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| Low Risk Protocol |
| PURPOSE: This template should be used by researchers when they are planning to submit a SALHN investigator led research application for Expedited Review under the Low-Risk pathway in accordance with the National Statement (2023). For instructions on how to complete this form, accurately, please see [Appendix 1](#_Appendix_1_–) at the end of this document. |

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# Project Title

Click here to enter text.

# Project team

## Chief Investigator responsible for activity at all sites

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| --- | --- | --- |
| Name: Click here to enter text. | Qualifications: Click here to enter text. | |
| Lead site and Department: Click here to enter text. | | |
| What is the position of this person on the research project? Click here to enter text. | | |
| 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 that you will submit with your application?  Yes /  No - Good Clinical Practice training is required by all listed investigators, as per National Clinical Trials Governance Framework action 1.2 and 1.6 | | |
| 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 responsible for each site

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| Name: Click here to enter text. | |
| Site and department: Click here to enter text. | |
| 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 that you will submit with your application?  Yes /  No - Good Clinical Practice training is required by all listed investigators, as per National Clinical Trials Governance Framework action 1.2 and 1.6 | |
| 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 Investigators – add additional tables or rows for all researchers involved in the study

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| Name: Click here to enter text. | |
| Site and Department: Click here to enter text. | |
| What is the position of this person on the research project? Click here to enter text. | |
| 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 that you will submit with your application?  Yes /  No - Good Clinical Practice training is required by all listed investigators, as per National Clinical Trials Governance Framework action 1.2 and 1.6 | |
| 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. |

## Research Overview

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| Please provide a brief overview of the study: |
| Background and literature review |
| Rationale / justification |
| Hypothesis and/or Research Question |
| 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? |

## Project design

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| **Anticipated start and finish dates:** |
| **Study Sites/Settings**: Please list all sites the research will be conducted. |
| **Recruitment target:** How many participants do you expect to recruit? |
| **Methodology -** 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 [Consumer and Community groups](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/consumer+resources+for+salhn+research) with the design of their research. Please outline any consultation that has occurred. |
| What are your outcomes for the research and how are they measured? |
| Inclusion criteria – detail the characteristics that clearly describe the study population that are required for a participant to be included in the study: |
| Exclusion Criteria **-** detail the characteristics/ basis on which prospective participants will be excluded from the study: |

## Funding

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| Please provide a brief explanation:  Funding source:  Funding amount:  Who will manage the study budget?  **Is there additional funding support provided by an external source?** |

## 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. |
| 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? - |

## Consent

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| **How you will be obtaining consent and/or what alternatives you will be using**? i.e., signed consent form provided at first visit, implied by return of survey |
| **Please advise (by name) which investigators will provide the information sheet and consent form to the participant?**  **Please advise (by name) investigators who will obtain consent?** |
| 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. |
| **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.  Yes  No |
| Who will be confirming or renegotiating consent with participants?  What process will be undertaken and how will participants be supported through this process? |

## Waiver of consent/Pre-screen Waiver of consent

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| Are you requesting a waiver of consent to pre-screen a data source for the purpose of identifying eligible potential candidates to invite to participate in this study?  If you need to access a patient’s medical records to pre-screen for eligible participants, and you do not have prior patient consent to do so or are not part of the patient’s clinical care team, you will need to apply for an exemption under 93(3)(f). The recruitment method must be compliant with the Health Care Act 2008.  ☐ No – I am part of the patient’s clinical care team.  ☐ Yes –Under s93(3),(f) of the Health Care Act 2008, we wish to apply for an exemption of patient consent to access their personal information for research purposes. In order to identify suitable participants for this research project, **<specify who or a title i.e., study coordinator>** will be required to access <specify what is being accessed>, prior to obtaining consent from the patient.  Are you requesting a waiver of consent and no participant information sheet or consent form will be used for this study?  No  Yes - **The waiver of consent must be justified using the National Statement chapter 2.3.9 and 2.3.10 (a) to (i).**  Please:   1. Demonstrate how involvement in this research carries no more than low risk to participants. Refer to The National Statement chapters 2.1.6 and 2.17 for guidance. 2. Explain how the benefits from the research justify any risks of harm associated with not seeking consent 3. Explain why it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records). 4. Explain why there is no known or likely reason for thinking that participants would not have consented if they had been asked. 5. Demonstrate there is sufficient protection of their privacy. 6. Demonstrate there is an adequate plan to protect the confidentiality of data. 7. Explain in the case the results have significance for the participant’s welfare there is, where practicable, a plan for making information arising from the research available to them i.e. via a disease-specific website or regional news media).   h) Explain the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants any financial benefits to which they would have been entitled.  (i) Demonstrate the waiver is not prohibited by State, Federal or international law. |

