Southern Adelaide Clinical Human Research Ethics Committee
(EC00188)

Standard Operating Procedures

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**Purpose**
The SAC HREC will assist the Chief Executive Officer, 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.

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:
- Clinical audits
- Low and negligible risk (LNR)
- General research
- Qualitative
- Clinical drug trials
- Authorised prescriber

Clinical audits and authorised prescriber applications are submitted via email to Research.ethics@health.sa.gov.au

LNR, general research, qualitative and clinical drug trials are submitted via the Online Forms application portal.

The committee request a fully completed NEAF application to be submitted where the SAC HREC is the lead committee for multi-site applications, and our local template is also required.

The committee only request sections 1 and 2 of the NEAF are completed and our local template is used for all applications that are single site.

The committee will not accept password protected documents and request all documents submitted have a version number and date to assist with document control.

The SAC HREC has the authority to request any additional documentation that they feel is necessary in the individual circumstances in order to discharge their responsibilities and review trial documentation fully.

If applications are incomplete, they will not be accepted and returned to the researcher to address the issues raised by the Executive Officer or Administration Officer.

Upon receipt of an acceptable application, an acknowledgement email will be sent advising of the application number for the submission and whether the application will be reviewed out of session or at full committee.

Submission by closing date does not guarantee it will be heard at that meeting, and could be carried over to the next meeting, depending on how many applications have been received.

Applications received after the closing date will be held over to the next meeting, if they are required to go to full committee.

Please refer to our submission guidelines document on the Research Ethics website for more information.
2. Timelines for review

The clinical drug trials, general research applications and other applications have varying review times due to the nature and complexity of the application.

The current review times for clinical audits are approximately 14 working days.

Current review times for drug trials, LNR, general research and qualitative applications are 60 working days.

The time runs from the meeting date or the date on which the application is given to a member and does not include weekends, public holidays, periods of leave by the 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 approximately every two weeks on a Monday between 1 and 4 pm in the L2 boardroom or appropriate meeting room at Flinders Medical Centre.

3.2 Attendance at meetings

At the full committee meeting, the Executive Officer, Administration Officer or Manager 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. This information is recorded the minutes and the attendance spreadsheet.

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 will 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 have the opportunity to provide their feedback via phone, email, to the Manager, 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 for the department.

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 L3 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. This may be via paper, email or other means as worked out between the department and the Manager.

3.7 Presentation of applications for ethical review
Upon receipt of an acceptable application, an acknowledgement email will be sent advising of the application number for the submission and whether the application will be reviewed out of session or at full committee.

All application documents are converted into a file for inclusion into the agenda and to be sent to the reviewers.

In the case of clinical drug trials, the investigators brochure and the clinical protocol would not ordinarily be in the agenda, however full copies are given to the reviewer and other members are free to request to see such documents.

3.8 Managing conflicts of interest
Each serving member has completed a Conflict of Interest (COI) declaration form upon acceptance onto the committee.

Where a member is not a chief 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 chief 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 Human Research Ethics Department 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
For example if an expert is invited to provide an opinion on an application, then 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.

Where COI’s are identified then the department will manage such conflicts as they arise and refer to chapter 5.4 of the National Statement.

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 meeting, the Manager or Executive Officer will advise the Chair and 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 the approval level and a detailed list of committee concerns that need to be addressed, before full ethical approval will be granted. It is standard practice to have the minutes emailed to researchers 7 days from the meeting so that they can respond comprehensively to the concerns of the committee.

All correspondence emailed to the researchers is stored electronically in the department which is password protected and resides on the server which is backed up twice daily.

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

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

3.12 Relevant expertise on committee
The Manager and Chair 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 has been explicitly stated in the member’s appointment letters.

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 the departmental staff.

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

5. Review process
Low or negligible risk applications: audits and low and negligible risk applications are expeditedly reviewed out of session by the Chair, the Deputy Chairs or a committee member with relevant qualifications or experience.

High 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.

Two reviewers are assigned to each application, one of whom reviews the scientific merit and the other reviews the ethical issues. Each reviewer is provided with a reviewers form to document their review and approval process. The reviewers provide the Executive Officer or Administration Officer with their review form after the meeting to assist in the preparation of the minute.

5.1 Prompt notification of decisions
The department aims for its decisions to be relayed to the researchers within 2 weeks of the meeting at which it was discussed.

If the application is expedited then the researcher is advised within 14 days of the result, depending upon the complexity of the application and the level of approval granted.

5.2 Participant’s interests (National Statement 5.2.16 – 5.2.17)
The committee asks often 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 and that our standard compensation statement is added. Both can be found on the Research Ethics website.

As a rule, the committee prefer PICFs to be around 12 pages long, free of any jargon and all acronyms explained. It should also 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 4 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.

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 department encourages meetings between the researchers, the Chair, the Manager or the Executive Officer. The SAC HREC believes that open communication between researchers, committee and the secretariat encourages engagement with guidelines and awareness of the National Statement.

