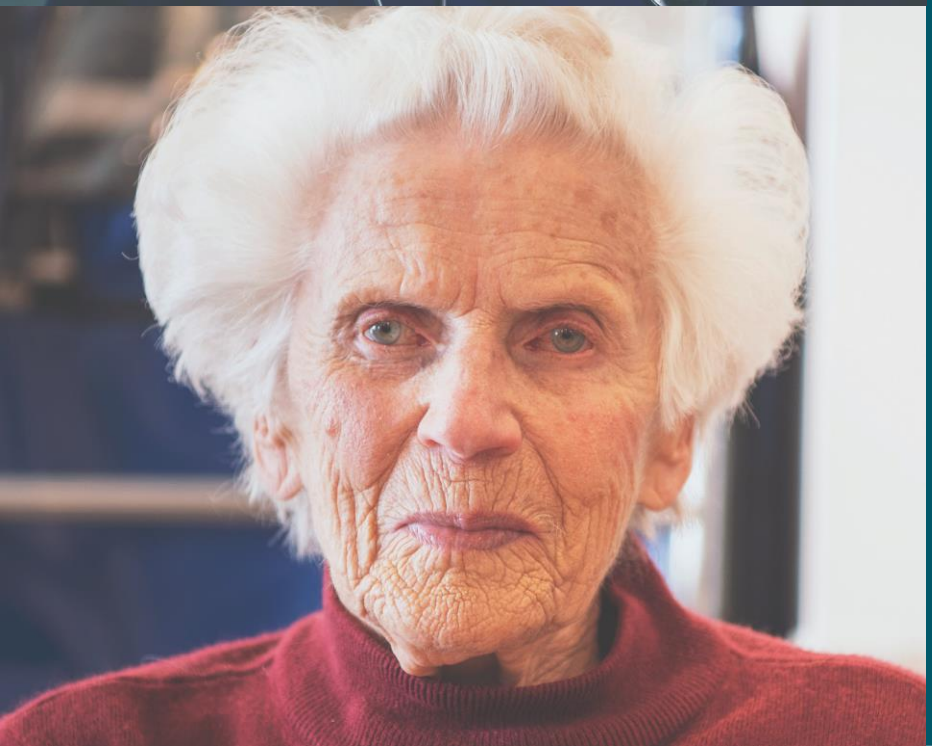

SAC HREC - EC00188 Standard Operating Procedure

SALHN Office for Research

Government of South Australia

Health
Southern Adelaide
Local Health Network

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Purpose
The Southern Adelaide Clinical Human Research Ethics Committee (SAC HREC) is a team of approximately 40 volunteers with a wide range of medical, clinical and life skills and experience, who work together to provide ethical and scientific review for all human research involving human participants and tissue.

The SAC HREC will assist the Chief Executive Officer of the Southern Adelaide Health Local Health Network and Deputy Vice-Chancellor (Research) Flinders University to discharge responsibilities in relation to the delivery of the highest standard of medical human research including the observance of ethical principles and practices. This follows ethical conventions and standards that outline how medical research is designed, reviewed and conducted in Australia. This is produced by the National Health and Medical Research Council (NHRMC), who are the peak body for supporting health and medical research.

The SAC HREC is a properly constituted Human Research Ethics Committee under the National Statement on Ethical Conduct in Human Research (2007, updated 2018). Under the section 6.4 of the terms of Reference (TOR) the SAC HREC will perform their work according to the following abstracted from the National Statement on Ethical Conduct in Human Research (The National Statement):

- Where there is conflict between the National Statement and any other regulatory instrument then the National Statement will prevail.
- Policy – all departmental policy is based on the National Statement. The following procedures have been derived from this document.

