Standard Operating Procedures
for
Coordinators of Reviewing HRECs

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

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Version: August 2017

Scope

In addition to these *SOPs for Coordinators of Reviewing HRECs*, specific SOPs are available for *Research Governance Officers*, and on *Streamlining Ethical Review of Research Projects* for investigators, project coordinators, sponsors, CROs and other parties; these provide general guidance to parties in all sectors of clinical trials and health/medical research.

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.

The *SOPs for Coordinators of Reviewing HRECs* describe the role of the reviewing Human Research Ethics Committee (HREC) Coordinator and the administrative processes for supporting the streamlined scientific and ethical review of research projects in Victoria and under the National Mutual Acceptance (NMA) initiative.

These SOPs represent the core standard operations of Victorian HRECs reviewing clinical trials and other health and medical research at public hospital organisations and are designed to provide guidance for research management staff of institutions hosting reviewing HREC.

The reviewing HRECs in the Victorian framework for streamlined ethical review and NMA are accredited in Victoria and have NHMRC certification. The reviewing HREC will be responsible for ethics matters throughout the duration of the project.

Research on humans must be conducted in a safe and ethically responsible manner. Ethical and scientific review should be in accordance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) (National Statement). Research has contributed enormously to the human good and it is important that "ethically good" research (as defined in the National Statement) is enabled by good communication and facilitation throughout the entire process of ethical and research governance review.

Multi-site research
Sites that accept the review and decision of a reviewing HREC for multi-site research will not involve their local HREC in matters of ethics concerning multi-site research projects. Those sites accepting a HREC review (accepting sites) will conduct research governance and site specific assessment only. In order to address governance requirements for a research project, a full set of the same documents that are submitted to the reviewing HREC are provided to accepting sites.

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.

Core supplementary document required for processing an HREC application:
• Ethics Cover Letter and Checklist

Contents

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
NEAF	National Ethics Application Form
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

SOP 01 Allocation and Submission of an Ethics Application to a Reviewing HREC

Purpose To describe the process undertaken for allocating an ethics application to a reviewing HREC and submitting it for review

1.1 Ethics applications for multi-site research projects in Victoria are allocated to a reviewing HREC by the Central Allocation System (CAS) operated by the Coordinating Office. Allocations to a reviewing HREC are based on the information provided by the CPI (or delegate) during the CAS booking.

When the CAS booking is finalised, an automated email will be sent to the CAS caller, the CPI and the reviewing HREC Coordinator. A record of the CAS booking will appear in the AU RED 'Work Area'.

If the HREC Coordinator has any queries regarding the allocation of an application to their HREC, they should contact the CAS administrator (Tel. 03 9096 7395) and the CPI.

1.2 Multi-site applications are registered on AU RED and the HREC Reference Number is assigned at the time of the CAS booking. The HREC Reference Number is the 'key identifier' for an HREC application in AU RED.

For single-site applications in AU RED, the HREC Reference Number is generated once the HREC Coordinator uploads the application from the **e-Submissions** tab (refer to *AU RED Training Manual (version 2)* page 18).

1.3 If an application is allocated to an HREC meeting through CAS and the CPI does not submit the application by the submission closing date (SCD), the HREC Coordinator should contact the CPI (or delegate) to discuss the submission.

The HREC Coordinator may allocate it to a subsequent HREC meeting (refer to *AU RED Training Manual (version 2)* page 29). Alternatively, if the application is to be withdrawn, the HREC Coordinator must update the AU RED **Application - Withdraw/Cancel** tab (refer to *AU RED Training Manual (version 2)* page 34).

The CAS booking will remain in the AU RED 'Work Area' until it is re-allocated to another meeting or withdrawn.

1.4 The HREC Coordinator is encouraged to communicate with the research team via the CPI (or delegate); onward communication with the sponsor and site PIs is the responsibility of the CPI. Exceptions to this pathway may apply, particularly in cases where urgent action is required.

1.5 Scientific and ethical review by the reviewing HREC and research governance site specific assessment (SSA) must occur in parallel.

Purpose To describe the procedure for validating and processing an ethics application submission

2.1 The HREC application form and supporting documents can be viewed on the AU RED **e-Submissions** tab (refer to *AU RED Training Manual (version 2)* page 18). If the application is not satisfactory, the reviewing HREC Coordinator should contact the CPI and request that they recall the application to address shortcomings.