The department and committee uses a combination of email, face to face and verbal communication with all parties involved.

5.5 Delegated authority
The SAC HREC has delegated authority to the Manager and 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 multi-centre research
The 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 keep 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 department staff and committee members.

All research materials are to be reviewed including the protocols, 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
The committee has a legal member and a non-practising member who is a lay member. Issues relating to research that have a legislative flavour will be referred to these members for comment and education of the rest of the committee. The committee will always maintain one practising lawyer and one non-practising lawyer on the membership. 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 is saved in the appropriate file on a secure server.

7. Approvals
The committee will apply one of three levels to an application based on the risk that it poses –

- Level 1 – the changes are mainly administrative in nature. The Executive Officer can issue the final approval.
- Level 2 – the assigned committee member to review the researcher response to committee concerns and will grant final approval if all issues have been addressed.
- Level 3 – the assigned committee member to review the researcher response to committee concerns, which will then be placed on the next agenda for full committee review.

It is the chair’s responsibility to provide terms and conditions commensurate with risk and the chair may delegate this role to another member or a staff member.

7.1 Letters
Approval letters will be sent once final approval has been granted by the SAC HREC.

Approval letters are sent as a PDF file via email on behalf of the Chair by the Executive Officer or Administration Officer.

It is the policy of the SAC HREC not to provide signed hardcopy or signed electronic approval letters, as our office has moved to electronic documentation. The SAC HREC office provides an unsigned electronic PDF version of the study approval letter to the Chief Investigator/Study Manager via email. These email approvals are generated via the email address research.ethics@health.sa.gov.au which can be linked back to the SAC HREC.

8. Submission of post approval documents
All templates can be found on the Research Ethics website.

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, 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 for applications 2011 onwards, ultimately, it is the researcher’s responsibility to submit the report, whether a reminder is sent or not. Please refer to chapter 5.6.1 – 5.5.5 of the National Statement.

Annual review and final reports will be acknowledged by the committee via email.

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 must be submitted via email 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 SAC HREC application form has been changed, it must be resigned and dated by the principal investigator.

Please use version numbers and dates on all 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 communicated in a formal letter via email.

8.3 Reporting and handling of adverse occurrences / safety reports

All Serious adverse events (SAE’s) are reported to the committee within 48 hours.

The report is submitted using the SAE report form and if the reviewer believes that more information is required then they will ask for this information via the Executive Officer or the Manager.

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 by the committee via email.

DMCs can be submitted via email for review and will be acknowledged by the committee via email.

Please refer to section 9.4 Suspension or Cessation of Research for more information.

8.4 Protocol violations and deviations

All violations and deviations are to be reported to the committee using the SAC HREC template and will be acknowledged by the committee via email.

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 by the committee 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.

9. Monitoring of approved research

9.1 Appropriate monitoring

Each application has a different degree of risk. The committee will decide how often monitoring of research applications will occur and whether any special conditions will be imposed. Most applications are monitored once a year via an annual review form.

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.

• 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 multi-centre 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 phone at first instance followed by an email.

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
• 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. 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 Researchers
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 Manager and the Chair to decide upon the next steps.

The Chair decides what the best course of action may be:

- 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 (2007)"

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

Once a resolution has been 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).

10.2.2 Appeals regarding HREC decisions
Where a SA public health system HREC rejects a research proposal outright on ethical grounds, makes an unfavourable 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

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

c) The panel will allow the HREC and the appellant the opportunity to make submissions.

d) The Chief Executive Officer / delegate will notify the HREC and the appellant of the outcome of the investigation. The possible outcomes include:

   a. The appeal is dismissed; or
   b. 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.

11. 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 Research Ethics or SA Health website.

12. 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.

Members and staff of the SAC HREC may contact the sponsor to answer legitimate ethical questions or to follow up on administrative matters. When such contact does occur it need only be reported to the department where a conflict of interest, perceived or actual may be impugned from the contact.

13. Training for members and staff
Upon acceptance as a new member to the SAC HREC, the new member will meet with the Chair 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.
The Chair, Manager 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.

**14. SAC HREC review of multi-centre research**

There are two approaches for multi-centre 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 multi-centre clinical trials (National Mutual Acceptance or NMA) has been developed to support the single ethical and scientific review of multi-centre clinical trials across participating Australian jurisdictions, from NHRMC certified HRECs. The participating public health institutions are in Queensland, New South Wales, Victoria and South Australia.

The SAC HREC will accept the outcomes of a single ethical and scientific review of multi-centre 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.

Please refer to the [SA Health website > Research Ethics](#) for more information.

**15. Governance**

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

**15.1 Site specific assessment**
Before a human 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 to Sarah Taylor, Manager, Business Management Services.
- 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 Online forms web portal (opens in a new window)**. It should then be 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 **SA Health website > Research Governance** for more information.

The SAC HREC Standard Operating Procedure v1.3 has been endorsed by Professor David Gordon, Chair SAC HREC:

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