
QLD	Not specified	Not specified	Reviewing HREC
SA	Not specified	Must follow SA Health procedure concerning complaints, available in the SA Health Research Ethics Operational Policy.	To HREC Chair in first instance and can be escalated to Institutional Chief Executive
VIC	Not specified	Dependent on HREC's institutional policy	CPI to reviewing HREC
WA	As required.	WA Health Research Complaint Form (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	CPI to Lead HREC.

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

State or Territory	Timeframe	Format	Submission
ACT	Not specified	No standard template. Complaints received in writing or via phone	Complainant directly to Head of Research Ethics and Governance
NSW	No State-wide timeframe	No State-wide form, but must be in writing	CPI or PI may submit complaint to Institutional Chief Executive
QLD	N/A – Local PI responsibility		
SA	N/A – Local PI responsibility		
VIC	N/A – Site PI responsibility		
WA	N/A – PI responsibility.		

GENERAL REPORTING

Commencement of a clinical trial/investigation

State or Territory	Timeframe	Format	Submission
ACT	To be reported in the first annual progress report	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	CPI or PI to HREC or local PI to RGO with a copy of the lead HREC acknowledgement letter, if applicable.
NSW	To be reported in the first annual progress report	No State-wide form, template stipulated by the reviewing HREC	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	Reviewing HREC
SA	To be reported in the first progress report	No State-wide form, template stipulated by the reviewing HREC	Reviewing HREC PI submits a Site Report copy to RGO
VIC	To be reported in first progress report	Progress Report - Project Form available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI communicates with sponsor. Sponsor submits to reviewing HREC.
WA	Reported in first Annual Progress Report (annual or as required by Lead HREC).	Annual Progress Report completed by CPI and PI with both whole of project and site specific details (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	CPI to Lead HREC (following insertion of site report by PI).

HREC Annual Report

State or Territory	Timeframe	Format	Submission
ACT	Annually from date of HREC approval (More frequent updates if directed by HREC)	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	CPI or PI to HREC or local PI to RGO with a copy of the lead HREC acknowledgement letter, if applicable.
NSW	Annually from date of HREC approval (More frequent updates if directed by HREC)	No State-wide form, template stipulated by the reviewing HREC	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	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	Reviewing HREC
VIC	Annually from date of HREC approval or date specified by HREC (or more frequently if directed by reviewing HREC)	Progress Report - Project Form available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI communicates with sponsor. Sponsor submits to reviewing HREC.
WA	Annually from Lead HREC approval date (or more frequent if required by Lead HREC).	Annual Progress Report completed by CPI and PI with both whole of project and site specific details (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	CPI to Lead HREC (following insertion of site report by PI).

HREC Final Report

State or Territory	Timeframe	Format	Submission
ACT	As soon as possible	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	CPI or PI to HREC or local PI to RGO with a copy of the lead HREC acknowledgement letter, if applicable.
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, template stipulated by the reviewing HREC	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	Reviewing HREC
SA	Within 30 calendar days of study completion	No State-wide form, template stipulated by the reviewing HREC	Reviewing HREC with copy provided to RGO by PI
VIC	Not specified	Project Final Report/Site Closure Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI communicates with sponsor. Sponsor submits to reviewing HREC.
WA	Within 30 calendar days of the project completion# at all sites.	WA Health Final Report (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	CPI to Lead HREC.

Research project closure at a site

State or Territory	Timeframe	Format	Submission
ACT	As soon as possible	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	Local PI to RGO with copy to CPI. CPI to HREC if lead site/HREC.
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, 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
SA	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	CPI to advise HREC PI to forward copy to RGO
VIC	Not specified	Project Final Report/Site Closure Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI (and/or site PI at closing site) communicates with sponsor. Sponsor submits to reviewing HREC.
WA	Within 30 calendar days of the project completion# at a site.	WA Health Final Report completed by PI with site specific details (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	CPI to Lead HREC (following completion of report by PI).