If the HREC application form is acceptable, the 'Upload' button should be selected.

After actioning the upload of a HREC application into AU RED (including all supporting documents uploaded by the applicant on the Online Forms website), the reviewing HREC Coordinator must verify that the application form, VSM and all supporting documents are complete, and address any deficiencies against the Ethics Cover Letter and Checklist.

2.2 The reviewing HREC Coordinator must ensure the following are present for an application to be deemed valid:
- HREC Reference Number on the application form, assigned by CAS for a multi-site application or added for a single-site application when the application is uploaded to AU RED (this is the 'unique identifier' for an application and is distinct from a Site/Local Reference Number)
- Signature or electronic authorisation of the CPI
- Ethics Cover Letter and Checklist

A draft application form (with 'DRAFT' watermark on each page) must **not** be accepted for review.

2.3 The following factors should be considered by the HREC Coordinator when assessing the validity of an application:
- The application form must be a truthful account of the protocol
- The protocol must be adequate for scientific review
- The PICF must meet the standard of the recommended PICF templates
- Privacy laws (Victorian, National and other states, if applicable) must be adhered to
- Medical Physicist reports, where required, must be present for all sites and contain the necessary information

2.4 If a New South Wales site is participating in a clinical trial under NMA, and the participants may include 'adult persons who are unable to give consent', a *NSW Privacy Form* (available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research) must be completed by a NSW site's PI and submitted by the CPI to the reviewing HREC.

2.5 If a Western Australia site is participating in a research project under NMA, a Western Australian Specific Module (WASM) is required for the ethics submission to the reviewing HREC. Details are available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/national-mutual-acceptance.

2.6 If an application is incomplete, and is not accepted for the meeting, the HREC Coordinator may allocate it to a subsequent HREC meeting. In AU RED, this is done following validation (refer to *AU RED Training Manual (version 2)* page 29). The record will remain in the AU RED 'Work Area' until validation occurs.

2.7 IMPORTANT: Information received on the Ethics Cover Letter and Checklist must be entered into AU RED (refer to *AU RED Training Manual (version 2)* Section 3). This data includes:
- 'Mode of HREC review' must be recorded on the **Application – References** tab
- 'Low or negligible risk review' must be recorded on the **Application - Details** tab

2.8 All documents uploaded as supporting documents to Online Forms by the CPI will be available in AU RED on the **Application - Checklist** tab and the **Application - Documents** tab in the 'Supporting Documents' folder.

If supporting documents have not been uploaded to the Online Forms website by the CPI (or delegate), the HREC Coordinator should contact them to do so as soon as possible. The AU RED user may record the application as Invalid in order for the applicant to action the required changes in Online Forms.

Any documents received in hard copy should be checked into AU RED under the **Application - Checklist** tab (refer to *AU RED Training Manual (version 2)* page 25). 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 approval letters.

For a complete electronic record of documents, the **Application - Documents** tab allows the upload of documents. These will appear in the checklist and **Application - Documents** tab in the 'Other Documents' folder.

Valid application

Timeline: Validate within 3 working days from receipt of the submission (submission closing date)

2.9 To validate an HREC application, go to the **Application - Validate/Start** tab, select 'Valid' and record the validation date (refer to *AU RED Training Manual (version 2)* page 26).

2.10 The HREC application must be added to a full meeting for review. Go to **Application - Meetings** and choose 'assign to Meeting' to add the application to the agenda (refer to *AU RED Training Manual (version 2)* page 29).

2.11 A decision on the valid status of an HREC application should be made by the reviewing HREC Coordinator within 3 working days after the HREC application submission closing date.

Invalid application

Timeline: An invalid decision notification within 3 working days from receipt of the submission (submission closing date)

2.12 An application may be deemed invalid and the CPI must be notified. An application may be invalid for the following reasons:
- Required supporting documents are not present (e.g. protocol, VSM, PICF(s))
- Documentation is deemed inadequate for the HREC to be able to complete a robust review

2.13 On the AU RED **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 indicating the decision can be generated by 'Generate Application Invalid Correspondence' and standard wording can be chosen, if applicable. The letter should be saved and can be attached to the email. A copy of the letter can be uploaded to the **Application - Document** tab in the 'Other Documents' folder.

