

Standard Operating Procedures for Research Governance Officers

**Streamlining Ethical Review of Research Projects
in Victoria and as part of National Mutual Acceptance**

Scope

Research Governance is a framework for institutions to use to ensure that research is conducted responsibly and safely and is scientifically and ethically sound. Research Governance considers legal compliance, financial management, accountability and risk management associated with research.

The Standard Operating Procedures (SOPs) are designed to provide guidance for research management staff when undertaking governance matters relating to the streamlined ethical review in Victoria and under the National Mutual Acceptance (NMA) initiative.

These SOPs describe the regulatory aspects of a clinical trial or health/medical research project. For guidance on the conduct of research visit <http://ichgcp.net>.

These SOPs provide guidance only; they do not describe research processes in their entirety, and should not be relied upon as a sole source of information for conduct of a research project.

Specific SOPs are also available for *Coordinators of Reviewing HRECs*, and on *Streamlining Ethical Review of Research Projects* for investigators, project coordinators, sponsors, CROs and other parties; these provide general guidance on clinical trials and health/medical research.

The Research Governance process involves cooperation between the Principal Investigator (PI) responsible for a research project at a site and the Research Governance Officer (RGO). Research Governance is intended to ensure that documentation is appropriate for site assessment so that a decision can be made by an organisation to either conduct or not conduct the research.

A guidance booklet, **Research Governance and Site Specific Assessment - Process and Practice**, is available to download from www2.health.vic.gov.au/about/clinical-trials-and-research.

It is a practical guide for research governance officers, investigators/trial coordinators and sponsors/contract research organisations.

The research governance assessment by an RGO at a site may involve, but will not be limited to, assessment of the following:

- Compatibility of the research project with the organisation's research aims
- Feasibility of the research project with consideration of the required resources at the organisation (e.g. financial, human resources, infrastructure)
- Expertise and experience of researchers, and ensuring that training for research staff is undertaken as required
- Compliance of the research project with relevant laws, policies and guidelines (such as radiation safety, confidentiality, intellectual property, biosafety and licensing standards)

Following the commencement of a research project, the RGO should also be involved in:

- Coordination of on-site monitoring of research projects
- Handling complaints relating to the conduct of research at the site.

For queries regarding these SOPs, or the ethics and governance processes for research projects in Victoria and NMA, please contact the Coordinating Office.

Tel. 03 9096 7398 or email multisite.ethics@dhhs.vic.gov.au

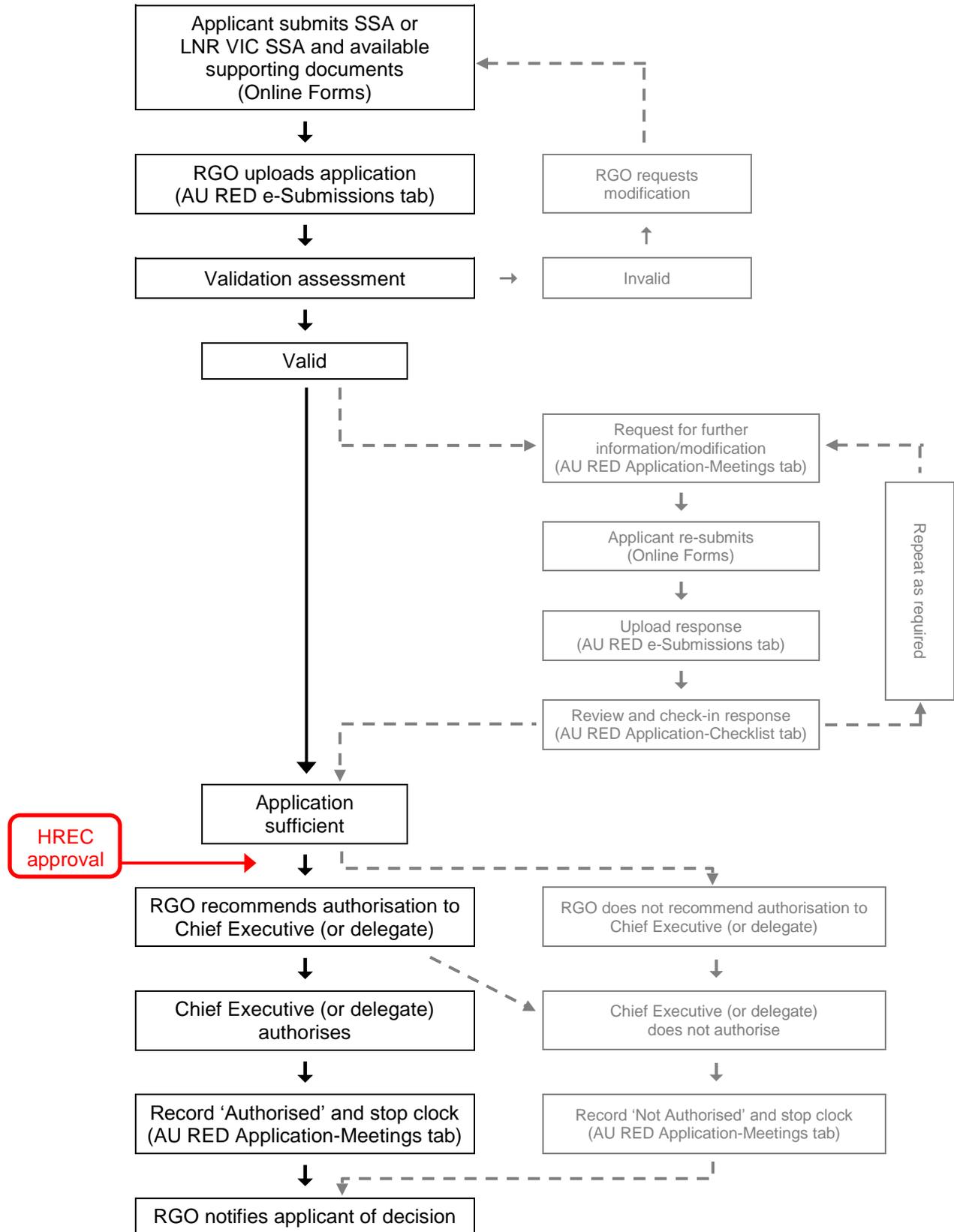
Clinical Trials and Research website: www2.health.vic.gov.au/about/clinical-trials-and-research.