Protocol deviation or violation report (Serious Breach)

State or Territory	Timeframe	Format	Submission
ACT	As soon as possible	PI to provide letter detailing deviation/violation, reason and resolution	Local PI to RGO with copy to CPI. CPI to HREC if lead site/HREC.
NSW	In a timely manner. PI's responsibility.	No State-wide form, as per reviewing HREC requirements	Reviewing HREC by local PI directly and copy of report to RGO
QLD	Not specified	Not specified	Reviewing HREC
SA	Not specified	No State-wide form, template stipulated by the reviewing HREC	CPI completes and submits to the reviewing HREC on notification by PIs. RGO only advised if further action required.
VIC	Not specified	Protocol Deviation or Violation Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	CPI communicates with site PI (at site where event occurred) and sponsor. Sponsor submits to reviewing HREC.
WA	Within 7 days. May be required to provide follow up reports as required.	WA Health Safety Report completed by Sponsor and/or CPI (https://rgs.health.wa.gov.au/Pages/Research-Ethics.aspx).	From sponsor via CPI to Lead 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.

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

In WA project completion is when no further contact with participants/data source is foreseen and includes the data analysis and reporting period.

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	Submission
ACT	SAEs no longer required		
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	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.	Submission directly to reviewing HREC by local PI Reviewing HREC is to respond directly to submitting PI
			Sponsor
			CPI
			Local RGO
SA	AE: As required and in accordance with the protocol.	Using the sponsor template.	PI to Sponsor.
	SAE: Within 24 hours of becoming aware of the event and in accordance with the protocol.	Using the sponsor template.	PI to Sponsor.
VIC	SAE: within 24 hours of becoming aware of the event.	Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI communicates with CPI and sponsor. Sponsor submits to reviewing HREC.
WA	AE: As required and in accordance with the protocol.	Capture and assess all AEs that occur at the site in accordance with the protocol using the sponsor template.	PI to Sponsor.
	SAE: Within 24 hours of becoming aware of the event and in accordance with the protocol.	All SAEs, except those that are identified in the protocol as not needing immediate reporting using the sponsor template.	PI to Sponsor.

Drug Research: Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the trial (Significant Safety Issue)

State or Territory	Timeframe	Format	Submission
ACT	Within 72 hours	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	CPI to lead HREC. Local PI or CPI to RGO.
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	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.	Submission directly to reviewing HREC by local PI Reviewing HREC is to respond directly to submitting PI Sponsor CPI Local RGO
SA	Within 24 hours of becoming aware of the event.	All SAEs (as per protocol), congenital abnormality/birth defect, Urgent Safety Measure (USM) instigated at site and safety critical events (as specified by the protocol) using the sponsor template.	PI to Sponsor.
	Within 72 hours of becoming aware of the event.	All Significant Safety Issues and SUSARs arising at the local site in format specified by RGO.	PI to RGO.
VIC	SAE, congenital anomaly/birth defect or USM: within 24 hours of becoming aware of the event SSI or SUSAR: within 72 hours	Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI communicates with CPI and sponsor. Sponsor submits to reviewing HREC. Site PI submits to site RGO.
WA	Within 24 hours of becoming aware of the event.	All SAEs (as per protocol), congenital abnormality/birth defect, Urgent Safety Measure (USM) instigated at site and safety critical events (as specified by the protocol) using the sponsor template.	PI to Sponsor.
	Within 72 hours of becoming aware of the event.	All Significant Safety Issues and SUSARs arising at the local site using the WA Health Safety Report (https://rgs.health.wa.gov.au/Pages/Research-Governance.aspx).	PI to RGO.

Drug Research: Australian and international SUSARs Industry report or DSMB report (Annual Safety Report and Updated Investigator's Brochure)

State or Territory	Timeframe	Format	Submission
ACT	SUSARs no longer required. DSMB at least annually.	No template. Letter to HREC or RGO with a copy of the DSMB report.	CPI to lead HREC or local PI to RGO.
NSW	SUSARs occurring at site are the PI's responsibility	No State-wide form, as per reviewing HREC, with comments from PI	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.	CPI
SA	Australian & SUSAR Industry Reports are a CPI responsibility.	Please refer to instructions against the CPI section.	
VIC	Annually	Annual Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI communicates with CPI. Site PI submits to site RGO.
WA	As required (by sponsor).	Provide updated Investigator Brochure or where applicable Product Information.	Sponsor to CPI/PI.