2.14 When an application is recorded as Invalid, the ethics from is 'unlocked' and the applicant can modify the application on Online Forms. After the application form is edited it should be e-submitted with supporting documents. On the **e-Submissions** tab, the HREC Coordinator must select 'Upload' for the revised application before proceeding to validation.

Processing an HREC application

2.15 There are two ways to access the HREA or LNR VIC in AU RED:
- On the **Applications - Details** tab, select the 'View' link under 'Form/Data Import History'

or
- On the **Application - Documents** tab, select the 'Submitted Forms' folder to locate the ethics form.

The ethics application form is not accessible on the **Application - Checklist** tab.

SOP 03 Compliance with VMIA Guidelines Regarding Indemnity for HREC Review

Purpose To describe indemnity requirements related to HREC review of a research project in Victorian public hospitals

3.1 The VMIA website www.vmia.vic.gov.au/learn/clinical-trials should be consulted for insurance and indemnity requirements.

3.2 If a research project is commercially sponsored, it is the responsibility of the sponsor to provide the indemnity documentation.

3.3 Commercially sponsored applications require an 'HREC Review Only' Form of Indemnity (available from https://medicinesaustralia.com.au) from public health organisations accepting that review.

Medicines Australia and the Medical Technology Association of Australia have standard indemnity forms for HREC review (available from https://medicinesaustralia.com.au or www.mtaa.org.au).

3.4 If a research project is not commercially sponsored (i.e. it is investigator-initiated, collaborative group or institution), indemnity is not required by participating public health organisations for HREC review.

Purpose To describe processes for administration of scientific review of an ethics application

4.1 The HREC Coordinator should ensure that appropriate relevant expertise is available for the review of the protocol. It should be determined whether the HREC or scientific subcommittee has sufficient expertise or whether independent expert review is required.

4.2 Scientific review of an HREC application may be conducted in a number of different ways including:
- Review by a scientific sub-committee prior to the HREC review
- Internal institutional review by experts
- External review by independent expert reviewer(s)
- HREC review that incorporates scientific and ethical review

4.3 Depending on the scientific review process, relevant documentation resulting from the scientific sub-committee or other review process must be included in the HREC agenda papers.

Scientific sub-committee review

4.4 If an HREC application is to be assigned to a scientific sub-committee this should be actioned in AU RED by using either the **Application - Meeting** tab (refer to *AU RED Training Manual (version 2)* page 29) or the **Meeting - Assign Applications** tab (refer to *AU RED Training Manual (version 2)* page 61).

4.5 Following the meeting of the Sub-committee, **a decision must be entered in AU RED** on the **Meeting - Decision** tab (refer to *AU RED Training Manual (version 2)* page 62).

Review by internal or external experts

4.6 If it is decided that an HREC application requires an expert review then it should be made clear to the reviewer that a response will be required within a specified timeframe so that the HREC application can be reviewed at the assigned HREC meeting.

Purpose To describe the administrative procedures for communication of the reviewing HREC's decision following review of an application

Timeline: The HREC must communicate the decision to the CPI in writing within 5 working days of the HREC meeting

HREC request for further information

5.1 When a request for further information is made by the reviewing HREC, the decision must be recorded in AU RED in the **Meetings - Decisions** tab (refer to *AU RED Training Manual (version 2)* page 62).

The **AU RED clock must be stopped.** An automatic system-generated email is sent to the applicant immediately. This should be followed promptly with an AU RED email detailing the issues regarding the application. A letter can be generated (edit as required) and attached to the email to the CPI (refer to *AU RED Training Manual (version 2)* page 74). For filing purposes the letter can be uploaded to a folder created in the **Application** - **Documents** tab.

5.2 Following a decision of 'Further information/modification requested', the applicant can modify the ethics form using Online Forms and upload new/modified supporting documents before re-submitting. On the **e-Submissions** tab, the HREC Coordinator must select 'Upload' under 'Submission response to further information request'.

5.3 On receipt of the re-submission from the CPI, the reviewing HREC Coordinator should review and ensure that all requested information has been provided so that the response can be finalised. This may involve contacting the CPI and discussing any shortcomings in their response.