1. Submission of new applications

The SAC HREC accepts the following type of applications:

- **Low and negligible risk/ audit-based research** and authorised prescriber applications are submitted via email to Health.SALHNofficeforresearch@sa.gov.au, using the templates on the Office for Research website. If the application qualifies as a low and negligible risk application, it will be reviewed out of session via the Expedited Review Panel. The Chair of the SAC HREC may refer a low risk application to the full committee if any ethical issues are identified that require further discussion.
    - For low risk retrospective audit applications, the SAC HREC has delegated oversight of waiver of consent requests to the Expedited Review Panel.
    - All communications are conducted via email with the Ethics Officer.

- **Greater than low risk applications** are submitted via the Research GEMS portal.
  Upon receipt of the application, the Office for Research will check the details to ensure the required documents have been provided and the application is eligible. The applicant will receive a receipt email or inquiry email from the Executive Officer or GEMS. Either communication will advise of a reference number, if any additional items are required, and if the application has progressed for review with the SAC HREC.
    - **Phase 1 clinical trials**
      Phase 1 applications will not commence ethical review until they have been reviewed by the following bodies and a report has been received by the Office for Research:
        - Drug related: the SALHN Drug and Therapeutic Committee for safety evaluation, prior to being listed for review by the SAC HREC or;
        - Device related: the New Health Technology and Clinical Practice Innovation Committee for safety evaluation, prior to being listed for review by the SAC HREC or;
        - Any relevant subcommittee of either of these two bodies as advised.

- **Authorised prescriber** - These are submitted via the authorized prescriber form and are reviewed at the SACHREC meeting. Governance submission not required

SALHN will accept the following HREC approvals:

- SAC HREC
- Bellberry Private HREC Investigator led clinical trial approvals
- National Mutual Acceptance HREC approvals that have been reviewed by a public health accredited/certified HREC. The Site will need to be listed on the approval letter

For more detailed information on application types and tips on writing the ethics application, please refer to the Office for Research Training page.

2. Timelines for review

Ethics applications have varying review times due to the nature and complexity of the application.

The current review times for audit-based research / low risk applications are 14 working days.

Current review times for Greater than low risk applications are 30 working days.

The time runs from the meeting date or the date on which the application is given to a committee member and does not include weekends, public holidays, periods of leave by the committee members, and any time that the research has taken in responding to committee concerns.

3. Meetings processes in place as per chapter 5.1.37 of the National Statement.

3.1 Frequency of meetings

Meetings will be held once every 4 weeks on a Monday between 1 and 4 pm at Flinders Medical Centre or via teleconference.

3.2 Attendance at meetings

At the full committee meeting, the Executive Officer or Administration Office will keep a record of which members attend the meeting, who is an apology and which National Statement category (5.1.30) the member belongs too.

3.3 Quorum

A quorum shall consist of eight members. If the eight members are not present then the Chairperson must be satisfied that these members have received all the relevant papers and had the opportunity to contribute their views and that these have been received and considered.

3.4 Conduct and structure of meetings and deliberations

The chair will conduct the meetings and if the chair is absent then the deputy chair is delegated to conduct the meetings on their behalf.

Meetings will generally follow the order of the agenda, but the chair may wish to vary the order in which items are discussed and also may add new items to the agenda.

Meetings are scheduled to allow at least one member in each national statement category (5.1.30) to attend and meeting papers are provided at least one working week prior to the meeting.

During meetings an exchange of views occurs between all members. If the meeting is inquorate, the chair must be satisfied that the members have received the papers and have had the chance to comment on them (5.2.30). Whilst this should ideally take place at the meeting there are occasions when the views of members not at the meeting are recorded via phone or email.

Members who are absent can provide their feedback via phone or email, to the Executive Officer or via another committee member. The feedback need not be in writing.

Decisions are reached by general consensus rather than unanimity.

Personnel observing the meetings other than staff or committee members will be asked to sign a confidentiality agreement before commencement of the meeting.

3.5 Preparation of agendas and minutes

The preparation and the agenda and minutes are undertaken by either the Executive Officer or the Administration Officer.

The minutes from the meeting will include an over view of the committee discussion of each application and a detailed list of concerns to be addressed. The minutes will also record any conflicts of interest, detail discussions of policy discussions, complaints, matters arising, general discussion items and any applications bought back to full committee for final approval.