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

State or Territory	Timeframe	Format	Submission
ACT	SAEs no longer required		
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	Reviewing HREC CPI RGO (If specified in protocol) sponsor
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.	Submission directly to reviewing HREC by local PI Reviewing HREC is to respond directly to submitting PI Sponsor CPI Local RGO
SA	AE/Device Deficiency: As required and in accordance with the clinical investigation plan.	Using the sponsor template.	PI to Sponsor.

	SAE/Device Deficiency: Without unjustified delay.	Using the sponsor template.	PI to Sponsor.
VIC	Without unjustified delay	Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI communicates with CPI and sponsor. Sponsor submits to reviewing HREC. Site PI submits to site RGO.
WA	AE/Device Deficiency: As required and in accordance with the clinical investigation plan.	Record and assess all AEs and observed device deficiency that occur at the site in accordance with the clinical investigation plan using the sponsor template.	PI to Sponsor.
	SAE/Device Deficiency: Without unjustified delay.	All SAEs and device deficiencies that could have led to a serious adverse device effect (SADE) using the sponsor template.	PI to Sponsor.

Device Research: Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the investigation (Significant Safety Issue)

State or Territory	Timeframe	Format	Submission
ACT	Within 72 hours	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	CPI to lead HREC. Local PI or CPI to RGO.
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	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.	Submission directly to reviewing HREC by local PI Reviewing HREC is to respond directly to submitting PI Sponsor CPI Local RGO
SA	Within 24 hours.	All SAEs and device deficiencies that could have led to a serious adverse device effect (SADE) or congenital abnormality/birth defect using the sponsor template. Follow up any pregnancy until outcome.	PI to Sponsor.
	Within 24 hours.	Any Urgent Safety Measure instigated at site, using sponsor template.	PI to Sponsor.
	Within 72 hours.	All Significant Safety Issues and USADEs occurring at the local site in format specified by RGO.	PI to RGO.
VIC	USM: within 24 hours SSA or USADE: within 72 hours	Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI communicates with CPI and sponsor. Sponsor submits to reviewing HREC. Site PI submits to site RGO.

WA	Within 24 hours.	All SAEs and device deficiencies that could have led to a serious adverse device effect (SADE), congenital abnormality/birth defect, Urgent Safety Measure (USM) instigated at site using the sponsor template. Follow up any pregnancy until outcome.	PI to Sponsor.
	Within 72 hours of the PI becoming aware of the event.	All Significant Safety Issues and USADEs occurring at the local site using the WA Health Safety Report (https://rgs.health.wa.gov.au/Pages/Research-Governance.aspx).	PI to RGO.

Device Research: Australian and international USADEs Industry report or DSMB report (Annual Safety Report and Updated Investigator's Brochure)

State or Territory	Timeframe	Format	Submission
ACT	USADEs no longer required. DSMB at least annually.	No template. Letter to HREC or RGO with a copy of the DSMB report.	CPI to lead HREC or local PI to RGO
NSW	USADEs occurring at site are the PI's responsibility	No State-wide form, as per reviewing HREC, with comments from PI	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 or line 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.	CPI
SA	Australian & USADE Industry Reports or DSMB reports are a CPI responsibility.	Please refer to instructions against the CPI section.	
VIC	Annually	Annual Safety Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI communicates with CPI. Site PI submits to site RGO.
WA	As required (by sponsor).	Provide updated Investigator Brochure or where applicable Instructions for Use.	Sponsor to CPI/PI.

AMENDMENTS

Amendments

State or Territory	Timeframe	Format	Submission
ACT	As required	No standard template. PI to submit letter detailing amendments and supporting documents as required. All documents to be provided in both clean and track changes versions with version numbers, dates and summary of changes for large documents (protocol/IB).	CPI or PI to reviewing HREC. Local PI to RGO with a copy of the lead HREC approval letter.
NSW	As required	No State-wide form, as requested by the 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 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	CPI submits to the reviewing HREC. CPI informs PI when approval obtained. PI submits a copy to local RGO
VIC	As required	Amendment Request Form available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI communicates with CPI. Site PI submits to site RGO.
WA	As required, for amendments that may have impact on site authorisation.	WA Health Amendment Form (https://rgs.health.wa.gov.au/Pages/Research-Governance.aspx).	PI to RGO.