5.4 A response from the CPI to the reviewing HREC should be promptly addressed so that a timely decision can be made.

5.5 In AU RED, the response and date received must be recorded by selecting the 'Response to Request for Further Information' checkbox in the **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; either the next reviewing HREC meeting or a delegated decision-maker's meeting (e.g. HREC Chair or sub-committee, HREC Coordinator). The decision must be recorded on the **Meetings - Decisions** tab (refer to *AU RED Training Manual (version 2)* page 62).

5.6 If the response provided by the CPI is considered insufficient, another information request can be made and recorded in AU RED. The HREC Coordinator must ensure that the first response is checked in and reviewed before a second request is generated in AU RED (refer to *AU RED Training Manual (version 2)* page 62).

HREC approval

Timeline: A HREC approval letter must be sent to the CPI within 5 working days of the HREC meeting decision

5.7 Once the reviewing HREC has issued approval for a research project, the decision must be recorded in AU RED on the **Meetings - Decisions** tab (refer to *AU RED Training Manual (version 2)* page 62).

The **AU RED clock must be stopped** and subsequent tabs in the 'Edit Application Decision' window can be used to record decision details. A letter should be generated (edit as required) and attached to an AU RED email sent to the CPI.

Ensure the communication and approval letter/certificate is attached and sent using the AU RED email – delivery is direct to the applicant and others' nominated with an Online Forms account. For filing purposes the letter can be uploaded to a folder created in the **Application** - **Documents** tab.

5.8 On the AU RED **Application - Post Approval** tab change the study state to 'Started' and save (refer to *AU RED Training Manual* (version 2) page 38).
N.B. This is not the commencement of the research project but refers specifically to the ethically-approved period for the conduct of the research.

Research project not approved

Timeline: A letter of non-approval must be sent to the CPI within 5 working days of the HREC meeting decision

5.9 If the reviewing HREC decides not to approve a research project, the decision must be recorded in AU RED on the **Meetings - Decisions** tab (refer to *AU RED Training Manual (version 2)* page 62).

The **AU RED clock must be stopped** and a letter generated (edit as required) and attached to an AU RED email sent to the applicant's Online Forms account.

For filing purposes the letter can be uploaded to the folder created in the **Application** - **Documents** tab.

5.10 Tabs subsequent to the 'Edit Application Decision' window can be used to record decision details.

SOP 06 Amendment to an Approved Research Project

Purpose To describe the administrative procedure for processing a request for approval of an amendment

Timeline: A decision notification letter must be sent to the applicant within 5 working days of the HREC decision

6.1 An amendment to an HREC-approved research project must be submitted on a standard **Amendment Request Form** (available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting).

6.2 The amendment application must be either validated or not validated by the reviewing HREC Coordinator.

6.3 An amendment must be registered in AU RED on the **Application - Post Approval** tab (refer to *AU RED Training Manual (version 2)* page 37); select 'Add New Amendment' and enter the relevant information. An amendment area opens up with several tabs used for processing the amendment.

6.4 On the **Amendment - Checklist** tab, check in the amendment (tick the 'Notification of Amendment') and any other document types then select 'Enter Selected Items'. The electronic documents relating to the amendment application should be saved and uploaded to the **Amendment - Documents** tab, in the folder created for the application.

6.5  If all the documents required for ethical review are present and adequately completed, validate the amendment request in the **Amendment - Validate/Start** tab and **start the AU RED clock** (to record the time for the amendment review process).

6.6 A letter can be generated indicating whether an amendment application is valid or invalid. Use of this acknowledgement letter for amendments is optional and can be sent using the AU RED Email system.

6.7 The HREC Coordinator should process the amendment request, with advice from the HREC Chair (as required). The following actions may be taken:
- Review by the HREC Chair - this may be processed with ratification by the HREC
- Sub-committee review - this may be processed with ratification from the HREC Chair
- Full HREC review - the process and timeframe should be according to that for full HREC review
- Review by the research office staff - for administrative amendments
- Other process - according to local policy.

6.8 On the AU RED **Amendment - Meetings** tab, assign the amendment to the relevant meeting type, if required. To allocate an amendment to a meeting, select the **Amendment - Meetings** tab and allocate to either an existing meeting or a new/other meeting. Once a decision has been made select the **Post Approval** tab, choose the **Amendment - Meetings** tab, record the decision and stop the clock.