Contents

- SOP 01 Early Action for Timely Governance**
- SOP 02 Review of CTRA and CIRA**
- SOP 03 Insurance and Indemnity Requirements**
- SOP 04 SSA or LNR VIC SSA Application Processing**
- SOP 05 SSA Validation**
- SOP 06 After HREC Approval**
- SOP 07 SSA Review and Decision**
- SOP 08 SSA Amendments**
- SOP 09 Reporting on progress of a project at a site**
- SOP 10 Safety Reporting**
- SOP 11 Complaints**

Glossary	
ACT	Australian Capital Territory
AE	Adverse Event
AHEC	Australian Health Ethics Committee
ARPANSA	Australian Radiation Protection and Nuclear Safety Agency
AU RED	Australian Research Ethics Database
CAS	Central Allocation System (Victoria)
CCS	Central Coordinating Service (Queensland)
CIRA	Clinical Investigation Research Agreement
CPI	Coordinating Principal Investigator
CRG	Collaborative Research Group
CRO	Contract Research Organisation
CTN	Clinical Trial Notification
CTX	Clinical Trial Exemption
CTRA	Clinical Trial Research Agreement
DHHS	Department of Health and Human Services (Victoria)
FTIH	First Time in Human
HREA	Human Research Ethics Application
HREC	Human Research Ethics Committee
IMA	Interstate Mutual Acceptance (superseded by NMA)
LNR	Low and Negligible Risk
LNR VIC	Victorian Low and Negligible Risk application form
LNR VIC SSA	Victorian Low and Negligible Risk Site Specific Assessment application form
MA	Medicines Australia
MOU	Memorandum of Understanding
MTAA	Medical Technology Association of Australia
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance
NSW	New South Wales
PI	Principal Investigator
PICF	Participant Information and Consent Form
QLD	Queensland
RGO	Research Governance Officer
RSO	Radiation Safety Officer
SA	South Australia
SAE	Serious Adverse Event
SCD	Submission Closing Date
SEBS	Southern Eastern Border States
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
SUSAR	Suspected Unexpected Serious Adverse Reaction
TGA	Therapeutic Goods Administration
USADE	Unanticipated Serious Adverse Device Effect
VIC	Victoria
VMIA	Victorian Managed Insurance Authority
VSM	Victorian Specific Module
WA	Western Australia
WASM	Western Australian Specific Module

Figure 1. Overview of research governance/SSA process



SOP 01 Early Action for Timely Governance

Purpose To describe initial administrative activity to ensure relevant site-specific departmental approvals are obtained