COMPLAINTS

Complaints concerning the conduct of a research project

State or Territory	Timeframe	Format	Submission
ACT	Not specified	No standard template. Complaints received in writing or via phone	Complainant directly to Head of Research Ethics and Governance
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	PI sends to CPI who reports to reviewing HREC PI sends report to RGO
QLD	Not specified	Not specified	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.	PI sends to CPI who reports to reviewing HREC PI sends report to RGO
VIC	Not specified	Complaint Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI submits to site RGO in first instance. If advised by RGO, site PI provides a copy to CPI for submission to reviewing HREC, and copy to sponsor.
WA	As required, complainant responsibility (not PI).	Complaint related to the conduct of the project specifically at the site using the WA Health Research Complaint Form (https://rgs.health.wa.gov.au/Pages/Research-Governance.aspx).	Complainant to RGO. The form can be completed by someone other than the complainant (e.g. the RGO on behalf of a participant) if the complaint is provided verbally. All complaints must be documented in writing.

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

State or Territory	Timeframe	Format	Submission
ACT	Not specified	No standard template. Complaints received in writing or via phone	Complainant directly to Head of Research Ethics and Governance
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, 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	N/A – CPI responsibility		
WA	N/A – CPI responsibility		

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

State or Territory	Timeframe	Format	Submission
ACT	Not specified	No standard template. Complaints received in writing or via phone	Complainant directly to Head of Research Ethics and Governance
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, as per reviewing HREC requirements	To Institutional Chief Executive
QLD	Not specified	Not specified	CPI Local RGO
SA	As required	Must follow SA Health procedure concerning research governance complaints, available in the SA Health Research Governance Policy.	RGO
VIC	Not specified	Dependent on PI's institutional policy	Institutional governance process
WA	As required.	WA Health Research Complaint Form (https://rgs.health.wa.gov.au/Pages/Research-Governance.aspx).	PI to RGO.

GENERAL REPORTING

Commencement of a clinical trial/investigation

State or Territory	Timeframe	Format	Submission
ACT	To be reported in the first annual progress report	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	CPI or PI to HREC or local PI to RGO with a copy of the lead HREC acknowledgement letter, if applicable
NSW	To be reported in the first annual progress report	No State-wide form, 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.d	CPI Site RGO
SA	To be reported in the first progress report	No State-wide form, as per reviewing HREC requirements	PI to CPI PI to RGO
VIC	To be reported in first progress report	Progress Report - Site Form available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI submits to site RGO.
WA	Reported in first Annual Progress Report (annual or as required by Lead HREC).	Annual Progress Report completed by CPI and PI with both whole of project and site specific details (https://rgs.health.wa.gov.au/Pages/Research-Governance.aspx).	PI to RGO.

HREC Annual Report

State or Territory	Timeframe	Format	Submission
ACT	Annually from date of HREC approval (More frequent updates if directed by HREC)	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	CPI or PI to HREC or local PI to RGO with a copy of the lead HREC acknowledgement letter, if applicable
NSW	Annually from date of HREC approval (More frequent updates if directed by HREC)	No State-wide form, template stipulated by the reviewing HREC	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	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 or date specified by HREC (or more frequently if directed by reviewing HREC)	As requested	Site PI communicates with CPI. Progress Report - Project Form (HREC annual report) is responsibility of sponsor, with CPI consultation. PI may be asked to provide information for inclusion in report. According to site policy, site PI may submit to site RGO.
WA	Annually from Lead HREC approval date (or more frequent if required by Lead HREC).	Annual Progress Report completed by CPI and PI with both whole of project and site specific details (https://rgs.health.wa.gov.au/Pages/Research-Governance.aspx).	PI to RGO.

HREC Final Report

State or Territory	Timeframe	Format	Submission
ACT	As soon as possible	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	CPI or PI to HREC or local PI to RGO with a copy of the lead HREC acknowledgement letter, if applicable
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, template stipulated by the reviewing HREC	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	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	As requested	Site PI communicates with CPI. Project Final Report/Site Closure Report is responsibility of sponsor, with CPI consultation. PI may be asked to provide information for inclusion in report. Site PI submits to site RGO.
WA	N/A – CPI responsibility.		

