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| **Research Study Protocol**  **High risk** |
| PURPOSE: This template should be used by researchers planning on submitting a research application for greater than low risk studies via the GEMS platform  For instructions on how to fill this form accurately, please see Appendix 1 at the end of this document. |

# Contents

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# Project Title

Click here to enter text.

# Project Setting

Where is the research being conducted i.e. FMC, GP Plus, Noarlunga Hospital, Flinders University, SAHMRI, Adelaide University, online forums and alternatives etc. Please ensure you include all sites and the departments involved in the study and the activity happening at each.(please note the SAC HREC can only provide approval for SA Health public sites. If you would like to seek ethics approval from the SAC HREC for a private facility, please contact the Office for Research for further details.

Click here to enter text.

# Project team

A student cannot be listed as the Coordinating Principal Investigator or Principal Investigator.

Explain the role in the study that each Investigator will perform at each site and clearly state whether Investigators will work on or off the relevant public LHN site(s).

Good Clinical Practice training is required by all listed investigators, as per National Clinical Trials Governance Framework action 1.2 and 1.6.

Copy and paste table to add more investigators or team members.

# Chief Investigator

The person listed as the Chief Investigator is responsible for the overall design, coordination and oversight across all Site/s involved in the research.

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| --- | --- | --- |
| Name: Click here to enter text. | Qualifications: Click here to enter text. | |
| Site/Department: Click here to enter text. | | |
| What is the position of this person on the research project? **Chief Investigator** | | |
| What are the research activities this person will be responsible for: Click here to enter text.  Does this person have a current Good Clinical Practice certificate?  Yes /  No  [Good Clinical Practice training](https://www.australianclinicaltrials.gov.au/researchers/good-clinical-practice) is required by all listed investigators, as per [National Clinical Trials Governance Framework action 1.2 and 1.6.](https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework) A free Good Clinical Practice course can be found on our [Training Resources page](https://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Our+Local+Health+Networks/Southern+Adelaide+Local+Health+Network/Research/For+Researchers/Training+resources+at+SALHN+Research) / A-CTEC | | |
| Contact details: a Health or University email address is preferred  I am the contact person for this project | | Phone: Click here to enter text.  Email: Click here to enter text. |

## Site Principal Investigator/s

Principal Investigator is responsible for the conduct of the research at each Site and provides oversight of Site study staff until completion of the project. (Copy and paste this table for each site)

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| Name: Click here to enter text. | |
| Site/Department: Click here to enter text. | |
| What is the position of this person on the research project? **Principal Investigator** | |
| What are the research activities this person will be responsible for? Click here to enter text.  Does this person have a current Good Clinical Practice certificate?  Yes /  No  [Good Clinical Practice training](https://www.australianclinicaltrials.gov.au/researchers/good-clinical-practice) is required by all listed investigators, as per [National Clinical Trials Governance Framework action 1.2 and 1.6.](https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework) A free Good Clinical Practice course can be found on our [Training Resources page](https://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Our+Local+Health+Networks/Southern+Adelaide+Local+Health+Network/Research/For+Researchers/Training+resources+at+SALHN+Research) / A-CTEC | |
| Contact details: a Health or University email address must be used  I am the contact person for this project | Phone: Click here to enter text.  Email: Click here to enter text. |

## Associate Investigator/s

Researchers that are contributing to the research at each site. Copy and paste this table for all associate researchers.

|  |  |
| --- | --- |
| Name: Click here to enter text. | |
| Site/Department: Click here to enter text. | |
| What is the position of this person on the research project? **Associate Researcher.** | |
| What are the research activities this person will be responsible for?  Click here to enter text.  Does this person have a current Good Clinical Practice certificate?  Yes /  No  [Good Clinical Practice training](https://www.australianclinicaltrials.gov.au/researchers/good-clinical-practice) is required by all listed investigators, as per [National Clinical Trials Governance Framework action 1.2 and 1.6.](https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework) A free Good Clinical Practice course can be found on our [Training Resources page](https://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Our+Local+Health+Networks/Southern+Adelaide+Local+Health+Network/Research/For+Researchers/Training+resources+at+SALHN+Research) / A-CTEC | |
| Contact details: a Health or University email address must be used  I am the contact person for this project | Phone: Click here to enter text.  Email: Click here to enter text. |

