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.

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:
Please treat your application as a piece of academic writing, taking into careful consideration readability, spelling and grammar.

Fill out all sections of the HREA and 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 Project Description form 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 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.

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

1. Create an account via the Online Forms Portal
2. Create New project > Select the jurisdictions which will apply to the research project > HREA.
3. Click Acknowledge and continue > Next > Next.
4. Provide the information requested in each section and do not refer to appendices or secondary documents, unless specified in the HREA form.
   - Every time you make a change to the HREA form, you need to generate a submission code to save the changes into the HREA.
5. The project description template can be found on the SAC HREC website here.
6. If you need any assistance with Online forms, refer to the HELP tab.
7. For all public health sites listed on your application, a separate Site Specific Assessment (SSA) must also be lodged before the research project can begin at any public health 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. In the case of SALHN applications, the Office for Research also encourages researchers to submit their Site Specific Assessment forms at the same time as the ethics application for concurrent review. This will assist in reducing the amount of time it takes for full authorisation to be granted. Please use the SSA form via the Online Forms portal.
Submitting your application

6. Once your application is ready to be submitted, go to the submission tab, and generate a code > email to Health:SALHNofficeforresearch@sa.gov.au

- Alternatively, you can generate a PDF version of the HREA, and submit via email with all the application files.
- Online Forms does not automatically notify the Office for Research that your application has been created; you must notify us of your application via email.

Application tips

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

- Provide an Office for Research cover letter.
- If applicable, an Invoicing and Fee form, declaring the funding for the study.
- The recruitment method must be compliant with the Health Care Act 2008. If you need to access a patient’s medical records to pre-screen for eligible participants, and you do not have prior patient consent to do so, you will need to apply for an exemption under 93(3)(f). Please refer to the Research and Patient Confidentiality FAQ for more information on our website.

- Please clearly state in the recruitment section:
  Under s93(3)(f) of the Health Care Act 2008, we wish to apply for an exemption of patient consent to access their personal information for research purposes. In order to identify suitable participants for this research project, <specify who or a title i.e. study coordinator> will be required to access <specify what is being accessed>, prior to obtaining consent from the patient.

- 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 this will be managed.

- Please declare all conflicts of interests and how they will be disclosed and managed. The conflicts may be actual, potential or perceived or 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.
  - Please refer to Office for Research Conflicts of Interest information sheet on the definition of a conflict of interest and how it needs to be disclosed and managed, which can be found on our website.
- Provide a letter from the Head of Department supporting the study: Where an investigator is also Head of Department, approval is to be sought from the person to whom the Head of Department is responsible. Investigators cannot support their own research on behalf of their Department.
  - If the HOD has or will sign the SSA, a separate letter is not required.
- Please provide evidence of indemnity for the study.
  - If the research project is being conducted during the investigators SA Health time, 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.
- Please ensure additional 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 SA Health or University email address in the application.

Document checklist (password protected documents will not be accepted):
- Cover letter – please use the cover letter template provided on the Office for Research website.
  - Please list all documents being submitted.
  - When any documents are changed or updated, please amend the cover letter accordingly.
- An Invoicing and Fee form, declaring the funding for the study.
- Project description / protocol – for non-commercially sponsored studies, please use the project description template found on our website.
- A literature review to support your study
- Proof of indemnity
- Participant Information/Consent Form (PICF). Download NHMRC 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 readability, 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 for any Victorian sites that the SAC HREC is providing
approval for.

- Project approvals from other HRECs.
- Aboriginal community approval (if applicable).
- Protocol and investigator brochure must be submitted for all clinical drug trials
- Questionnaires or surveys being used in the study.
  - Please provide approval from the owner to use validated questionnaires
- Data collection tools.
- Recruitment advertisements such as flyers and posters.
- Relevant Head of Department (HOD) endorsement letter(s).
- Letter of support from Flinders Medical Centre pharmacy (if applicable).
- Radiation Safety Report (if applicable).
- Proof of registration with Australian Register of Therapeutic Goods

Once your application is received by the Office for Research

1. Once your application has been received it will undergo an administrative check to ensure the required documents have been provided and basic details are correct in the application. Incomplete applications will be returned.

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 the OFR 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 any changes are required, you will receive an email from the Ethics 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 with the minute from this meeting, outlining any questions or changes required from the committee.

6. If the application qualifies as a low and negligible risk application, it will not go to full committee and be reviewed out of session.

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.

- Annual review – this is required annually for the life of the study, on the anniversary of the approval date. Please use the template on our website.
- 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.

Please refer to the Monitoring and Reporting Guidelines on our website.

For more information

SALHN Office for Research
Ward C / Room 6A – 219
Flinders Medical Centre
Telephone: (08) 8204 6453
Email: Health.SALHNofficeforresearch@sa.gov.au

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