3.6 Timely distribution of papers prior to meetings

Agendas will be distributed at least 5 working days prior to each meeting. Reviewers will receive their review material at least one week prior to the meeting in an electronic format.

3.7 Presentation of applications for ethical review

After full committee review the researcher will receive an email with the minute from this meeting, outlining

any questions or changes required from the committee.

The SAC HREC will request any additional documentation they require to assist in the review of the application.

3.8 Managing conflicts of interest

Each serving member is required to disclose and manage conflicts of interest in line with the guidance in Chapter 5.4 of the National Statement.

Where a member is not an investigator on an application they may sit in on the discussion of that application after they have declared their interest and the matter has been discussed with other members by the chair.

Members who are investigators will not be allowed to stay in session for the discussion of their application and will be asked to leave and return at a suitable time.

The Office for research requires all COI's to be declared, irrespective of whether the conflict is institutional, between the researchers or between the ethical review bodies, their members and their advisors.

3.9 External Assessors

If an expert is invited to provide an opinion on an application, that person would have no ties with the company or researcher undertaking the research. If ties exist then they are declared and managed by the chair with the assistance of the Manager, Research Governance and Ethics

When a conflict of interest is identified the Office for Research will manage such conflicts as they arise and refer to chapter 5.4 of the National Statement and the institution's Conflict of Interest policy.

Institutions will be advised of COI's that the committee believes pose a significant risk to the standing of the institution.

Expert advisors and observers attending the meeting will be asked to sign a confidentiality agreement prior to the meeting.

Please also refer to section 5.3.

3.10 Researchers attending meetings

Where a researcher requests to attend the full committee meeting, the Executive Officer will advise the chair who will decide if the researcher's attendance is appropriate. If accepted, the Executive Officer will arrange a suitable time for the researcher to attend and address the committee.

The researcher may be required to sign a confidentiality agreement and it is the researcher's responsibility to declare any conflicts of interest they may have.

3.11 Communicating with researchers

After each meeting, the researcher will be informed by email or GEMS of the approval level and a detailed list of committees concerns that need to be addressed, before full ethical approval will be granted. It is standard practice to have the minutes provided to researchers within 7 days from the meeting to allow a timely response to the minute.

All correspondence to the researchers is securely stored electronically in the Office for Research or in GEMS.

The SAC HREC utilises face to face communication especially for research applications that have been not approved and for teaching purposes.

The Executive Officer can only communicate with the sponsor in relation to administrative matters. If any further communication between the Executive Officer and the sponsor develops that could be construed as a conflict of interest, then the Executive Officer must declare such an interest to the committee and be appropriately managed.

3.12 Relevant expertise on committee

The Manager, Research Governance and Ethics, with the assistance of the Executive Officer are responsible for maintaining the number of scientific and ethical reviewers on the committee to ensure that all applications are reviewed by those with appropriate experience.

4. Confidentiality

All material discussed at meetings whether related to an application or policies are confidential as outlined

in the confidentiality deed all members are required to sign.

Commercial sponsors who are anxious about submitting document electronically should be reassured that any submissions are treated with the strictest confidence and will only be seen by the committee members or Office for Research staff.

People observing the meeting other than staff or committee members will be asked to sign a confidentiality agreement before commencement of the meeting.

5. Review process

Low or negligible risk applications: audit-based research /low and negligible risk applications are reviewed out of session by the Chair, the Deputy Chairs and a lay member or committee member with relevant qualifications or experience via the Expedited Review Panel (ERP).

The SAC HREC has delegated to the ERP the function of reviewing waiver of consent requests for retrospective data access applications.

Greater than low risk applications are always reviewed at full committee. These include clinical drug trials, devices and any other research involving new interventions or randomisation or involving vulnerable populations, registries / databanks, all interventions, waiver of consent involving participants, opt out requests, genetic research, biobanks, exploration of any sensitive personal or cultural issues.