Research project closure at a site

State or Territory	Timeframe	Format	Submission
ACT	As soon as possible	Template to be completed: www.health.act.gov.au/datapublications/research/human-research-ethics-committee	Local PI to RGO with copy to CPI. CPI to HREC if lead site/HREC.
NSW	No State-wide timeframe, as per reviewing HREC requirements	No State-wide form, 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

SA	Not specified	No State-wide form, as per reviewing HREC/RGO requirements	HREC PI to CPI PI to local RGO
VIC	Not specified	Project Final Report/Site Closure Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI at closing site communicates with CPI and sponsor. Site PI submits to site RGO.
WA	Within 30 calendar days of the project completion# at a site.	WA Health Final Report completed by PI with site specific details (https://rgs.health.wa.gov.au/Pages/Research-Governance.aspx).	PI to RGO and copy to CPI (to notify Lead HREC).

Protocol deviation or violation report (Serious Breach)

State or Territory	Timeframe	Format	Submission
ACT	As soon as possible	PI to provide letter detailing deviation/violation, reason and resolution	Local PI to RGO with copy to CPI. CPI to HREC if lead site/HREC.
NSW	"In a timely manner"	No State-wide form, 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.	Local RGO CPI
SA	Not specified	No State-wide form, 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	Protocol Deviation or Violation Report available at https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting	Site PI (at site where event ocurred) communicates with CPI and sponsor informed. Site PI submits to site RGO.
WA	Within 72 hours of becoming aware of the suspected breach.	Sponsor template.	PI to sponsor.
	Within 72 hours of being notified and confirmed by the sponsor that a serious breach has occurred at the site.	WA Health Safety Report (https://rgs.health.wa.gov.au/Pages/Research-Governance.aspx).	PI 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.

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

In WA project completion is when no further contact with participants/data source is foreseen and includes the data analysis and reporting period.

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	Recipient(s)
ACT	HREC Applications are acknowledged as soon as possible after receipt	Acknowledgement is sent via email confirming reference number and meeting date	CPI, coordinator, person who sent electronic submission
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	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	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.	CPI
VIC	On receipt of a HREC application, notification of the valid status within 3 working days.	Recommended to use AU RED email facility.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Within 3 calendar days of receipt of a ethics (HREC) application, validate and provide validation status.	RGS standard validation email notification with status of valid, additional information required and not valid.	CPI and CPI Delegate.

HREC Decision

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 working days after the HREC meeting decision date. A 30 working day benchmark for HREC decision applies.	Request for further information Advise the CPI to submit a satisfactory response as soon as possible Application approved includes list of approved documents, duration of HREC approval and conditions of approval	CPI, PI, Coordinator

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).	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
QLD	Within 60 calendar days of 'clock start' – HREC closing date	Application not requiring HREC review Initial notification may be electronic Recommended standard letter: SL5 Not requiring review by HREC	CPI
		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.	
		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)	
		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	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	Notification of the HREC decision within 5 working days after the HREC meeting date	Recommended to use AU RED email facility; letter can be attached. Request for further information should clearly identify the requirements and advise the CPI to submit a response within a specified timeframe. Approval notification should include: list of sites approved, list of documentation reviewed and approved with version date, duration of HREC approval. Not-approved notification should provide explanation.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Within 7 calendar days after the HREC meeting date.	RGS standard letters informing of the HREC decision. If additional information required, the CPI must respond within 4 months.	CPI and CPI Delegate.

POST-APPROVAL

Amendments

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 working days after the HREC meeting date. A 30 working day benchmark for HREC decision applies.	Request for further information Advise the CPI to submit a satisfactory response as soon as possible Application approved includes list of approved documents, duration of HREC approval and conditions of approval	CPI, PI, Coordinator
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* .	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	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.	CPI
VIC	Within 5 working days of the HREC meeting date.	Recommended to use AU RED email facility; letter can be attached.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Within 3 calendar days of receipt of a ethics amendment, validate and provide validation status.	RGS standard validation email notification with status of valid, additional information required and not valid.	CPI and CPI Delegate.
	Within 7 calendar days after the HREC meeting date.	RGS standard letters informing of the HREC decision. If additional information required, the CPI must respond within 4 months.	