6.9 Registering an amendment decision in AU RED must be done on the **Meeting - Decisions** tab (refer to *AU RED Training Manual (version 2)* page 63). Select 'Edit' for the relevant amendment application and the 'Edit Amendment Decision' window will open with the 'Decision Info' tab, in the 'Decisions' drop-down menu choose the decision type (e.g. approved) and save.

 Within the 'Clocks and Correspondence' tab, **stop the AU RED clock**.

6.10 An amendment approval letter should be sent using the AU RED **Email** tab (refer to *AU RED Training Manual (version 2)* page 75). For filing purposes the letter should be uploaded to the folder created in the **Amendment** - **Documents** tab.

6.11 The amendment approval letter **must** include a statement explaining that an amendment cannot be implemented at a given site until the SSA amendment (if required) is authorised, e.g.

'investigators will require final authorisation of an amendment from their own Research Governance Office before implementing the amendment at their site'.

6.12 In cases of high risk to participants, an amendment may be expedited for purposes of patient safety, according to local policy.

SOP 07 Monitoring of an Approved Research Project

Purpose To describe the requirements for monitoring an approved research project throughout its duration

7.1 The *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) indicates that the HREC has monitoring responsibilities of ethical conduct of approved research. The site(s) where the research is being conducted also have an important role in monitoring the conduct of the research. Refer to the *National Statement* Chapter 5.5 *Monitoring Approved Research*.

7.2 HREC Coordinators should refer to the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) and the *Australian Code for the Responsible Conduct of Research* (NHMRC, 2007) to guide decision making.

7.3 HREC Coordinators are responsible for facilitating monitoring of approved research projects as required by the reviewing HREC.

7.4 HREC Coordinators should encourage the use of standard reporting forms, available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting.

SOP 08 Safety Reporting for an Approved Clinical Trial

Purpose To describe the administrative procedures for review of safety reports for an approved clinical trial

8.1 HREC Coordinators should refer to the *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016). The reviewing HREC has an obligation to ensure that any changes in the benefit or risk balance of a project are compatible with continued ethical approval.

8.2 The Sponsor has the primary responsibility for monitoring ongoing safety of investigational products.
The required timeliness for clinical trial sponsor notification to the HREC is:
- Written notification to the HREC should be within 72 hours of an urgent safety measure and 15 days of a significant safety issue occurring (may or may not be a SUSAR)
- Notification of an amendment to the HREC without undue delay
- Notification of temporary halt of a trial for safety reasons within 15 calendar days of the temporary halt
- Notification of an early termination for safety reasons should be submitted within 15 calendar days of the early trial termination

8.3 If an urgent safety issue arises at a participating site, the PI must submit a completed **Safety Report** within 24 hours to the sponsor for HREC review if the event is possibly, probably or definitely related to participation in a research project within Australia. The participating institution (site) should receive a report within 72 hours from the PI.

8.4 If the sponsor decides an amendment is required to an approved project, based on the degree of seriousness of the safety occurrence, a request for an amendment should be made (using the standard **Amendment Request Form**) and submitted to the reviewing HREC together with the safety event report (refer to SOP 06 for amendment processing).

8.5 Safety event reports should be registered in AU RED on the **Application - Post Approval** tab, under 'Serious Adverse Events' (refer to *AU RED Training Manual* (version 2) page 37). To assign the safety report to a HREC meeting, select 'Assign to meeting' in the safety report table. A copy of the report should be uploaded to the **Application - Documents** tab for filing.

8.6 Following review of a safety report, the reviewing HREC must communicate the outcome of the review to the sponsor.

If the reviewing HREC has requested any changes to the ethics approval in addition to those indicated on a safety report this must be detailed in the letter to the sponsor.

8.7 To record the decision in AU RED following the review meeting, go to the **Meeting - Decisions** tab and select 'Edit' next to the listed SAE. The 'Edit SAE Decision' window will open; choose a decision and save.

8.8 Where the Australian sponsor's advice or the HREC review determines that the immediate suspension or termination of a research projects is required, ethical approval may be withdrawn. The reviewing HREC **must immediately** notify the sponsor. The reviewing HREC Coordinator should also **immediately** notify all other relevant parties and sites where the project is being conducted, this includes notifying the Investigators, RGOs, and Project Coordinator. Notification in writing should be given as soon as possible.