Two reviewers are assigned to each application, one of whom reviews the scientific merit and the other reviews the ethical issues.

Each reviewer completes their review in GEMS.

Studies involving Aboriginal and Torres Strait Islander people are triaged according to the following process:

- Non-Interventional – No SAC HREC – Governance only - LNR
- Interventional – SAC HREC & Governance - GEMS

5.1 Prompt notification of decisions

The Office for Research aims for its decisions to be relayed to the researchers within 7 days of the meeting at which it was discussed.

5.2 Participant's interests (National Statement 5.2.16 – 5.2.17)

The committee often requests that the participant Information Sheet and Consent Form (PICF) be amended so that participants will be able to understand the proposed research and therefore make an informed choice as to whether they would like to participate.

The committee request the NHRMC PICF templates are used for all applications.

Researchers should complete a thorough spelling, grammar and formatting check of the PICF, to ensure readability, consistency for a high-quality document.

As a rule, the committee prefers PICFs to be free of any jargon and all acronyms explained.

The footer must have a version number and date for document control.

The PICF should be written for the average 12-year-old, so they are easy to understand.

Where the research will involve a variety of cultures then the committee may ask that the PICF be translated into the relevant language.

The committee has a number of lay members, all of whom have regular ethics reviews and focus on the PICFs. This is the manner in which this committee seeks participant advocate input. Researchers are encouraged to discuss their study design and PICF with consumers and incorporate their input prior to submission.

5.3 Researchers or experts at review body meetings

Experts may be invited to assist in the review of an application. Such experts will have to sign a confidentiality agreement and also declare any conflicts of interest. They are bound by the same restraints as other committee members.

5.4 Good communication between review bodies and researchers

This Office for Research encourages meetings between the researchers, the Chair, the Manager, Research Governance and Ethics, and the Ethics Officer/Executive Officer. The SAC HREC believes that open communication between researchers, committee and the secretariat encourage engagement with guidelines and awareness of the National Statement.

The Office for Research and committee uses a combination of email, face to face, electronic conference and verbal communication with all parties involved.

5.5 Delegated authority

The SAC HREC has delegated authority to the Manager, Research Governance and Ethics and the Executive Officer of the Secretariat to communicate to researchers on its behalf, e.g. acknowledgement of reporting documentation, approval letters and all other forms of communication required, to committee members, researchers and the wider research community.

5.6 Communicating with other HREC's regarding multicenter research

Staff or committee members can make enquiries about an application submitted to another HREC to verify any issues raised by the application.

The Chair may choose to expedite research applications that have been approved by other HREC's however this does not apply to clinical drug trials.

5.7 Record keeping

The secretariat retain in electronic file format, a copy of each research proposal and application submitted for ethical approval, including all supporting documentation and email correspondence. The files are kept on a secure server with access limited to the secretariat and the documentation is only used by the Office for Research and committee members.

All research materials are to be reviewed including the protocols, recruitment adverts, participant information sheets and consent forms, letters of invitation and other relevant documents including evidence of indemnity from either a private or public institution.

The documents that will be retained by the department are consistent with those of section 5.2.24 of the national Statement and include:

- Name of the institution to which the approval is provided
- Application number for tracking purposes
- The names of the researchers including the chief investigator and any site specific
- investigators
- Project title
- All correspondence between the researchers and the reviewing HREC, including any
    - Decision about the project
    - The proposed date of completion
    - Final ethical approval or Not approved including date
    - Terms and conditions of approval
    - Duration of the approval
    - Name of the review body

5.8 Varying legislative and administrative frameworks – management of

Issues relating to research that have are legislative in nature will be referred to the committee's legal members for comment and education of the rest of the committee. The manner in which issues are dealt with will depend on the nature of the issue raised.

6. Items discussed out of session

When significant issues/policy/general opinions are required to be discussed outside of the full committee meetings, committee members are emailed all information and documents, and invited to provide their comments and or opinions on the matter. Once the Chair has made a decision, it is shared with the committee via email.