- 1.1 The RGO should encourage the research project's PI to submit their SSA application early, provide assistance or advice to the PI as needed, and ensure that the PI provides proof of local investigator appointment status.
- 1.2 The **Research Governance Cover Letter and Checklist** (available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research) details the documents to be submitted to the RGO at each stage of the research governance process. It should be used by both the PI and RGO to track document submission.
- 1.3 For a commercially sponsored project, the Australian sponsor should provide study documentation to the site PI as soon as it is agreed that the site will participate in the research project. The PI should commence collecting and preparing site-specific documentation relating to the research governance process as soon as the pre-submission material is received from the sponsor. The RGO should encourage the PI to submit these documents for research governance assessment as early as possible. Required documents may include:
 - Detailed budget (draft)
 - Research Governance review fee
 - Project protocol
 - Standard Form of Indemnity
 - Insurance Certificate
 - Clinical Trial Research Agreement (CTRA)
 - Radiation assessment – if radiation exposure is additional to that received as normal clinical management/care an independent assessment report by a Medical Physicist of the total effective dose, relevant organ doses and a risk assessment is required for review by an ethics committee.
 - Supporting service department approvals, e.g. nursing, health information, radiology/medical imaging, pathology, pharmacy, tissue bank(s), commitment from interpreting service, budget approval
- 1.4 The RGO should encourage the PI to submit (from Online Forms) the completed documents for research governance assessment as soon as they are available. It is not necessary for all documents to be completed and submitted at the same time. A partial or fully complete SSA form or LNR VIC SSA form may be submitted from Online Forms with available supporting documents. This allows the RGO to assess the documents and obtain legal or other review without causing a delay to the overall governance process.
- 1.5 A **Research Governance Cover Letter and Checklist** (available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research) should be submitted with the research governance/SSA documentation. It provides a summary and any additional information to inform the RGO.

E-submission of a SSA

- 1.6 The SSA form and supporting documents can be viewed on the AU RED **e-Submissions** tab (refer to *AU RED Training Manual (version 2)* page 41). If the SSA application is not satisfactory, the RGO should contact the PI and request that they recall the application (in Online Forms) to address shortcomings.

If the SSA application from is acceptable, select the 'Upload' button. After uploading a SSA application into AU RED (including all supporting documents uploaded by the applicant on the Online Forms website), the RGO can proceed with the SSA assessment.

SOP 02 Review of CTRA and CIRA

Purpose To describe the procedures for review of a Clinical Trial Research Agreement (CTRA) or Clinical Investigation Research Agreement (CIRA)

- 2.1 In accordance with the *Australian Code for the Responsible Conduct of Research* (NHMRC, 2007), organisations involved in a joint research program, such as an externally sponsored clinical trial, should ensure that an agreement is reached between the parties on the management of the research. This agreement should be in writing.
- 2.2 Standard clinical trial research agreements for commercially sponsored clinical trials are available on the Medicines Australia website <https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/> and Medical Technology Association of Australia website www.mtaa.org.au/clinical-investigations. For reasons of timeliness and cost, and compliance with insurance requirements, it is recommended that the standard agreements are used as appropriate.
- 2.3 A standard clinical trial research agreement for an Investigator-initiated study is available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/site-specific-assessment-and-research-governance-in-clinical-trials for non-commercially sponsored clinical trials.
- 2.4 Schedule 7 of the CIRA and Commercially Sponsored CTRA, and Schedule 4 of the Collaborative Research Group and Investigator-initiated CTRA may be used to incorporate any unique operational requirements that are required by a party to the agreement to facilitate the conduct of the clinical trial. They are not to be used to substantially amend the contract or to introduce provisions that contradict or otherwise undermine the substantive provisions or intent of the contract.
- 2.5 The Coordinating Office will provide a file of pre-agreed Schedule 4s and Schedule 7s to RGOs to confirm that submitted contracts are acceptable for use in Victorian public hospitals. The Southern Eastern Border States (SEBS) panel reviews and agrees on the Schedule 4s and Schedule 7s for sponsored research; updates will be provided to RGOs from time to time.
- 2.6 RGOs should review contracts and any special conditions that may be included as Schedules to the contracts. In the event that a sponsor submits a contract that has not been prepared using a standard template, or a non-standard agreement, or a Schedule 4 or Schedule 7 that has not been agreed by the SEBS committee, the RGO must review and seek legal advice (through in-house or external legal counsel) as deemed necessary and in accordance with their own institution's policies and practices. Legal advice is at the sponsor's expense. Institutions should preferably choose not to accept a "non-standard" agreement and request the sponsor to prepare a new agreement using the appropriate template.
- 2.7 The PI must sign acknowledgement of a contract but the RGO should ensure that the relevant authorising representative signs on behalf of the organisation, in accordance with the organisation's delegation policy.