# Resources/Funding

It is important to explain who the sponsors and funders of the study are. It should clarify the involvement and potential influence of any party. Identification of the study sponsor provides transparency and accountability. Your protocol should explicitly outline the roles and responsibilities of any funder(s) in study design, data analysis and interpretation, manuscript writing and dissemination of results.

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| **Sponsor**  Click here to enter text.  The sponsor is defined as the institution or organisation assuming overall responsibility for the study |
| **Resources and site activity**  Click here to enter text.  What resources are necessary for the project to be conducted? |
| **Funding**  Click here to enter text.  Please describe how your research study activities will be funded. Eg will grant funding be sought in the future, what funds are readily available, will collaborating institutions need to contribute some ‘in kind’ support for some activities (this might include researchers time or stationery etc.) |

# Research Overview

Please refer to the National Statement Chapter 3.1 Elements of Research for guidance on to how to ensure this research is conducted in line with core ethical principles.

Introduce the reader to the main topic of the study and provide the context for the research. Carefully define the disease, condition, or topic of interest noting such things as prevalence, economic or social burden, or other aspects of importance.

It may be helpful to use the PICOT method (Population, Intervention, Comparator, Outcome, and Time).

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| **Introduction** – Please provide a brief overview of the study: |
| **Background and literature review –** please provide an overview of why the study needs to be done, and explain to the committee how the literature review demonstrates the originality and relevance of your research. |
| **Hypothesis** - What is the scientifically valid research question being asked? |
| **Aims** - What do the investigators intend to achieve with this research project? |
| **Objectives** - How will investigators achieve the aims of the research project? |
| **Expected outcomes** - What do the investigators anticipate the outcomes of this research will be? |
| **Rationale / justification** - How the research will fill any gaps and/or contribute to the field of research or contribute to existing or improved practice? |
| Research Design |
| **Methodological approach -** clearly describe the specific procedures or techniques that will be used to answer the research question and meet the aims. |
| **Consumer and Community engagement –** investigators are encouraged to consult with [Consumers](https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/southern+adelaide+local+health+network/research/for+researchers/consumer+resources+for+salhn+research) with the design of their research. Please outline any consultation that has occurred. |
| **What are your outcome measures**? |
| **Project duration**: |

# Participant selection and activities

Describe sources and methods that will be employed in the identification and recruitment/selection of potential participants (e.g., clinics, referring doctors, adverts, and time periods) or of historical data (e.g., medical records, databases).

It is not appropriate to cold call patients to invite them into your research project.

You should make a distinction between how you will recruit/select control participants compared to other groups if performing a comparative intervention.

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| **How many participants will be selected for the study**? |
| **How are they identified as possible participants?** i.e., checking medical records for eligibility first, clinic lists, medical records, self-select via flyer /advert.  **How will participants be recruited into the study**? Please provide a detailed step by step description of the recruitment methods i.e., flyers, adverts, direct approach, invitation letter.  **How will they be approached?** Which staff / research team members are approaching the participants? When is this occurring? I.e., clinic, inpatient. |
| **Are participants reimbursed for parking, travel or time involved?** Please refer to the National Statement 2.2.10 and 2.2.11 for guidance.  No  Yes  **Please detail what is being reimbursed and the amount:** i.e., $35 per hour for 20 hours, gift card, vouchers |
| **What are the inclusion and exclusion criteria? -** Detail the characteristics that clearly describe the study population that are required to be either included or excluded in the research.  **Inclusion**:  **Exclusion**: |
| **Participant commitment** -What will their participation involve? I.e. study visits, procedures, tests, tissue samples, questionnaires, wearing of any devices. |
| **Participant follow up** – how are participants monitored during the study? |

# Consent

Please refer to the National Statement 2.2 for guidance on consenting participants.

