Research ethics and governance frequently asked questions

Does my research project need ethical approval?

Human research that involves the following methodologies generally requires ethics approval by a properly constituted Human Research Ethics Committee (HREC):

- conducting surveys, interviews or focus groups
- performing psychological, physiological or medical testing or treatment
- observational studies
- collection and use of body organs, tissues or fluids (for example skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or exhaled breath
- accessing personal information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.

If you are unsure of whether your project requires ethical review please contact the relevant Executive Officer associated with the Human Research Ethics Committee at the institution where you plan to undertake your research.

Do I need approvals to carry out my research in the SA public health system?

Yes. There are two main types of approval you will need to obtain:

1. Ethical approval
2. Research governance approval, via a site specific assessment (SSA) application

What if my research does not involve the SA public health system?

If your research is not being undertaken within the public health system, you are not required to receive approval from a public health sector HREC.

You will need to refer your project to the relevant HREC at the site at which your research will be carried out. Please refer to the National Health and Medical Research Council (NHMRC) website for a full list of HRECs in Australia (PDF 370KB).

SA Health HRECs can choose to review projects that do not involve the public health system. Fees will be charged according to the SA Health fees schedule, and the decision to undertake the review is up to each HREC.

How do I receive ethics approval from a SA public health system HREC?

To obtain ethics approval you will need to apply to the relevant HREC associated with the institution where the research is to be conducted. Researchers are encouraged to visit the SA Health research ethics | SA Health website for further information including submission requirements and meeting dates.

How do I receive governance approval?

To obtain governance approval you need to submit a site specific assessment (SSA) application for each site where the research will be undertaken. For greater than low risk

studies, the SSA form should be completed via Research GEMS online. For lower risk studies, review the relevant LHN website for a SSA low risk form.

The SSA application is first reviewed by the selected Head of Department and is then assessed by a Research Governance Officer (RGO) associated with the site. Their assessment will be provided to an institutional authority (e.g., Chief Executive Officer or delegate) who will authorise the project to commence. This process must be completed for all research projects at each site across the South Australian public health system.

What does it mean if I do not receive ethics approval?

If your project is not approved, it is recommended that you discuss the decision further with the Executive Officer of the HREC. This may assist you in responding to any issues raised by the HREC or in understanding their decision. A project cannot commence at a SA Health institution until ethics approval and SSA authorisation have been obtained.

Which HREC will review my research project?

Researchers should apply to the most relevant SA Health HREC for their study. Generally, this is the HREC that is associated with the institution where the research is to be conducted, however it can also include where the Principal Investigator is located, or the type of research and the specialties of the HREC.

What if I only need access to a database or registry at the site, do I still need approval?

Generally, ethics applications predominantly involving access to a database or data registry held by a site or institution should be submitted to the HREC attached to the site or institution. If there are multiple sites involved, you only need to apply to one HREC. If the data is state-wide, the DHW HREC is the most appropriate HREC. If children are involved, the WCHN HREC is the most appropriate HREC.

When can I start my research project?

A research project can commence once both the ethics application is approved and SSA application is authorised for the relevant site/s. Projects accessing many sites may commence at the first site once the corresponding SSA is authorised, i.e., the project can have a staggered start. Approvals are provided via written letters from the HREC and Research Governance Officer/s.

Is the process different for research conducted on Aboriginal or Torres Strait Islander peoples?

Yes. If your research involves any of the following, you are advised to discuss the proposal with the Aboriginal Health Research Ethics Committee (AHREC) in South Australia.

- the experience of Aboriginal and Torres Strait Islander people is an explicit focus of all or part of the research
- data collection is explicitly directed at Aboriginal and Torres Strait Islander people
- where it is proposed to separately identify Aboriginal and Torres Strait Islander people in the results
- the information has an impact on one or more Aboriginal and Torres Strait Islander communities
- the geographic location of the research is such that a significant number of the population are likely to be of Aboriginal and Torres Strait Islander origin (based on 4.7.6 of the *National Statement* 2023)

- where terms such as ‘resilience’, ‘well-being’, ‘cultural safely’, ‘cultural health’ and ‘language and culture’ are used in the description and design of the project indicating that the project has important health implications
- Aboriginal and Torres Strait Islander health funds are a source of funding.

How will I be impacted by the SA Health single review model?

Researchers undertaking multi-site research across the SA public health system can apply for ethics approval from one SA Health HREC. This approval will be accepted by all other SA Health sites/institutions. A site specific assessment (SSA) authorisation is also required at each site before the project can commence.

Does the single ethical review model apply for research being done outside the SA public health system?

No. If your research is being conducted outside the SA public health system, you should discuss your research with the institution where the research will be conducted. It is entirely up to that institution whether they wish to accept the ethical review undertaken by the SA public health system HREC or require their own institutional HREC to conduct an additional ethical review.

What is a SSA?

A SSA is a site specific assessment and is a separate process to the ethics submission and review process. The SSA is a research governance assessment, and will consider whether there are adequate processes, resources and approvals in place to conduct the research at the respective site or institution.

Do I still need to complete a SSA form for each site even though I am using the single ethical review?

Yes. You are still required to submit a site specific assessment (SSA) application to each institution or site across the South Australian public health system where your research will be undertaken for a research governance review.

Can I make an amendment or modify my research project?

Yes. To modify a project that was submitted through Research GEMS and has already been approved by a SA Health HREC, refer to the GEMS user guide Ethics amendment - completing and submitting.

For projects that were not submitted via Research GEMS (low risk studies), refer to the website of the approving HREC.

Where can I get further information or advice?

For information specific to your project, please refer to the relevant Human Research Ethics Committee website.

Information regarding Research GEMS can be found on the GEMS user guides page.

For more information

Contact the relevant SA Health research office

www.sahealth.sa.gov.au

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