Every email and response are saved in the appropriate file on a secure server.

7. Approvals

Once reviewed at full committee, the SAC HREC will advise via the minute if the application is approved, needs to return to the next available full committee meeting, or if the response to the minute can be reviewed out of session.

Applications reviewed via the ERP are either approved, approved subject to changes or need to return to ERP for further review.

7.1 Letters

Approval letters will be emailed or provided via GEMS once final approval has been granted by the SAC HREC.

In the case where a Site-Specific Assessment (SSA) form is required for governance review, the ethics approval letter will not be provided until governance authorisation is granted.

The researcher will receive a copy of the Ethics and Governance approval letters by email when full authorisation for the study to commence has been granted.

8. Submission of post approval documents

All templates and guidance documents can be found on the Office for Research website. At this stage amendments are not submitted via GEMS.

8.1 Annual reviews / extension requests / final reports

Each year, on the anniversary of the approval of the research application, the researcher is required to submit an annual review of their project either via email or GEMs, as per the terms and conditions on the approval letter. The annual review must include a summary of the study findings to date and copies of any reports, publications or posters generate from the study.

If the ethics approval is due to expire, the researcher must also fill out the extension request section. The committee request ethics approval is kept current until all reports and publications have been finalised. Once approved, a formal approval with the new approval dates will be issued via email.

If the study is completed and all reports and publications finalised, a final report must be submitted.

While reminders are sent to researchers via email or GEMS, ultimately, it is the researcher's responsibility to submit the report, whether a reminder is sent or not.

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.

8.2 Amendments

Any change to the approved ethics application requires an amendment to be submitted. The amendment could be anything from a change of study coordinator to revision of the study design due to safety issues.

All amendments are submitted via email or via GEMS to the committee with a project amendment form, plus all updated documentation with changes tracked, so the committee can clearly see what has been changed.

If the HREA has been changed, it must be resigned and dated by the principal investigator.

Please update the version number and date in footer of all submitted documents to assist with document control.

The amendment cannot be incorporated into the study until the ethical approval has been granted by the committee, which will be a communicated in a formal letter via email or via GEMS.

8.3 Reporting and handling of adverse occurrences / safety reports

Serious adverse events (SAE's) only need to be reported if they are definitely, probably or possibly related to the study, within 72 hours of the occurrence, unless the Principal Investigator considers immediate notification is necessary.

SAE's occurring where there is no impact or relationship to the clinical trial does not need to be reported to the SAC HREC.

The report is submitted using the SAE report form or via Research GEMS.

Where the adverse event may cause harm to patients at FMC or patients involved in SAC HREC approved research at other institutions, then the chair will suspend recruitment to the project and notify the researcher via an urgent email and via phone.

Other safety reports required by the committee are Serious Unexpected Suspected Adverse Reactions (SUSARs), Adverse Events (AEs), Adverse Device Events (ADEs) and Data Monitoring Committee (DMC/IDMC) reports.

These are to be reported immediately if they have an impact on the safety of the study within SALHN or patients involved in SAC HREC approved research at other institutions, otherwise they are to be reported at least every six months.

SUSARs, AEs, ADEs must be submitted via email with a declaration of safety form and will be acknowledged via email.

DMCs can be submitted via email for review and will be acknowledged via email. Please refer to section 9.4 Suspension or Cessation of Research for more information.

8.4 Protocol violations and deviations

If there is no site impact, deviations and violations do not need to be reported.

Protocol Violations or Deviations are only reported, where there is an impact on the participant's safety within 72 hours of the occurrence.

The PI should acknowledge the Violation or Deviation and corrective action should be outlined.

The violation or deviations is to be reported to the committee using the SAC HREC template, or via Research GEMS.

8.5 Notifications

Any other letters, insurance certificates and minor communications from sponsors or researchers can be submitted via email for review and will be acknowledged via email.