Withdrawal/Suspension of Ethical Approval

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 24 hours of HREC decision	No standard letter	CPI, PI, Coordinator
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	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.	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	CPI CPI to provide copies to the PI and RGO at each site where study is being conducted.
VIC	Immediate	Recommended to use AU RED email facility; letter can be attached.	CPI Copy to: PI(s), RGO, sponsor, trial coordinator
WA	Within 24 hours of the HREC decision.	RGS standard letters informing of the HREC decision.	CPI and CPI Delegate.

SAFETY REPORTING

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

State or Territory	Timeframe	Format	Recipient(s)
ACT	SAEs no longer required		
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	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	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	CPI
VIC	Not required		
WA	N/A - refer to: National Health and Medical Research Council (2016) *Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods.*		

Adverse and serious adverse event reporting: material impact on the continued ethical acceptability of the trial (Significant Safety Issue)

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 working days of HREC decision	Standard letter	CPI, PI, Coordinator
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	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	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	CPI
VIC	HREC to notify within 5 working days of review or HREC meeting date	Recommended to use AU RED email facility; letter can be attached. Notification should include HREC decision re continued ethical acceptability of the research project.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Significant Safety Issue only: Within 24 hours of the HREC decision.	RGS standard letters informing of the HREC decision.	CPI and CPI Delegate.

Australian and international SUSARs Industry report or DSMB report (Annual Safety Report and Updated Investigator's Brochure)

State or Territory	Timeframe	Format	Recipient(s)
ACT	SUSARs no longer required Within 5 working days of HREC decision	Standard letter	CPI, PI, Coordinator
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	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	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	CPI
VIC	Not specified	Recommended to use AU RED email facility; letter can be attached. Notification should include HREC acknowledgement/decision re continued ethical acceptability of the research project. Notification according to reviewing HREC policy.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Within 7 calendar days after the HREC meeting date.	RGS standard letters informing of the HREC decision.	CPI and CPI Delegate.

COMPLAINTS

Complaints concerning the conduct of a project

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 working days of receipt	Standard letter	Complainant
NSW	No timeframe specified.	Acknowledgement in writing to be sent to complainant, where possible. No State-wide standard letter.	Complainant
QLD	Notification within 7 calendar days of being received by HREC	Recommended standard letter: SL25: Acknowledgement of receipt of complaint	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.	Complainant Discretion to notify CPI
VIC	Not specified	Recommended to use AU RED email facility; letter can be attached. Notification should include HREC decision re continued ethical acceptability of the research project.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Within 7 calendar days of the complaint being received by the HREC related to the overall conduct of the project. Following resolution of the complaint, within 7 calendar days after the HREC meeting date.	RGS standard letter: • Acknowledge receipt of complaint. • Outcome of complaint review.	Complainant, CPI, CPI Delegate.

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

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 working days of receipt	Standard letter	Complainant
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.	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	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.	CPI
VIC	Not specified	Recommended to use AU RED email facility; letter can be attached. Notification should include explanation of HREC decision.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Within 7 calendar days of the complaint being received by the HREC. Following resolution of the complaint, within 7 calendar days after the HREC meeting date.	RGS standard letter: • Acknowledge receipt of complaint. • Outcome of complaint review.	CPI and CPI Delegate.

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

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 working days of receipt	Standard letter	Complainant
NSW	N/A – local RGO responsibility		
QLD	N/A – local RGO responsibility		
SA	N/A – local RGO responsibility		
VIC	N/A – site RGO responsibility		
WA	N/A – RGO responsibility		

GENERAL REPORTING

HREC Annual Report

State or Territory	Timeframe	Format	Recipient(s)
ACT	Progress report reminders are sent to PI/coordinator one month before due date	Standard letter	CPI, PI, Coordinator
	Progress reports may be received without reminder from HREC		
	All progress reports submissions are acknowledged within 5 days of HREC meeting date		
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	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	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).	CPI
VIC	Request/reminder and receipt notification according to reviewing HREC policy.	Recommended to use AU RED email facility; letter can be attached.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Within 7 calendar days after the HREC meeting date.	RGS standard letters informing of the HREC decision.	CPI and CPI Delegate.

HREC Final Report

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 days of HREC meeting date	Standard letter	CPI, PI, Coordinator

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	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	CPI
SA	Within 10 working days of the HREC meeting	Acknowledgement provided in writing (may be electronic).	CPI Copy to: PI(s). Each PI to forward to site RGO.
VIC	Request/reminder and receipt notification according to reviewing HREC policy.	Recommended to use AU RED email facility; letter can be attached.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Within 7 calendar days after the HREC meeting date.	RGS standard letters informing of the HREC decision.	CPI and CPI Delegate.