SOP 03 Insurance and Indemnity Requirements

Purpose To describe the administrative steps for checking the adequacy of insurance and indemnity arrangements

3.1 RGOs may consult the VMIA if they have any concerns regarding insurance or indemnity. Information is available at www.vmia.vic.gov.au/learn/clinical-trials.

Insurance

3.2 The insurance certificate must display the full legal name of the sponsor organisation for clinical trials. The full legal name of a commercial sponsor organisation must be identical to that on the commercial indemnity certificate.

Indemnity

3.3 Review of a form of indemnity for a clinical trial should ensure that the indemnity:

- Bears the declaration signature of the sponsor and the Chief Executive or duly authorised representative of the organisation
- Is provided by the commercial sponsor in a form no less favourable than the current version of the Medicines Australia Form of Indemnity for Clinical Trials or the MTAA Indemnity Form.
- Has the full legal name (identical to that on insurance certificate), address and ABN (all Australian) of the sponsor organisation
- Paragraph 1 clearly identifies sites and PIs conducting the research.

SOP 04 SSA or LNR VIC SSA Application Processing

Purpose To describe the process for accepting a SSA or LNR VIC SSA application from a PI

- 4.1 A signed or electronically authorised SSA or LNR VIC SSA form and supporting documents must be submitted to the RGO by the site PI.
- 4.2 Supporting documents for the SSA or LNR VIC SSA must be uploaded to the Online Forms website by the site PI (or delegate). All supporting documents uploaded to the Online Forms ethics application form will automatically be transferred to the corresponding SSA or LNR VIC SSA.
- 4.3 A completed **Research Governance Cover Letter and Checklist** (available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research) should be submitted with the SSA or LNR VIC SSA documentation.

Mandatory submission components of all research governance applications are to be submitted immediately after the HREC submission. Documents include:

- SSA form (must be Victorian version) or LNR VIC SSA form
- Supporting documents including the HREA or LNR VIC, Victorian Specific Module (if ethics application is HREA)
- Detailed budget (final) signed by the site PI
- Master PICF(s) and (if applicable) Site master PICF(s)

- 4.4 A draft application form (with 'DRAFT' watermark on each page) must not be accepted for assessment.
- 4.5 Multi-site applications will be registered on AU RED by the Coordinating Office, and will have an HREC Reference Number assigned by the Central Allocation System (CAS).

Single-site applications will not have an HREC Reference Number allocated in advance, the HREC Reference Number is generated when the HREC Coordinator uploads the ethics application into AU RED. Note: the ethics application **must** be uploaded through e-submission in AU RED before the SSA or LNR VIC SSA can be submitted from Online Forms.

- 4.6 A new submission of a SSA or LNR VIC SSA and supporting documents can be viewed on the AU RED **e-Submissions** tab (refer to *AU RED Training Manual (version 2)* page 41). If the form is not satisfactory, the RGO should contact the PI and request that they recall the application to address shortcomings.
- 4.7 After uploading a SSA or LNR VIC SSA into AU RED (including all supporting documents uploaded by the applicant on Online Forms), the RGO must address any deficiencies against the **Research Governance Cover Letter and Checklist**.
- 4.8 All documents uploaded as supporting documents to Online Forms by the CPI (ethics application) and PI (research governance application) will be available in AU RED on the **SSA Application - Checklist** tab, and also the **SSA Application - Document** tab in the 'Supporting Documents' folder.

Any additional documents received in hard copy should be checked into AU RED on the **SSA Application - Checklist** tab (refer to *AU RED Training Manual (version 2)* page 46). All documents listed in the checklist, regardless of whether they are available as electronic copy or not, will be listed by default in AU RED authorisation letters.

- 4.9 The SSA form or LNR VIC SSA form is accessible on the **SSA Applications - Details** tab under 'Form/Data Import History' by selecting 'View'. It can also be accessed in the **SSA Application - Documents** tab, within the 'Submitted Forms' folder. The SSA form is not accessible on the **SSA Application - Checklist** tab.