## Participant selection and activities

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| **How are potential participants identified as suitable for the research?** i.e., 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 etc. |
| **Who is approaching the participants about this research project?**  **When is this occurring?** I.e., clinic, inpatient, invitation letter |
| **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 |
| **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? i.e., follow up phone calls, in clinic check-ups |

## 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 |
| **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 and how it will be managed:** |

## Data management plan

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| Which listed investigators will collect the study data / information? |
| **What type of data will be used?**  Data that has never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified.  Identifiable - data that contains an identifier or combination of identifiers i.e.name, date of birth, image, address, URN  Data in which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets.  **If the data being used has the potential to identify a patient, please justify and describe how accidental re-identification will avoided?** |
| **If the participant’s medical records are being accessed - please state where the information is being collected**   * i.e., registries or databases, medical records, EPAS, OASIS, Sunrise * My Health Record data is not available for research and public health purposes. |
| Data sets - please list the data sets being collected, and provide a copy of the data collection sheet |
| 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 - |
| 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 during the research? 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 to other sites? |
| 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? |
| Who is responsible for the study data disposal? |

## Analysis

Clearly detail the statistical analysis methods that will be used to meet the study aims and/or test the study hypothesis.

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| 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? |
| Participants may withdraw from the study by choice, what impact will a participant withdrawing have on the data?  How will this be responded to? |

## Results, reporting, outcomes, and future plans

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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? |

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# Appendix 1 – Low Risk Protocol Instructions

Delete this page when complete

The preparation of a research protocol is an important first step in the research process. It ensures research activities are well-planned from the outset and provides a clear record for investigators to refer to throughout the project. Both scientific and ethical considerations should be addressed in accordance with the [NHMRC National Statement (2023](https://nhmrc.govcms.gov.au/node/8345)).

Please ensure you address all sections contained in this template. The content should be treated as a piece of academic writing, taking into careful consideration readability, spelling, and grammar. All acronyms should be explained before being used throughout the document and any clinical terms explained in full to ensure the reviewers understand your field of expertise which they may not be familiar with.

# Application submission

Low risk applications are submitted via email and are reviewed by the Expedited Review Panel.

As per the [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) chapter 2.1.6, low risk research is defined as’...the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.’.

Please review the National Statement carefully before choosing to complete a Low-Risk application form via the ERP pathway. If incorrect, the reviewers will request you to re-submit your application via the Greater than Low Pathway via [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).

Do not submit a low-risk application via GEMS.

Triggers to identify your research as greater than low risk are:

* Studies among Aboriginal / Torres Strait Islander people
* Involvement of vulnerable population groups such as mental illness, cognitive or intellectual impairment, pregnant women, or their foetus
* Interventions which may cause a higher risk of harm and foreseeable burden to the individual, group, community, societal or global
* You have requested an opt out or waiver of consent (where there is active participation)
* Genetic testing studies
* Creation of a databank, biobank, or registry
* Exploration of sensitive personal or cultural issues.

# Study Protocol Guidelines

There are a number of pre-requisites that may assist both ethics and governance reviewers when assessing your research. The quality of your application will impact the time it takes for your study to be approved. Below are a few tips which will help you to ensure that you have addressed both ethics and governance criteria.

# 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 action 1.2 and 1.6

# 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).

Please note, 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.

# 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