Protocol deviation or violation report (Serious Breach)

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 days of HREC meeting date	Standard letter	CPI, PI, Coordinator
NSW	No timeframe specified	Format of HREC acknowledgement not specified, but should be in writing. (May be electronic). No State-wide standard letter.	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.	CPI
SA	Within 10 working days of the HREC meeting	No standard letter Acknowledgement provided in writing (may be electronic).	CPI
VIC	Not specified	Recommended to use AU RED email facility; letter can be attached.	CPI (and all others nominated by the CPI in Online Forms to receive email notifications)
WA	Serious Breach: Within 24 hours of the HREC decision.	RGS standard letters informing of the HREC decision.	CPI and CPI Delegate.

* 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.

*** 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	Recipient(s)
ACT	RGO applications are acknowledged as soon as possible after receipt	Acknowledgement is sent via email confirming reference number and meeting date	CPI, coordinator, person who sent electronic submission
NSW	Not specified	Acknowledgement may be by letter or email Recommended standard letters: SSA Acknowledgement Invalid SSA Notification.	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.	PI
SA	Not specified	Acknowledgement may be letter or electronic (email). If SSA is deemed invalid, PI to be notified with request to resubmit / amend SSA.	PI
VIC	Notification of the valid status within 5 working days of receipt of SSA application	Recommended to use AU RED email facility; letter can be attached.	PI (and all others nominated in Online Forms to receive email notifications)
WA	Within 3 calendar days of receipt of a governance (SSA) application, validate and provide validation status.	RGS standard validation email notification with status of valid, additional information required and not valid.	PI and PI Delegate.

Research Governance decisions – authorisation process

State or Territory	Timeframe	Format	Recipient(s)
ACT	As soon as possible. A 30 working day benchmark for decision applies	Request for further information Advise the CPI to submit a satisfactory response as soon as possible Application approved includes list of approved documents, duration of HREC approval and conditions of approval	CPI, PI, coordinator
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	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	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 letter or electronic (email). RGO will issue either: 1) SSA authorisation letter 2) SSA not authorised letter	PI
VIC	Notification of site RGO decision within 1 working day of decision	Recommended to use AU RED email facility; letter can be attached.	PI (and all others nominated in Online Forms to receive email notifications)
WA	Within 7 calendar days of either the RGO review or the Chief Executive/delegate decision.	RGS standard letters informing of either the RGO review if additional information is required or the Chief Executive/delegate decision. If additional information required, the PI must respond within 4 months.	PI and PI Delegate.

AFTER SSA AUTHORISATION

Amendments

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 working days of receiving the submission. A 30 working day benchmark for HREC decision applies.	Request for further information Advise the CPI to submit a satisfactory response as soon as possible Application approved includes list of approved documents, duration of HREC approval and conditions of approval	CPI, PI, Coordinator
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	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	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	PI
VIC	Notification of site RGO decision within 1 working day of decision	Recommended to use AU RED email facility; letter can be attached.	PI (and all others nominated in Online Forms to receive email notifications)
WA	Within 3 calendar days of receipt of a governance amendment, validate and provide validation status.	RGS standard validation email notification with status of valid, additional information required and not valid.	PI and PI Delegate.
	Within 7 calendar days after the Chief Executive/delegate decision.	RGS standard letters informing of the Chief Executive/delegate decision. If additional information required, the PI must respond within 4 months.	

Withdrawal/suspension of SSA authorisation for research at a site

State or Territory	Timeframe	Format	Submission
ACT	Within 24 hours of RGO decision	No standard letter	CPI, PI, Coordinator
NSW	Notification is to be immediate.	Notification of suspension or withdrawal should be verbal.	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.	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.	PI
VIC	Within 24 hours of decision	Recommended to use AU RED email facility; letter can be attached. Notification must include reason for withdrawal of authorisation, conditions that may restore authorisation, recommended actions for participants currently enrolled in the research project.	PI (and all others nominated in Online Forms to receive email notifications)
WA	Within 24 hours of the Chief Executive/delegate decision.	RGS standard letters informing of the Chief Executive/delegate decision.	PI and PI Delegate.