Purpose To describe the procedure for validating a SSA or LNR VIC SSA

- 5.1 The RGO must ensure the SSA or LNR VIC SSA form and all supporting documents are present.
- 5.2 The RGO should be flexible and communicate with PIs so that research governance/SSA requirements can be met efficiently. If the SSA or LNR VIC SSA form and supporting documents have minor shortcomings then the PI may need assistance to complete the documents.

Valid application

- 5.3 Following assessment of the application and it being considered valid, in the AU RED SSA **Application - Validate/Start** tab select 'Valid'.



Start the SSA clock by setting the application received date and selecting '**Start Clock**'.

A SSA Valid letter can be sent to the PI acknowledging that the SSA or LNR VIC SSA is valid. The letter can be accessed under 'SSA Valid Letter' by selecting 'Print'. It can be saved and attached to an AU RED Email to send to the applicant. The letter can be uploaded to the SSA **Application - Documents** tab for filing in an administration folder (Other Documents) (refer to *AU RED Training Manual (version 2)* page 66).

Invalid application

- 5.4 Following assessment of the application as being invalid, in the AU RED SSA **Application - Validate/Start** tab select 'Invalid'.

An automatic system-generated email is sent to the applicant immediately. This should be followed promptly with an email sent from AU RED detailing the deficiency of the application.

A letter can be sent to the PI acknowledging that the SSA or LNR VIC SSA is invalid. Under 'Generate Application Invalid Correspondence' choose either 'SSA form not submitted' or 'SSA form not complete'. Provide any details in the notes text box then select 'Print', and an invalid letter template will open. The letter to the PI should give detailed reason(s) why the research governance/SSA application is invalid. It can be saved and attached to the AU RED email; it should be uploaded to the SSA **Application - Documents** tab in the 'Other-Documents' folder for filing.

- 5.5 Following an application being recorded as Invalid, the applicant can modify the application using the Online Forms website. They can alter the application form and/or upload new/modified supporting documents before submitting again. The RGO must upload the revised application from the **e-Submissions** tab then proceed to validate the SSA submission.

Purpose To describe the procedures required after HREC approval has been given

- 6.1 The RGO must receive all documents which have been approved by the reviewing HREC. These must be submitted to the RGO by the site PI who will have received them from the CPI (via Online Forms). All documents must be a full, complete copy of the final approved version. These include the:
- HREC approval letter/certificate
 - HREA or LNR VIC
 - Victorian Specific Module (if ethics application is HREA).
 - If applicable, a Medical Physicist's radiation assessment report for the site
 - Master PICF(s)
 - Site master PICF(s) (if applicable)
 - Advertisements
 - Letters of invitation/brochure
 - Relevant correspondence between the CPI and the reviewing HREC

Clinical Trial Notification (CTN) acknowledgment by TGA

- 6.2 Following submission of the online CTN form with payment of the relevant fee to the TGA the clinical trial is deemed to have been notified. Once the CTN submission has been processed by TGA it appears in the 'CTN Trials Repository' and the final submission can be printed.

The RGO should make clear to the PI that that the sponsor should forward a copy of the final processed CTN submission to the PI, who should then forward a copy to the RGO.

Radiation assessment and notification

- 6.3 A research project involving the use of ionising radiation must be HREC reviewed according to the *Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes* (ARPANSA, 2005).

Radiation safety in research involving the exposure of human volunteers to ionising radiation is the responsibility of the institution at which the research is being undertaken. The PI at each site is responsible for ensuring that any advice provided by a Medical Physicist in relation to a particular research project is complied with in full.

If the dose of radiation is above the dose constraint of the ARPANSA Code and approval has been given by the HREC, then the organisation (licence holder) must notify the Radiation Team, DHHS, within 14 days of research governance/SSA authorisation. The project may commence prior to notification being submitted to DHHS.

If the dose of radiation is below the dose constraint of the ARPANSA Code and approval has been given by the HREC, no DHHS notification is required.

Purpose To describe the administrative procedures for the recording and communicating the SSA or LNR VIC SSA review and decision

7.1 Following validation of the SSA or LNR VIC SSA submission, the RGO should assess the documentation.

Request for further information/modification

7.2 If the PI is required to provide more information the RGO should facilitate this process by communicating with the PI in a timely manner via AU RED email. The RGO should advise the PI on how to meet the research governance requirements.



The RGO must record requests for information in AU RED in the CEO/delegate section of the SSA **Application - Meetings** tab (refer to *AU RED Training Manual (version 2)* page 50), enter a date and select **'Stop Clock'**.

An automatic system-generated email is sent to the applicant immediately. This should be followed promptly with an email sent from AU RED detailing the deficiency of the application.