8.6 Discontinuation of research projects

All approved projects that have, for various reasons, decided to be discontinued must notify the committee in writing and advise the reason why the project has been discontinued via the Withdrawal of Research template found on the Officer for Research website.

9. Monitoring of approved research

9.1 Appropriate monitoring

Each application has a different degree of risk. The committee will advise if additional monitoring of research applications is required and whether any special conditions will be imposed.

All applications are monitored once a year via an annual review form at a minimum.

The Office for Research also conducts desk top or site audits to monitor the progress of approved research projects.

9.2 Reporting on its activities

The SAC HREC reports annually to:

- The Chief Executive Officer of the Southern Health Local Network,
- The Vice Chancellor – Research (DVCR) of Flinders University; and the
- NHRMC.

9.3 Monitoring approved clinical research

The SAC HREC monitor all research approved within the SALHN through various channels.

- Desk top audits
- Site visit audits
- Annual reviews
- Amendments
- Serious adverse events and safety reporting
- Data monitoring Committee letters
- Inspection of research files: upon receiving any of the above and/ or enquires from

researchers about their study, to ensure that the approved application is being run in accordance with National Statement guidelines.

Under the National Mutual Acceptance System, information on the monitoring responsibilities for multicenter trials for researchers, HRECs and Research Governance can be found on the SA Health Website > National Mutual Acceptance

9.4 Suspension or cessation of research

A research project can be suspended or revoked if:

- A project has the potential to adversely impact the welfare of participants
- It is not being conducted or cannot be conducted as per the ethical approval; or
- If the SAC HREC believes research misconduct has occurred.

The Chair will communicate with the Principal Investigator via email at first instance, potentially followed by a phone call.

The manner and form of the notification must be in writing and contain the following minimum information:

- Title, application number and the reason for withdrawing ethical approval.
- Provide a pathway for researchers to address the issues, if possible.
- Instruct the researchers to inform participants that withdrawal of ethical approval has occurred.

When ethical approval is withdrawn the researcher, institutions and where possible the participants should be notified.

The research cannot be restarted until the Principal Investigator can demonstrate that continuance will not compromise participant welfare, or the research is modified to provide sufficient protection for participants, and that that modification is ethically reviewed and the modified research is approved.

The terms of reference allow this committee to advise other institutions to which the same research application has been submitted about their ethical concerns regarding that project.

For multi-site projects, where SAC HRC is the lead HREC, the Chair will inform the site Principal Investigator and/or Coordinating investigator that the research has been suspended / ethical approval has been withdrawn via phone or email, in addition to impacted research offices. The Secretariat, through the Chair will provide the Principal Investigator with any further information and decisions.
Where the SAC HREC is not the lead HREC, we require to be informed immediately of any cessation or suspension of ethics approvals and studies being conducted within SALHN.

9.5 Communication to the SAC HREC

Researchers should inform the committee with a full explanation and, wherever possible, the research participants, if the research project is to be discontinued before the expected date of completion.

10. Complaints

10.1 Receiving and handling of complaints

The SAC HREC may receive complaints about researchers, the conduct of research, the conduct of an HREC, or other ethical review body, participants, researchers and staff.

The Executive Officer is the first point of contact for all complaints, especially participants.

Once a complaint is received, the Executive Officer gathers as much information as possible to perform a preliminary investigation, and then discusses the complaint with the Manger, Research Governance and Ethics, and the Chair to decide upon the next steps.

The Chair and Manager, Research Governance and Ethics decides what the best course of action may be. Possible pathways include:

- Dismiss the complaint
- Seek further explanation from the respondent and complainant
- Meet with either the respondent or complainant
- Revoke the ethical approval of the application in question
- Place conditions on the ethical approval of the application in question
- Where research misconduct is raised, follow the procedures outlined in the "Australian Code for the Responsible Conduct of Research (2018)"

The complaint will also be tabled at the next available committee meeting for discussion.

Once a resolution has been the reached all parties involved will be communicated to via phone or email with the outcome.

Where the complaint is specifically querying the decision of an HREC the following processes are followed.

