

INSTRUCTIONS ON HOW TO PREPARE A MULTI-SITE RESEARCH APPLICATION



HREC Approval and Supporting Documents

1) Preparation

The Human Research Ethics Committees (HRECs) of the below institutions are accredited for single ethical review:

- Alfred Health
- Austin Health
- Melbourne Health
- Peter MacCallum Cancer Centre
- The Royal Children's Hospital
- Monash Health
- St Vincent's Hospital (Melbourne)

Applications for a single ethical review of multi-site projects are submitted via the Clinical Trial Research Coordinating Office, the Department of Health. Confirm your research involves at least one of the institutions listed above in collaboration with one or more of the listed institutions and/or any public sector institution located in the states of NSW, Queensland or South Australia.

2) Allocation of a HREC application to a reviewing HREC

Call the Central Allocation System if your HREC application will be ready to submit to a reviewing HREC in approximately two weeks time – Central Allocation System (Monday – Friday, 10am – 5pm): (03) 9096 7395.

The Central Allocation System (CAS) requires applicants to identify a discipline that applies to the research project – identify the [primary category by clicking here](#). Researchers should factor the meeting schedule of the reviewing HREC into their timeframe for approval.

3) Completing the HREC application form

The Human Research Ethics Application (HREA) is required to be used for application to a certified HREC.

The HREA should be completed via the [Online Forms website](#), and all supporting documents should be uploaded electronically where possible. The Coordinating Principal Investigator (CPI) or Principal Investigator (PI) (at a single site) must submit the appropriate documentation, as well as the following forms, as part of their application:

- [Ethics Checklist](#)
- [HREC Application Cover Letter](#)

For a Low and Negligible Risk (LNR) research project, the HREA can also be used. The form must be completed via the [Online Forms website](#), and all supporting documents should be uploaded electronically.

For greater than low risk studies in Victoria, the Victorian Specific Module (VSM) must be completed in addition to the HREA. The VSM is mandatory and must be uploaded as a supporting document. A VSM is not required for low risk projects.

In Victoria, there is a requirement to comply with legislation relevant to human research involving information privacy (Information Privacy Act 2000), health information (Health Records Act 2001) and the use of ionising radiation (Radiation Act 2005 and Radiation Regulations 2007).

In addition, consent under circumstances where the Guardianship and Administration Act 1986, and the Mental Health Act 2014, must meet legislative requirements in Victoria. The VSM has specific sections for human research in Victoria and these have been designed so that the HREC can address legislative requirements.

The VSM may be modified and updated from time to time. Please access it from the below links each time you make a new application, to ensure that you have the latest version:

- [Victorian Specific Module](#)
- [Victorian Specific Module Guidelines](#)

The following documents regarding legal information are referred to in the Victorian Specific Module:

- [Guardianship and Administration Act 1986 – Information Summary](#)
- [‘Guidelines’ – Health Records Act 2001 \(VIC\) Statutory Guidelines on Research, issued for the purposes of Health Privacy Principles 1.1\(e\)\(iii\) & 2.2\(g\)\(iii\), February 2002](#)

4) Participant Information and Consent Forms (PICFs)

Complete the relevant Participant Information and Consent Forms (PICFs) using the recommended templates for health and medical research projects and genetic research available from the [Department of Health & Human Services \(DHHS\) website](#).

5) Submission of the HREC application to the reviewing HREC

When the HREC application is complete, submit the form electronically through the Online Forms account using the ‘Submission’ tab and following the steps. The application form can be printed and, if required, the CPI can sign the document in hard copy. Each PI must provide the CPI with site-related documents, if applicable, and these must be attached to the HREC application by the CPI as supporting documents.

Site-related documents could include:

- Site Specific PICFs with site-specific wording
- Use of Ionising Radiation Section 4 and radiation risk assessment complete with signatures
- [Section 4 – Use of ionising radiation](#)
- [Section 4 – Use of ionising radiation guidelines](#)

6) Post-HREC approval – Reports and amendments

The reviewing HREC will have oversight of the clinical trial and ensure that it complies with all ethical, scientific and safety requirements, as appropriate. Investigators will be required to provide regular progress reports, other required reports, and safety reports to the reviewing HREC. For more information, refer to the [Standard Operating Procedures](#).

Standard templates for monitoring and reporting

Standard templates for monitoring and reporting to the reviewing HREC and for research governance are available below. These can be filled in online and then saved. These documents should be submitted using Online Forms electronic submission. The templates are revised on an ongoing basis – always use the most recent version:

- [HREC Amendment Form](#)
- [AE and SAE Report](#)
- [Protocol Deviation or Violation Report](#)

- [HREC Progress Report – CPI Cover Sheet](#)
- [HREC Progress Report – Site Report](#)
- [HREC Final Report](#)
- [Site Audit Report for Research](#)
- [Complaints Report to HREC](#)

Research Governance and Site Specific Assessment (SSA)

The NMA Scheme provides for ethical and scientific approval only. Each participating public health jurisdiction will have a Site Specific Assessment (SSA) form for use within that jurisdiction.

Authorisation must occur at all organisations conducting multi-site health and medical research before the research can commence there.

The ethics application must be created before accessing the research governance SSA form via Online Forms.

How to make a SSA application

1) Research governance checklist and standard cover letter

The Research governance checklist provides guidance to assist PIs meet the requirements of research governance/SSA. A copy of both the checklist and cover letter must be attached to every SSA application:

- [Research governance cover letter and checklist](#)

Site-specific assessment will require the researcher to complete and submit the SSA form via the [Online Forms website](#). All PIs, including the CPI, must complete a SSA form for their site.

The SSA form addresses the resources, study budget details, site-specific policies, and declarations from departments, etc. The organisation conducting the research, following HREC approval, must authorise the SSA before a research project can commence at that site.

2) Accessing an SSA form

The CPI is responsible for generating the SSA form for all PIs at study sites and transferring the SSA form to each PI using the 'transfer' function in the Online Forms website.

An automatic email alert will be sent to each PI indicating that a SSA form is waiting for completion. Using the Online Forms website, the PIs must fill in the SSA form.

PIs will require the NEAF (or LNR Application Form for the relevant Victorian studies only) and supporting documents (same as submitted to the reviewing HREC). These are required as SSA supporting documents and should be uploaded to the Online Forms SSA. All other site specific supporting documents should be uploaded to the Online Forms website using the multi-upload function.

When completing the SSA form, some fields relating to declarations and authorisation are blocked as these are not to be completed by PIs. Signatures required for declarations can be obtained on the printed hard copy of the SSA form.

3) Submitting the SSA form to the Research Governance Officer (RGO) at your site

Submission of the SSA form and supporting documents will be through electronic submission through Online Forms using the e-submissions tab. These documents will be received by the Research Governance Officer (RGO) for administration of the site assessment process. If the SSA form is correctly completed, the RGO will validate the submission. If the SSA is not validated, the RGO will notify the PI and request that the SSA form is completed and supporting documents are correct.

4) Participating organisations and RGO contact details

Research governance contact details for organisations participating in the streamlined system can be found by [clicking here](#).