7.3 Following an application being recorded as 'request for further information/modification', the applicant can modify their application using Online Forms. Following modification by the applicant, the application form and/or upload new/modified supporting documents can be submitted again. The RGO must upload the re-submitted application from the **e-Submissions** tab.



In AU RED, the response and date received must be recorded by selecting the 'Response to Request for Further Information' checkbox in the SSA **Application - Checklist** tab. This automatically **re-starts the AU RED clock** from the supplied date of receipt. The application must then be assigned to a meeting in order for a decision to be made

SSA Decision

Timeline: The RGO must notify the PI of the authorisation status of a SSA or LNR VIC SSA within one working day of the decision being made.

7.4 Once the RGO has reviewed the SSA or LNR VIC SSA documents, including any additional information provided by the PI, the RGO should make a decision whether or not to recommend authorisation to the CEO/delegate.

In AU RED, the decision should be recorded on the SSA **Application - Meetings** tab by selecting the RGO recommendation from the drop-down list then selecting 'Save Recommendation' (refer to *AU RED Training Manual (version 2)* page 50).

The RGO can generate a recommendation memo to send to the CEO or delegate by selecting 'Print/Preview'. For filing purposes the memo can be uploaded to a folder created in the SSA **Application - Documents** tab.

7.5 The RGO's memo to the CEO/delegate for SSA recommendation should detail any issues, make a recommendation for or against SSA authorisation, and be signed and dated. The recommendation options on the memo to the CEO or delegate are: 'Recommended', 'Not recommended' and 'Requires Chief Executive/delegate consideration'.

7.6 If the RGO has the delegated responsibility of the CEO and is therefore responsible for the authorisation of SSAs, it is not necessary to generate the memo unless required for auditing.

7.7 Once the CEO/delegate has made a decision it must be recorded in AU RED by the RGO in the CEO/delegate section of the SSA **Application - Meetings** tab. The final decision may be 'Not Authorised', 'Authorised' or 'Authorised with Conditions'. The decision must be saved and a letter to the PI can be generated with the CEO's recommendation.



The AU RED clock must be stopped; enter a date and select '**Stop Clock**'.

- 7.8 The letter to the PI allows the RGO to detail any special conditions imposed by the CEO/delegate. It should be emailed from AU RED (refer to *AU RED Training Manual (version 2)* page 74). For filing purposes the letter can be uploaded to the 'Other-documents' folder created in the SSA **Application - Documents** tab.
- 7.9 A copy of authorised documents should be sent to the PI with the authorisation letter. Documents include the signed CTRA and indemnity.

The RGO must ensure that one original copy of the fully executed CTRA/CIRA and Indemnity is provided to the organisation (following signature by the other party). The RGO should ensure the PI has a copy of the authorised documents, if they differ from the original submitted version.

Purpose To describe the administrative procedures relating to an amendment to a SSA or LNR VIC SSA of an approved and authorised research project

- 8.1 An amendment may be required to an authorised SSA or LNR VIC SSA due to an approved HREC amendment which affects the research project at all sites, or an individual site-specific amendment. Local site policy should determine the implications of an HREC amendment on the authorised SSA or LNR VIC SSA at that site.

Some site-specific changes may require HREC approval (e.g. alteration to an HREC-approved Site-master PICF) and both HREC approval and research governance/SSA authorisation of an amendment are required before the amendment can be implemented at a site.

For modifications that are administrative only then the RGO should assess the required change.

- 8.2 On Online Forms the PI should upload as supporting documents any amended document, along with an explanatory cover letter for the SSA or LNR VIC SSA project. The amendment-related documents must then be submitted from Online Forms and will appear under the AU RED e-Submissions tab under 'New/changed documents'. The RGO should upload the new/amended supporting documents from the AU RED e-Submissions tab.

Note: The authorised SSA or LNR VIC SSA form cannot be altered – any amendment to the form or other document must be communicated as a supporting document.

Timeline: The RGO must notify the PI of SSA or LNR VIC SSA amendment authorisation within one working day of the decision.

- 8.3 The RGO should register a SSA or LNR VIC SSA amendment in AU RED on the SSA **Application - Post Approval** tab. Under 'Amendments' select 'Add New Amendment', complete details and save (refer to *AU RED Training Manual (version 2)* page 57). Once the amendment has been added, tabs appear for processing the amendment. On the SSA **Amendment - Checklist** tab, the 'Notification of amendment' box must be checked, and all revised documents relevant to the amendment must be checked in.