Where possible, informed consent should be sought from individuals to participate in research or to access their data for research purposes.

If patient data is accessed without consent or an approved waiver of consent, you are in breach of the Research Governance Directive, The National Statement, the SA Health Ethics Policy and the SA Health Privacy Policy

Consent can be provided in writing, implied (i.e., by return of a survey), opt in, opt out or verbally.

If consent cannot be obtained from the participant, a waiver of consent can be applied for which is reviewed and approved by the SAC HREC. The waiver of consent must be justified using the National Statement chapter 2.3.9 and 2.3.10 (a) to (i) below.

The investigator(s) should: Determine, according to level of risk to participants, who of the study team is appropriate to lead the participant informed consent process. This should be documented on the “Delegation of Duties” log. (ICH GCP 5.7)

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| **How you will be obtaining consent and/or what alternatives you will be using**: |
| **Are you requesting a waiver of consent?**  **Yes –** please justify why the waiver of consent is appropriate in the HREA  **No** |
| **Which investigators will issue the information sheets and consent forms**? |
| **How much time will participants have to consider participation -** Potential participants should be given adequate time to decide whether they wish to participate in a study. At least one week should generally be given for most research. If potential participants are given less than a week, strong justification should be provided as to why. |
| **Please specify which investigators will obtain consent from participants**: |
| **Will there be an opportunity to confirm or renegotiate consent during the research project**? – I.e., the capacity of the participant changes or the terms of consent / participation changes. |
| **Who will be confirming or renegotiating consent with participants and what process will be undertaken**? |
| **Conflicts of interest:** Please refer to the National Statement chapter 5.4, and your institutional policy for guidance.  Yes /  No  **Please provide details of the conflict of interest**:  **How will the conflict be managed**? |

# Storage of blood and/or tissue samples

Please refer to the National Statement 3.2 for guidance on consent, collection, and storage.

Not applicable for this research study - please delete this section if not relevant

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| Is consent being sought for the samples?  Yes. Please outline the consent process in the below consent section.  No. Please advise why:  If you are requesting a waiver of consent to access the samples, please refer to the consent section below and justify why the waiver is appropriate. |

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| **What type of sample is being taken?** |
| **Are the samples:**  Identifiable  De-identified - identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual.  Non-identifiable - outline how data identifiers will be removed, by whom, and whether a list of identifiers will be kept. |
| **Is any genetic testing being conducted on the samples?**  Yes. Please provide details on what testing will be done.  No. |
| **How are the samples being collected?** - |
| **Who is the custodian of the samples?** - |
| **Who will be accessing the samples?** - |
| **Where will the samples be stored during the research?** - |
| **Are the samples being stored for future research?**  **Has consent been obtained from the participant for this to occur to their sample?** |
| **How are the samples being destroyed once the research is completed?** - |

# Ethical considerations

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| **Please describe the risk and burden associated with your research**. The National Statement chapter 2.1 provides guidance and advice on the definition of risk and how to gauge and manage it. |
| **How will any risks be managed**? |
| **Benefits** – please identify and explain the expected outcomes and benefits of the study |
| **Does a dependant or unequal relationship exist between the participant and the researcher?** Please refer to the National Statement 4.3 for advice and guidance on how to manage this**.**  Yes -  How will the dependant / unequal relationship be managed?  No |

# Data management plan

Describe how participants’ privacy and confidentiality will be protected. As per the National Statement 3.1.45, researchers must have a data management plan in place. The disposal of research records must be made in accordance with The State Records Act 1997 (the Act). Under that Act records must be disposed of as outlined in the general disposal schedules.

**Public health institutions** fall under general disposal schedule 28. As per item 6 of general disposal schedule 28, the researchers records of research including results, notes, completed questionnaires, signed consent forms, data, reports, and study findings must be kept for 15 years after the research project has been completed before being destroyed. This includes all types of research.