10.2 HREC complaints and appeals process

10.2.1 Background

Section 5.1(4) of the *National Statement* states that Institutions need to establish processes to handle complaints concerning research. This process specifically outlines a process for managing complaints made by ethics applicants for decisions made by a SA public health system Human Research Ethics Committee (HREC).

10.2 Appeals regarding HREC decisions

Where a SA public health system HREC rejects a research proposal outright on ethical grounds, makes an unfavorable decision about a component of the research proposal, or fails to reach a decision about the ethics of a research proposal, the investigator has the following rights:

a) Where a proposal has been rejected, the investigator may submit a new application to the HREC, taking due account of the HREC's concerns. The revised application will be processed and reviewed in accordance with the HREC's usual processes; or

Where (a) does not apply, the investigator may lodge a written appeal with the HREC

b) Chairperson specifying the grounds of the appeal. The Chairperson will investigate the appeal, and recommend to the HREC the appropriate course of action within 4 weeks from the date of the appeal being lodged. The HREC will notify the appellant of the course of action and determination in a timely manner.

10.2.3 Appeal to the Chief Executive Officer / delegate

Following an appeal under section 1b, if the appellant considers that the HREC has not followed due process or remains unsatisfied with the decision, they may choose to lodge an appeal with the Chief Executive Officer / delegate responsible for the HREC.

The following process will be followed:

a) The Chairperson will provide the Chief Executive Officer / delegate with all relevant material, including:
   - o Details of the appeal;
   - o Material reviewed by the HREC; and
   - o The outcome/decision of the ethical review process.

b) The Chief Executive Officer / delegate will determine if further investigation of the appeal is necessary. If so, a panel will be established to consider the appeal.

The panel will include the following members:

a. The Chief Executive Officer / delegate;
b. Two nominees of the Chief Executive Officer / delegate (not members of the HREC);
c. At least one nominee with relevant expertise in human research ethics; and
d. Expert(s) in a discipline of research related to the project under consideration.
e. The panel will allow the HREC and the appellant the opportunity to make submissions.
f. The Chief Executive Officer / delegate will notify the HREC and the appellant of the outcome of the investigation. The possible outcomes include:
g. The appeal is dismissed; or
h. The appeal is upheld, and the panel makes recommendation to resolve the issues based on the findings of the panel. The panel does not have the authority to approve an ethics application but may choose to refer an ethics application to an independent ethics committee for re-review.

If the panel or Chief Executive Officer / delegate requests that a second ethical review is required as a recommendation of the investigation, an alternative SA public health system HREC (where possible) with suitable expertise and no prior involvement in the matter will be invited to undertake this review.

The panel or Chief Executive Officer / delegate cannot reverse the final determination of any HREC.

10. Fees

Fees are charged when the study is sponsored by a commercial company or another company acting on behalf of a commercial company or a Cooperative Research Group (CRG) Clinical trials.

The SAC HREC charge fees for the review of new applications and amendments.

The Research Governance Officer charge a fee for the review Site Specific Assessment reviews and the review of contracts (nonstandard CTRAs)

There is a schedule of fees available on the SA Health website.

An invoicing form must be provided with all applications where fees are applicable.

11. Communication with research sponsors

The SAC HREC prefers all queries regarding an application or study are referred through the Study Coordinator and Secretariat is not contacted directly.

The Secretariat will accept phone calls from sponsors regarding billing enquiries.

12. Training for members and staff

Upon acceptance as a new member to the SAC HREC, the new member will meet with the Executive Officer to discuss their responsibilities and work load on the committee.

If required, the new member will be paired with an experienced committee member to be mentored in reviewing of applications.

All members receive an induction pack, which provides copies of the National Statement, Australian Code for the Responsible Conduct of Research, Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, Terms of Reference, confidentiality agreement, meeting dates and the current membership list and an overview of the SAC HREC roles and responsibilities.

The Chair, Manager, Research Governance and Ethics, and Executive Officer also provide ongoing support and guidance for all members.