If all documents required for an amendment are in order, on the SSA **Amendment - Validate/Start** tab select 'Valid', enter a date and '**Start Clock**'.

- 8.4 If the amendment documentation is insufficient, the RGO should record 'Invalid' on the AU RED SSA **Amendment - Validate/Start** tab, enter the relevant information and generate a letter to notify the PI. The letter can be attached to an AU RED email (refer to *AU RED Training Manual (version 2)* page 74). For filing purposes the letter can be uploaded to a folder created in the SSA **Amendment - Documents** tab.

- 8.5 The RGO should review and process the documents for the valid SSA or LNR VIC SSA amendment. On the AU RED SSA **Amendment - Meeting** tab, the RGO should make a recommendation to authorise or not, and generate a memo to the CEO/delegate by selecting 'Print/Preview'. For filing purposes the memo can be uploaded to a folder created in the SSA **Amendment - Documents** tab.

- 8.6 The SSA or LNR VIC SSA amendment decision made by the CEO/delegate must be recorded in AU RED in the CEO/delegate section of the SSA **Application - Meeting** tab. The decisions available are 'Not Authorised', 'Authorised' and 'Authorised with Conditions'.

If the RGO has the delegated responsibility of the CEO and is therefore responsible for the authorisation of SSAs, it is not necessary to generate the memo unless required for site auditing.

Once the amendment decision is saved a letter to the PI can be generated stating the CEO's/delegate's recommendation.



The AU RED clock must be stopped; enter a date and select '**Stop Clock**'.

- 8.7 The letter to the PI allows the RGO to detail any special conditions imposed by the CEO or delegate. It can be emailed from AU RED (refer to *AU RED Training Manual (version 2)* page 74). For filing purposes the letter can be uploaded to the folder created in the SSA **Amendment - Documents** tab.

SOP 09 Reporting on progress of a project at a site

Purpose To describe the communication to the RGO for annual/progress reporting and final reporting/site closure

9.1 Institutions are responsible for ensuring that any human research they conduct or for which they are responsible is designed and conducted in accordance with the *Australian Code for the Responsible Conduct of Research* (NHMRC, 2007); and ethically approved and monitored in accordance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007).

Reports provide essential information to institutions to ensure research projects are being conducted in accordance with conditions of ethics approval and research governance/SSA authorisation, and allow institutions to monitor the progress of the research against institutional performance standards. Progress of research should be reported annually as a condition of HREC approval, or more frequently if required by the reviewing HREC.

9.2 In Victoria, the sponsor is responsible for **reporting on the project** (as a whole) to the HREC. The report submission is available to PI(s) in Online Forms. The PI can provide a copy of the project report to the RGO.
The reviewing HREC Coordinator may send an acknowledgement letter to the sponsor, who may then forward it to the PI(s) to provide to their RGO.

Annual/progress report at a site

- 9.3 The RGO is responsible for monitoring the research project at a site and the PI is responsible for reporting to the RGO for the site's activity.
- 9.4 For reporting to the RGO the PI should complete the standard **Progress Report – Site Form**, available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting. The PI should upload the form to supporting documents (of the SSA) and submit from Online Forms to the RGO.
- 9.5 The RGO should upload, from the **e-Submissions** tab, the **Progress Report – Site Form** which will appear under 'New/changed documents'.
- 9.6 AU RED should be updated on the SSA **Application - Post Approval** tab under 'Other Reports'. Choose 'Add New Report' to register the report, fill in the details and save (refer to *AU RED Training Manual (version 2)* page 58). For filing purposes the **Progress Report – Site Form** can be uploaded to the 'Other Documents' folder in the SSA **Application - Documents** tab.
- 9.7 Depending on site policy the report may be assessed by the RGO or other representatives of the institution.
- 9.8 If site policy requires a meeting to consider reports then the report can be allocated to a meeting in AU RED. In the table on the SSA **Application - Post Approval** tab under 'Other Reports' select 'Assign to Meeting'. It can be assigned to an existing meeting, or a specific non-HREC review meeting (e.g. Other) in AU RED (refer to *AU RED Training Manual (version 2)* page 9).

IMPORTANT: Following review, the meeting decision regarding the report **must** be recorded by selecting 'Edit' on the AU RED **Meeting - Decisions** tab.

Final report/site closure

9.9 A **Final Report/Site Closure Report** for either completion of the research project at all sites or closure of a specific site is the sponsor's responsibility. The sponsor must provide the **Final Report/Site Closure Report** as a supporting document to the HREA and submit it to the reviewing HREC. A copy of the **Final Report/Site Closure Report** will be available to PI(s) in the Online Forms SSA. The PI can provide a copy of the project report to the RGO.

