Human Research Ethics Application Guidelines

These guidelines are designed to give applicants information for an ethics application that is being submitted to the Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) using the Human Research Ethics Application (HREA) form under the Higher Risk pathway

The SAC HREC is accredited by the National Health and Medical Research Council (NHMRC) to be a lead HREC in South Australia. It reviews multi-site (both state and national) and single site research being undertaken within SA Health including the Southern Adelaide Local Health Network and Flinders University. The SAC HREC can review applications at the request of other HRECs in South Australia.

Instructions:

The HREA is to be used for all research projects that are considered higher risk.

Triggers to identify your research as higher risk are:

- All interventions
- Your research involves Aboriginal / Torres Strait Islanders as participants.
- Your research involves participants with mental illness, cognitive or intellectual impairment, pregnant women or their foetus.
- All requests for opt out or waiver of consent.
- Genetic testing
- Creating of a databank, biobank, or registry
- Exploration of sensitive personal or cultural issues.

If you are submitting a **Low Risk** application, please use the Low risk application form and protocol templates on our website. **Do not submit a low-risk application in GEMS.**

Fill out all sections of the HREA and protocol (project description) in a clear and concise manner, so anyone reading your application will be able to understand what your research project involves.

- The HREA form ensures the project complies with the National Statement on the Ethical Conduct in Human Research
- The protocol (project description) provides the HREC with the details on how the research project will be conducted.

Please refer to National Statement on Ethical Conduct in Human Research Section 3.1 for guidance on the elements of research project design.

Please check that you have provided all the required documents and the below items are addressed. Incomplete applications will be returned to the researchers.

Please contact the Office for Research if your project:

- Is a phase 1 clinical trial.
- Is being conducted at the Jamie Larcombe Centre and involves Veterans.

The Office for Research have handy ethics and governance essentials guides, which provides in depth information about preparing and writing your applications. You can find them here.

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Creating your application

All higher risk applications are submitted via the Research GEMS system. The SA Health Research GEMS webpage has user guides that will help you create, manage and submit your application.

The ethics application is created in two steps:

1. Project registration – this creates the workflow for the HREA and Site-Specific Assessment (SSA).
    - Click New Project
    - Answer the questions.
    - Click complete registration to finalise the form.
2. Once the project registration is complete, select HREA and complete all sections.
    a. Upload all required documents (see below)
    b. Make sure SALHN is added as the site to assist with SSA generation.
    c. Click Generate HREA document to submit to the Office for Research.
3. The SSA will automatically be generated once the HREA is submitted to the HREC, providing SALHN is listed as a site.

For all public health sites listed on your application, a separate SSA must also be lodged before the research project can begin at any public heath site listed in the application. **Your research cannot commence until it has been authorised by the Chief Executive/delegate of the public health site where the project is to be undertaken.** If the research project is being conducted at a university, please contact the University's Governance Officer for institutional requirements.

Application tips

For a timely review and to meet current research governance requirements, please ensure you adhere to the following tips:

- Please treat your application as a piece of academic writing, taking into careful consideration readability, spelling and grammar.
- The **recruitment method** must be compliant with s93(3)(f) of the *Health Care Act 2008*. Investigators and research teams cannot commence pre-screening and screening until the protocol has both ethical approval and governance authorisation, including head of department endorsement.

  These records are referred to as a participant screening log and participant enrolment log respectively.
- If you do not have the patient's consent to access their medical records for research purposes, you must either obtain their consent or apply for **waiver of consent**. The waiver must be justified using The National Statement sections 2.3.9 / 2.3.10 (a-i).
- Please consider and address any **dependent relationships** between participant and researchers in the HREA and use the National Statement chapter 4.3 for guidance on how this will be managed. It is best practice to have participant consent taken by someone independent to the research (N.S 4.3.9).
- Please declare all **conflicts of interests** and how they will be disclosed and managed. The conflicts may be actual, potential, perceived, personal, financial or professional. It is important the conflicts are declared and information on how they will be managed provided to the committee.
  - Please refer to the National Statement chapter 5.4 for guidance and to your institutions policies on how to handle a conflict of interest.
- **Consumer engagement** in your research is vital, as it will strengthen the research design as it can be tailored to suit and support your participants with a lived experience. For more information, refer to our Consumer Resources webpage.
- Please ensure all documents are correctly named and have a version number and date in the footer using the Office for Research document naming guidelines i.e., PICF v2 dated 01.01.17
- Please do not refer to participants as subjects.
- Please only use a SA Health, University or professional email address in the application.