8.9 The suspension or termination of a project must be recorded in AU RED by changing the 'Study State' on the **Application - Post Approval** tab (refer to *AU RED Training Manual (version 2)* page 37).

SOP 09 Annual or Progress Reports for an Approved Research Project

Purpose To describe the administrative procedure for review of annual or progress reports by the reviewing HREC

9.1 Reporting the progress of a project is the responsibility of the sponsor according to reporting intervals determined by the HREC, either annually or more frequently. The sponsor is responsible for reporting on the entire project (to include all sites if a multi-site project) and providing this to the to the HREC.

9.2 The HREC Coordinator should ensure that progress of research is reported annually (at a minimum) or as required by the reviewing HREC. Reports must be submitted on the **Progress Report – Project Form** available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting.

9.3 The Work Area in AU RED has reminder alerts for the reviewing HREC Coordinator regarding the reporting status for a project. A reminder letter can be accessed on the **Work Area - Progress Reports** tab and provided to the sponsor. The scheduled number of 'Reports per Year' can be altered on the **Application - Post Approval** tab; Work Area reminders will reflect the frequency of reports that has been selected.

9.4 AU RED must be updated on the **Application - Post Approval** tab when a report is received (refer to *AU RED Training Manual (version 2)* page 37). A copy of the report should be uploaded to the **Application - Documents** tab for filing.

In the 'Progress/Final Reports' table, once a progress report is added an option to 'Print Letter' appears. This letter acknowledges receipt of the report and should be sent to the sponsor. The letter can be emailed using an AU RED email. A copy of the letter should be uploaded to the **Application - Documents** tab for filing.

9.5 Reports may be reviewed by the HREC or by a delegated committee or individual, in accordance with local policy.

If required, the report can be assigned to a meeting. On the **Application - Post Approval** tab, the 'Progress/Final Reports' table has the option to 'Assign to meeting'. The 'Search Meetings' page opens and the report can be assigned to a chosen meeting.

9.6 **IMPORTANT:** If a report is assigned to a meeting and the HREC (or delegate) has considered the report, **the HREC Coordinator must finalise the decision by recording the outcome** on the **Meetings - Decisions** tab. The HREC Coordinator may send an AU RED email acknowledgement to the sponsor, to forward to the Investigators.

SOP 10 Project Final Report/Site Closure Report for an Approved Research Project

Purpose To describe the administrative procedure for HREC review of a final report or site closure report for an approved research project.

Completion of a research project

10.1 Upon completion of an approved research project, the Sponsor will submit a **Project Final Report/Site Closure Report** form to the reviewing HREC (available from www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting).

10.2 The sponsor is responsible for preparing and submitting the project final report to the reviewing HREC Coordinator, the report must be registered on AU RED on the **Application - Post Approval** tab by selecting 'Add Final Report' (refer to *AU RED Training Manual (version 2)* page 37). A copy of the report should be uploaded to the **Application - Documents** tab for filing.

10.3 The HREC Coordinator should send a letter to the sponsor acknowledging receipt of the project final report. On the AU RED **Application - Post Approval** tab, the 'Final Report' area has the option to 'Print Acknowledgement Letter for Final Report'. The letter can be emailed using an AU RED email. A copy of the letter should be uploaded to the **Application - Documents** tab for filing.

10.4 A project final report may be reviewed at the full HREC meeting or by a delegated committee or individual, in accordance with local policy.

To record a decision in AU RED, the report must be assigned to a meeting. On the **Application - Post Approval** tab, the 'Final Report' section has the option to 'Assign to meeting'. The 'Search Meetings' page opens and the report can be assigned to a chosen meeting.

10.5 **IMPORTANT:** After a meeting the decision must be recorded in AU RED to complete the process. The HREC Coordinator must record the outcome on the **Meetings - Decisions** tab and may send an AU RED email acknowledgement to the sponsor.

10.6 **IMPORTANT:** The 'Study State' must be changed to 'Finished' in AU RED so project status is correct and searchable (refer to *AU RED Training Manual (version 2)* page 38) .

Closure of a research project (before the approved end date)

10.7 **IMPORTANT:** When a project final report has been processed, the **Application - Post Approval** tab 'Study State' must be changed to 'Closed and archived' (refer to *AU RED Training Manual (version 2)* page 38).