**Universities** fall under general disposal schedule 24. As per section 9 of general disposal schedule 24 research data records should be kept for duration according to the nature of the study. For short term research projects such as study research projects, data should be kept for 1 year after last action. Research data from clinical trials should be kept for 15 years after action completed. All other research data and results should be kept for 5 years after publication, conclusion, or abandonment of the project. Data should be destroyed after the mandatory retention period.

Unless informed consent has been obtained from the participant, or legally authorised person, or the HREC has expressly approved otherwise, personal information used or disclosed for research purposes, must be de-identified.

Only SA Health employees will perform the de-identification process prior to releasing the information for research purposes.

My Health Record data cannot not be accessed for research and public health purposes.

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| **Please list which investigators will collect the study data / information?** i.e., from surveys, questionnaires, focus groups.  **Please list which investigators are accessing medical records** – only SA Health / SALHN employees may access medical records: |
| **What format will the data or information be stored**? i.e., spreadsheet, Redcap, Qualtrics |
| **Please provide details regarding training of the research team on maintaining the integrity and security of the data** – please demonstrate to the HREC the listed investigators understand the importance of data security. |
| **What conditions can the data be accessed or granted to others**? |
| **How will the research data be stored and what security measures are in place to protect it**? It is not appropriate to store research data on a USB or personal computer or google docs. |
| **How will you provide access to, disclose, use/re-use or transfer the data**? |
| **How long will the data be retained for?**  The data will be kept for 15 years – for all SA Health research  The data will be kept for 5 years – for all University research, |
| **What plans are in place to store / archive the study data once the research is completed**?  **What is the archive plan if the chief investigator leaves the institution and no longer has access to the study data?** |
| **How will the study data be destroyed**? |
| **Matching and sampling strategies**: |
| **Accounting for potential bias, confounding factors and missing information**: |
| **Sample size and statistical or power issues** – Make sure the size and profile of the sample to be recruited is adequate to answer the research question – please provide details: |
| **How will you measure, manipulate and/or analyse the information collected**? |
| **Data linkage** –what linkages are planned or anticipated? |
| **What impact will a participant withdrawing have on the data and how will this be responded to**? |

# Results, reporting, outcomes, and future plans

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

* Annual review – this is required annually by 30 April for the life of the research
* Final report – this is required to be submitted on completion of the research.
* Amendments – any change to the approved protocol must be reported to the lead HREC.

Failure to submit the required reports is 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 of the study. This failure to submit the required report may result in the ethics approval being withdrawn and the application closed.

The Office for Research has a [Research Safety and Quality](https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/southern+adelaide+local+health+network/research/for+researchers/research+safety+and+quality+at+salhn) page, which provides the channels in which all SALHN approved studies are monitored, plus self-monitoring tools for our researchers.

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| **Please detail your plans for the return of the research results to the participants**: as per The National Statement chapter 3 / element 5, unless the results will cause distress, participants should be provided a copy of the study results. The Expedited Review Panel suggest adding a tick box to the consent form for participants to advise if they wish to receive a copy of the results. |
| **What are your plans for dissemination and publication of project outcomes**?  **Will you be providing a de-identified data set to the journal for verification purposes**? |
| **Please detail other potential uses of the data at the end of the project**: |
| **What are your plans for sharing and/or future use of data and/or follow-up research?** i.e., anticipated secondary use of data: |
| **What is the project closure process?** I.e., a final report will be submitted to the HREC, where will the study data and/or samples will be stored? |

# Appendix 1

# Study Protocol Instructions

The preparation of a research protocol is an important first step in the research process. The aim of a study protocol is to ensure all research activities are well-planned from the outset, and that a clear record is available for investigators (and the research office) to refer to throughout the project.

This SALHN Study Protocol Template is designed in accordance with the Australian National Statement (2023). Please treat this as a piece of academic writing, taking into careful consideration readability, spelling and grammar. Please also ensure your document is written in lay language with acronyms kept to a minimum or laid out in full at least once before use.