All committee members and staff are invited to attend conferences, workshops and training opportunities as they arise, which is communicated via email.

There are free training resources for HREC staff, committee members and researchers on the Office for Research Training Page.

13. SAC HREC review of multicenter research

There are two approaches for multicenter research applications to be submitted and reviewed:

1. SA Health single ethical review model
2. National Mutual Acceptance (NMA) model

14.1 SA Health single ethical review model

The Single Review Model applies to all multi-site research taking place within SA public health system. This model enables researchers to seek ethical and scientific approval through one HREC only (referred to as the lead committee). This approval will be accepted by all SA Health HRECs and institutions.

The SAC HREC will accept ethics approval of the lead SA Health HREC for all research taking place within the SA Health public health system.

As a rule the lead committee will be located at the institution of the CPI. The applicant will assume responsibility for submitting all required documentation in accordance with SA Health and local HREC requirements.

The SAC HREC is responsible for notifying the CPI of the outcome of the review. It is the CPIs responsibility to notify the outcome of this review to each of the other sites where the project is

proposed to take place, via the Research Governance Officer associated with the site/s.

For further information, please refer to the SA Health Research Ethics Operational Policy.

14.2 National Mutual Acceptance (NMA) model

A national streamlined system for multicenter clinical trials (National Mutual Acceptance or NMA) has been developed to support the single ethical and scientific review of multicenter clinical trials across participating Australian jurisdictions, from NHRMC certified HRECs. The participating public health institutions are in Queensland, New South Wales, ACT, Victoria and South Australia.

SA Health will accept the review and approval from a private sector HREC for commercially sponsored trials and Collaborative Research Group trials where SALHN is not the lead site.

The SAC HREC will accept the outcomes of a single ethical and scientific review of multicenter research. The following types of research will be eligible for consideration under NMA:

- interventional research involving a drug/device trial,
- radiation therapy,
- surgery, treatment or diagnostic procedure and studies associated with ongoing activities relating to trials that have been conducted. This may include post-trial activities such as observational research and evaluation of a trial, developing a registry and other post-marketing surveillance activities.

Across SA Health institutions, the following categories of trials will be excluded from a single review process:

- Phase 0 (first time in human) and Phase 1 clinical trials
- Clinical trials involving South Australian Aboriginal and Torres Strait Islander participants, for which all applications will need to be reviewed by the Aboriginal Human Research Ethics Committee in addition to a Certified HREC.

14. Governance

Research governance is concerned with the quality, safety, privacy, risk management, financial management and ethical acceptability of research and is separate to research ethics processes.

15.1 Site specific Assessment

Before a research project can commence in any SALHN facilities, it must undergo a research governance review once the ethics has been approved. This includes all single and multi- site studies, regardless of whether the SAC HREC has provided the ethical approval for the study.

A Site Specific Assessment (SSA) supports the research governance process by enabling the institution to consider key areas relevant to the governance of the research.

The SSA is completely separate to the Ethics application, and considers a range of areas, including:

- The availability of local resources to support the project
- Whether relevant approvals have been obtained to enable the project to occur (e.g.

Departments and/or Facilities where the project is to be conducted)

- Financial arrangements – all SSAs are submitted to SALHN Finance for comment
- Insurance arrangements – via SA Health, Flinders University or the sponsor.
- The training and expertise of research staff.

The Site Specific Assessment must be completed online using the Research GEMS portal and submitted to the appropriate Research Governance Officer (RGO).

The RGO requires the submission of all relevant documentation to accompany the SSA for approval. This includes indemnities, CVs, contracts, CTN/CTX, approval letter from the lead HREC. Once the SSA has been reviewed and authorised by the RGO, it will be sent to the Office of the Chief Executive for final authorisation. Once this has been granted, a formal authorisation letter will be granted to the CPI, and the study may commence at the sites /s listed on the letter.

Please refer to the Office for Research website for more information.

Document History

Custodian	SALHN Office for Research	
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