SOP 10 Safety Reporting

Purpose To describe the administrative procedures for communicating safety reports including Suspected Unexpected Serious Adverse Reactions (SUSARs) or Unanticipated Serious Adverse Device Effects (USADEs) (at Australian sites only) occurring during a research project

Clinical trials

- 10.1 The sponsor is responsible for review of safety reports to investigators, HREC and TGA, arising from all participating sites. The details for safety reporting are set out in the *Safety monitoring and reporting in clinical trials involving therapeutic goods* (NHMRC, 2016).
- 10.2 The RGO may be involved in the assessment of a safety event that arises from their site. The RGO should assist the PI to comply with institution-specific policies, procedures and guidelines relating to management of a safety event at the site.
- 10.3 If a significant safety issue arises, is urgent and may have a material impact on ethical approval and participant safety, the PI must report the event to the sponsor. The sponsor must send the report to the reviewing HREC in a prompt manner (within 72 hours of an event) and other investigators.

A standard **Safety Report** is available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting.

The RGO should be notified by the PI of the significant safety event as per institutional policy. Refer to the VMIA website www.vmia.vic.gov.au/learn/clinical-trials for information regarding SUSAR and USADE reporting.

Clinical trials and Health and medical research

- 10.4 If a significant safety issue occurs at a site, the institution at which the event has occurred will reserve the right to suspend or close the project at that site, as the institution with legal liability for the participant. The site PI must contact the sponsor so that the reviewing HREC and other PIs are informed.
- 10.5 A site safety event can be recorded on AU RED in the SSA **Application - Post Approval** tab. Under 'Other Reports' select 'Add New Report'; complete the relevant details and save. For filing purposes the report can be uploaded to the 'Other Documents' folder created in the **SSA Application - Documents** tab.

The report may be assigned to a meeting for review and consideration of any action to be taken at the site. On the AU RED SSA **Application - Post Approval** tab select 'Assign to Meeting' next to the report. The report can be assigned to an existing meeting, or a specific review meeting can be created (e.g. other meeting) by selecting 'Add New Meeting' (refer to *AU RED Training Manual (version 2)* page 9).

IMPORTANT: Following review, the meeting decision regarding the report **must** be recorded by selecting 'Edit' on the AU RED **Meeting - Decisions** tab.

- 10.6 If a decision is made to suspend or terminate a research project at a site, AU RED must be updated accordingly. On the SSA **Application - Post Approval** tab, under 'Study State' select 'Change' and choose the relevant option from the drop-down list.
- 10.7 If, after review of a significant safety event, the reviewing HREC determines that suspension or termination of ethical approval is required, the reviewing HREC Coordinator will immediately notify the sponsor who will notify all sites where the project is being conducted. This includes notifying all PIs and RGOs.

SOP 11 Complaints

Purpose To describe the administrative procedures involved in reporting a complaint regarding an HREC approved research project at a site

- 11.1 The organisations conducting the research are responsible for complaints handling regarding conduct of the research.
- 11.2 PICFs based on the national template should provide separate complaint contact details for matters relating to the site and matters relating to an aspect of the research or the conduct of the research project. Depending on the nature of the complaint, the RGO may be required to liaise with a complaints contact person and/or the reviewing HREC Coordinator.
- 11.3 Organisations should have a nominated person to receive complaints and have established procedures for handling and seeking a resolution to any complaint.
- 11.4 The nominated person to receive complaints regarding investigators or the conduct of the research should provide information regarding the complaint to the site RGO. The institution should deal with the complaint in a prompt manner.
- 11.5 If a complaint is to be reviewed by the HREC, the PI for the site at which the complaint has arisen should provide the sponsor with a completed **Complaints Report** (available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting). The PI should submit one copy to their site's RGO and forward one copy to the sponsor for submission to the HREC.
- 11.6 The RGO should enter details in AU RED on the **SSA Application - Complaints** tab (refer to *AU RED Training Manual (version 2)* page 52). The status of the complaint is 'Open' or 'Closed', depending on the decision of the RGO. If the complaint is saved as 'Open' and review at a meeting is required, it can be assigned to an existing meeting (refer to *AU RED Training Manual (version 2)* page 9). For filing purposes the **Complaint Report** can be uploaded to the folder (Other Documents) created in the **SSA Application - Documents** tab.