If you are copying and pasting from another document into this template please click ‘keep text only (T). Please ensure you add a version number and date in the header of this document.

# Submitting your ethics and governance application form

A higher risk application should be submitted via the GEMS platform. For more information on how to submit an ethics application via the GEMS platform, please visit the SA Health information page located at: [GEMS.](https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/health+and+medical+research/research+gems/research+gems+user+guides)

For each project in GEMS, you will need to create a project. Once you have done so, you will need to create a form/s (application/s) for review as follows:

* A Human Research Ethics Application form (HREA) (if ethics approval has not been achieved interstate or via Bellberry HREC). The aim of the HREA is to inform the ethics committee that the project has complied with the National Statement on the Ethical Conduct in Human Research.

and/or

* A Site-Specific Application form if your research is being conducted at a SAH Public Health facility. The aim of the SSA is to inform the Research Governance Officer what activities are taking place at the site and that the research is complying with all safety and quality standards, policies and procedures.

This study protocol must be uploaded with your application form/s to provide the ethics committee and research governance officer/s more details in relation to the study design, objectives, methodology and rationale on how the research project will be conducted.

Please visit the SALHN research web page for more information on the [Higher Risk Research](https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/southern+adelaide+local+health+network/research/for+researchers/greater+than+low+risk+research+at+salhn) information or our Ethics and Governance Essential guides. Our SALHN webpage also contains training resources and free Good Clinical Practice - see [Training Resources](https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/southern+adelaide+local+health+network/research/for+researchers/training+resources+at+salhn+research) /A-CTEC.

# Project team

* The person listed as the Chief Investigator / Principal Investigator is responsible for the conduct of the research and listed study staff until completion of the project.
* A student cannot be listed as the Coordinating Principal Investigator or Principal Investigator.
* Explain the role in the study that each Investigator will perform at each site and clearly state whether Investigators will work on or off the relevant public LHN site(s).
* Copy and paste table to add more investigators or team members.
* Good Clinical Practice training is required by all listed investigators, as per [National Clinical Trials Governance Framework](https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework) action 1.2 and 1.6
* A free course can be found on our [Training Page / A-CTEC Australia](https://www.sahealth.sa.gov.au/wps/wcm/connect/Public+Content/SA+Health+Internet/About+us/Our+Local+Health+Networks/Southern+Adelaide+Local+Health+Network/Research/For+researchers/training+resources+at+salhn+research)

# Research Overview

Please refer to the National Statement Chapter 3.1 Elements of Research for guidance on to how to ensure this research is conducted in line with core ethical principles.

* Introduce the reader to the main topic of the study and provide the context for the research. Carefully define the disease, condition, or topic of interest noting such things as prevalence, economic or social burden, or other aspects of importance.
* It may be helpful to use the PICOT method (Population, Intervention, Comparator, Outcome, and Time).
* Literature Review - Please explain why the study needs to be done and how the literature review demonstrates the originality and relevance of your research.
* Justification - How the research will fill any gaps and/or contribute to the field of) research or contribute to existing or improved practice:
* Hypothesis/research question - What is the scientifically valid research question being asked?

# Project Design

Describe how the design and methods will adequately address the research question and aims. Information provided by the [Centre for Evidence Based Medicine](https://www.cebm.net/2014/04/study-designs/) may assist emerging researchers with study design terminology. If the project is made up of components or will be delivered via a number of phases, as for example in a mixed methods study, describe each component/phase and time frame for its delivery.

# Funding

Ensure you have included information that demonstrates your study will be adequately resourced from beginning to end.

# Participant Consent

Please refer to the National Statement 2.2 for guidance on consenting participant. Where possible, informed consent should be sought from individuals to participate in research or to access their data for research purposes. If patient data is accessed without consent or an approved waiver of consent you are in breach of the Research Governance Policy Directive.