SAFETY REPORTING

Adverse event and serious adverse event reporting for local site

State or Territory	Timeframe	Format	Recipient(s)
ACT	SAEs no longer required		
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	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	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	PI
VIC	Notification within 5 working days of review/decision by site RGO	Recommended to use AU RED email facility; letter can be attached.	PI (and all others nominated in Online Forms to receive email notifications)
WA	Significant Safety Issue and local SUSAR/USADE only: Within 24 hours of the Chief Executive/delegate decision.	RGS standard letters informing of the Chief Executive/delegate decision.	PI and PI Delegate.

Australian and international SUSARs Industry report or DSMB report

State or Territory	Timeframe	Format	Recipient(s)
ACT	SUSARs no longer required. DSMB at least annually.	Standard letter for DSMB	CPI, PI, Coordinator
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		
WA	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	Recipient(s)
ACT	Within 5 working days of receipt	Standard letter	Complainant
NSW	Timeframe not specified.	Complaints to PHO should be sent to RGO Complainant to receive acknowledgement in writing, where possible. No standard format	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	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 Reviewing HREC
SA	Timeframe not specified	Complaints should be submitted in writing to the RGO. Complainant to receive acknowledgement in writing. No standard format	PI Reviewing HREC (if applicable)
VIC	Timely action	No standard format. Institution policy.	PI and reviewing HREC (if applicable) (and all others nominated in Online Forms to receive email notifications)
WA	Within 7 calendar days of the complaint being received by the RGO related to the conduct of the project specifically at the site. Following resolution of the complaint, within 7 calendar days after the Chief Executive/delegate decision.	RGS standard letter: • Acknowledge receipt of complaint. • Outcome of complaint review.	Complainant, PI, PI Delegate.

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

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 working days of receipt	Standard letter	Complainant
NSW	N/A – reviewing HREC responsibility		
QLD	N/A – reviewing HREC responsibility		
SA	N/A – reviewing HREC responsibility		
VIC	N/A – reviewing HREC responsibility		
WA	N/A – Lead HREC responsibility.		

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

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 working days of receipt	Standard letter	Complainant
NSW	No timeframe specified	Appeals on authorisation decisions to be in writing. Management of complaint to be determined by Chief Executive	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	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).	PI
VIC	Timely action	No standard format. Institution policy.	Institution's executive PI (and all others nominated in Online Forms to receive email notifications)
WA	Within 7 calendar days of the complaint being received by the RGO related to the conduct of the project specifically at the site. Following resolution of the complaint, within 7 calendar days after the Chief Executive/delegate decision.	RGS standard letter: • Acknowledge receipt of complaint. • Outcome of complaint review.	PI and PI Delegate.

GENERAL REPORTING

Study Annual Report

State or Territory	Timeframe	Format	Recipient(s)
ACT	Progress report reminders are sent to PI/coordinator one month before due date	Standard letter	CPI, PI, Coordinator
	Progress reports may be received without reminder from HREC		
	All progress reports submissions are acknowledged within 5 days of HREC meeting date		
NSW	Timeframe not specified	No standard format	PI (if required at site)
QLD	Within 5 calendar days of being received by RGO	Receipt notification No standard format	PI
SA	Timeframe not specified	Receipt notification No standard format	PI
VIC	Site report: request/reminder and receipt notification according to site policy.	Recommended to use AU RED email facility; letter can be attached.	PI
WA	Within 7 calendar days after the RGO decision.	RGS standard letters informing of the RGO decision.	PI and PI Delegate.

Study Final Report

State or Territory	Timeframe	Format	Recipient(s)
ACT	Within 5 days of HREC meeting date	Standard letter	CPI, PI, Coordinator
NSW	Timeframe not specified	No standard format	PI (if required at site)
QLD	Within 5 calendar days of being received by RGO	Receipt notification No standard format	PI
SA	Timeframe not specified	Receipt notification No standard format	PI
VIC	Not specified	Recommended to use AU RED email facility; letter can be attached.	PI
WA	Within 7 calendar days after the RGO decision.	RGS standard letters informing of the RGO decision.	PI and PI Delegate.

* 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.

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