Document checklist (password protected documents will not be accepted):

- Project protocol – protocol template is on our website.
- Participant Information/Consent Form (PICF). Download the InFORMED PICF template.
  - For a multi-site application submit the 'master' PICF in a generic format to be used at all sites. The site specific will be reviewed in the governance process.
  - Please write the PICF to a readability age of 12 years old.
  - Please take into careful consideration spelling and grammar.

        - It is acceptable to remove any sections not relevant to your study
        - The Office for Research contact details can be found on our website.
    - Victorian specific module or Western Australian Specific Module for any Victorian/Western Australian sites that the SAC HREC is providing approval for.
    - Approvals from other HRECs.
    - Aboriginal community approval (if applicable).
    - Investigator brochure must be submitted for all clinical drug trials.
    - Questionnaires or surveys being used in the study.
    - Data collection tools.
    - Recruitment tools i.e., advertisements such as flyers, posters, print media adverts, letters of invitations.
    - Letter of support from Flinders Medical Centre pharmacy (if SSA being submitted, a separate letter is not required).
    - Radiation Safety Report (if applicable).
    - Proof of registration with Australian Register of Therapeutic Goods.
    - Evidence of indemnity for the study.
        - If the research project is being conducted as a SA Health employee, additional indemnity is not required.
        - If the research project is being conducted as a FUSA staff member or student, indemnity is required from FUSA Insurance Services.
        - If the research is commercially sponsored, a certificate of currency is required.

Once your application is received by the Office for Research

1. Once your application has been received it will undergo an Eligibility Check in GEMS to ensure the required documents have been provided and basic details are correct in the application. Incomplete applications will be returned via GEMS, advising what needs to be provided.
2. Once the administrative items have been addressed, the application is registered and assigned an OFR number (i.e., 123.17) and you will receive a receipt email advising you of your application number. Please use this reference number when making inquiries about your application/s. If you do not receive this email within two days of submitting your application, please contact the Office for Research.
3. Your research funding will be assessed to determine if any review fees are applicable.
4. The application will go through a quality assurance review, to make sure it complies with the above guidelines. If changes are required, you will receive an email from the Executive Officer outlining what needs to be amended.
5. When the application is ready to be reviewed by the SAC HREC, it will be assigned to the next available full committee meeting. After full committee review you will receive an email from the Executive Officer with the committee feedback.

Please note: your research cannot commence until you have received both ethics approval and governance authorisation letters.

Post approval monitoring and reporting

Once you have received ethics and governance authorisation for your research project, there are mandatory reporting requirements you must adhere to as per The National Statement chapter 5.5.

Failure to do is a breach of a breach of the NHRMC Australian Code for the Responsible Conduct of Research R17, R22, the National Statement chapter 5.5 and the terms and conditions of the ethical approval for this study. Failure to submit the required report may result in the ethics approval being withdrawn and the application closed.

You can submit your post approval reporting via your GEMS account.

- Annual review – this is required annually for the life of the study, on the anniversary of the approval date
- Final report – this is required to be submitted on completion of the research project.
- Safety reporting – depending on nature of your research project, you may need to submit Serious Adverse Event reports, protocol violations or Development Safety reports.
- Amendments – any change to the approved protocol must be reported to the lead HREC.

The Monitoring and Reporting Guidelines provides useful information on what type or report needs to be submitted and when.

The Office for Research also has a Research Safety and Quality webpage, which provides the channels in which all SALHN approved studies are monitored, plus self-monitoring tools for our researchers.

This page also contains information and resources on the National Clinical Trials Governance Framework.

Training resources

The Office for Research has a Training Resources webpage, which provides resources for our staff and researchers who are looking to update their skill set, gain GCP certification and understand the National Statement.