The National Statement (2023), the SA Health Ethics Policy and the SA Health Privacy Policy. Consent can be provided in writing, implied (i.e.., by return of a survey), opt in or verbally. If consent cannot be obtained from the participant a waiver of consent can be applied for which is reviewed and approved by the SAC HREC. The waiver of consent must be justified using the National Statement Chapter 2.3.9 and 2.3.10 a-I. The investigators should determine according to level of risk to participants, who the study team is appropriate to lead the participant consent process. This should be documented on the ‘Delegation of Duties log as per ‘GCP”.

Participant selection and activities

Describe sources and methods that will be employed in the identification and recruitment/selection of potential participants (e.g., clinics, referring doctors, adverts, and time periods) or of historical data (e.g., medical records, databases).

It is not appropriate to cold call patients to invite them into your research project.

You should make a distinction between how you will recruit/select control participants compared to other groups if performing a comparative intervention.

Potential participants should be given adequate time to decide whether they wish to participate in a study. At least one week should generally be given for most research. If potential participants are given less than a week, strong justification should be provided as to why.

There are several steps involved in participant recruitment into health and medical research, including clinical trials. These can be summarised into developing a recruitment plan or strategies that cover the entire recruitment period. This process includes pre-screening and screening the participant to ensure that they meet the inclusion and exclusion criteria mapped out in the approved research protocol.

When conducting health and medical research, including clinical trials within SA Health in accordance with section 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.

# Data management plan

Describe how participants’ privacy and confidentiality will be protected. As per the National Statement 3.1.45, researchers must have a data management plan in place. The disposal of research records must be made in accordance with The State Records Act 1997 (the Act). Under that Act records must be disposed of as outlined in the general disposal schedules.

Public health institutions fall under general disposal schedule 28. As per item 6 of general disposal schedule 28, the researchers record of research including results, notes, completed questionnaires, signed consent forms, data, reports, and study findings must be kept for 15 years after the research project has been completed before being destroyed. This includes all types of research.

Universities fall under general disposal schedule 24. As per section 9 of general disposal schedule 24 research data records should be kept for duration according to the nature of the study. For short term research projects such as study research projects, data should be kept for 1 year after last action. Research data from clinical trials should be kept for 15 years after action completed. All other research data and results should be kept for 5 years after publication, conclusion, or abandonment of the project. Data should be destroyed after the mandatory retention period.

Unless informed consent has been obtained from the participant, or legally authorised person, or the HREC has expressly approved otherwise, personal information used or disclosed for research purposes, must be de-identified.

Only SA Health employees will perform the de-identification process prior to releasing the information for research purposes.

# Results, reporting, outcomes, and future plans

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

* Annual review –this must be submitted to the SAC HREC and SALHN governance by the ethics approval date, stated on the approval letter, each year for the life of the research project.
* Submission of a valid progress report will continue the SAC HREC approval for the next 12 months, at which point a new progress report will be due.
* Final report – this is required to be submitted on completion of the research.
* Amendments – any change to the approved protocol must be reported to the lead HREC.

Failure to submit the required reports is a breach of the NHRMC Australian Code for the Responsible Conduct of Research R17, R22, the National Statement chapter 5.5, the SA Health Ethics Policy and the terms and conditions of the ethical approval of the study. This failure to submit the required report will result in the ethics approval being withdrawn and the application closed.

The Office for Research has a [Research Integrity](https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/about+us/our+local+health+networks/southern+adelaide+local+health+network/research/for+researchers/research+integrity+at+salhn) page, which provides the channels in which all SALHN approved studies are monitored, plus self-monitoring tools for our researchers.

# Reference documents:

* National Statement on Ethical Conduct in Human Research (2007, updated 2018, 2023)
* SA Health Research Governance Policy
* SA Health Research Ethics Policy
* SALHN Privacy and Confidentiality of Patient Information
* The National Clinical Trials Governance Framework
* Good Clinical Practice (GCP) for Clinical Trials in Australia