Site closure report (closing one site in a multi-site project)

10.8 A project may be either completed or may be closed for other reasons at one site only. The sponsor must submit a **Project Final Report/Site Closure Report** form to the reviewing HREC (as above).

SOP 11 Complaint about an Approved Research Project or Site

Purpose To describe the administrative procedures for dealing with a complaint regarding an approved research project

11.1 In accordance with *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007), and the *Australian Code for the Responsible Conduct of Research* (NHMRC, 2007), complaints regarding a research project may be directed to either the reviewing HREC or the site conducting the research.

11.2 The PICF(s) 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 HREC Coordinator may be required to liaise with a complaints contact person and/or a site's RGO.

11.3 Institutions should have a nominated person to receive complaints and have established procedures for handling and seeking a resolution to any complaint. The institution should deal with the complaint in a prompt manner. The HREC Coordinator may liaise with the complaints contact person to discuss review of the complaint by the HREC.

11.4 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 **Complaint 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.

11.5 When a **Complaint Report** is received by the reviewing HREC Coordinator, the report should be registered on AU RED on the **Application - Post Approval** tab under 'Other Reports' (refer to *AU RED Training Manual (version 2)* page 37). A copy of the report should be uploaded to the **Application - Documents** tab for filing, as should any other correspondence regarding the complaint.

11.6 On the **Application - Complaints** tab the details should be recorded then 'Save' selected (refer to *AU RED Training Manual (version 2)* page 32). The 'Complaints - Open' section provides the option to 'Assign to meeting', which allows the complaint to be allocated for HREC review.

11.7 **IMPORTANT:** The outcome of the complaint process and decision should be recorded in AU RED following the HREC meeting decision to complete the process. Other parties should be notified as appropriate in a timely manner.

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SOP 12 Expanding a Research Project HREC Approval to Include Additional Sites

Purpose To describe the administrative procedures for HREC approval to include additional sites

12.1 HREC Coordinators should encourage potential applicants to utilise the Victorian streamlined system or NMA for their application if it is considered likely that multiple sites will be involved in the project, even if there is only one site confirmed at the time of the HREC application. However, if the streamlined system or NMA was not utilised for a single-site project an application can be amended to include additional sites.

12.2 If a single-site research project has been approved by a Victorian HREC that is accredited to review a multi-site project, the original approval can be expanded to multi-site approval. The start dates for the streamlined systems are detailed in the tables below.

Multi-site projects in Victoria only:

Research Type	Start Date
Clinical trials	November 2009
Clinical trials and health/medical research	February 2015

Multi-site projects in Victoria and other states/territories:

Streamlined System	Research Type	States/Territories	Start Date
IMA	Clinical trials	QLD, VIC	October 2011
		NSW, QLD, VIC	February 2012
NMA	Clinical trials	NSW, QLD, SA, VIC	November 2013
	All human research	NSW, QLD, SA, VIC	December 2015
		ACT, NSW, QLD, SA, VIC	August 2016
		ACT, NSW, QLD, SA, VIC, WA	31 August 2017

12.3 If the HREC Coordinator agrees that a single site approval will be expanded to multi-site, the applicant must contact CAS.

The addition of site(s) to the original application should be submitted to the HREC research office as an amendment request (refer to SOP 06).

12.4 On the existing AU RED record, the HREC Coordinator must check the 'Single to Multi-site' checkbox on the **Application - References** tab (refer to *AU RED Training Manual (version 2)* page 22).

If the additional site is outside Victoria, the 'Mode of HREC Review' must be updated to 'National Mutual Acceptance' on the **Application - References** tab (refer to *AU RED Training Manual (version 2)* page 22).

12.5 HREC approval for addition of site(s) to the original application should be processed in AU RED as an amendment (refer to SOP 06). AU RED data entered for the original application (e.g. validation date, approval date) must not be altered in AU RED.

12.6 The HREC Coordinator should make clear to the CPI that research governance authorisation is required for the additional site(s) and that SSA authorisation must be given before the research can commence at any new site.

12.7 Sites that gain ethical approval from a reviewing HREC are required to comply with the ongoing monitoring and reporting requirements of the reviewing HREC.

12.8 For a research project that is approved as a multi-site project in the streamlined system, additional sites can be added via an amendment process (refer to SOP 06).