* **DELETE THIS PAGE AFTER READING.**
* **Every study submitted to the DHW Human Research Ethics Committee must have a study protocol.**
* **This template can be used to create a protocol.**
* **Text in blue should be replaced or deleted if not applicable.**
* **If using your own protocol template/format, please refer to this document as a guide to ensure all required headings/information has been captured.**
* **Delete all prompts from final version.**

**The DHW HREC is committed to reducing duplication between the protocol and the national Human Research Ethics Application (HREA), that is completed via Research GEMS online. Please include all project details within the protocol, and when completing the HREA online, respond with ‘Refer to section xxx in the protocol’.**

**Useful resources:**

* + *[NHMRC National Statement of Ethical Conduct in Human Research (2023)](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)*
	+ [*NHMRC Australia Code for the Responsible Conduct of Research (2018)*](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)
	+ [*NHMRC* *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders*](https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities)

*References to the National Statement on Ethical Conduct in Human Research (2023) (National Statement) are provided in each section to assist with the types of ethics considerations required to be described. They are a guide only and are not exclusive for the ethical considerations within each section.*

**RESEARCH PROTOCOL**

***Full Title:*** *XXXXXXX*

***Short Title:*** *XXXXXXX (if applicable)*

**STUDY INVESTIGATOR(S)**

**Add/delete rows as required**

# Principal Investigator(s):

|  |  |
| --- | --- |
| [name][position][unit/dept][org][address] Ph. xxxxxxxxxxEmail: xxxxxxxxxx@xxxxxxxxxx*[Role e.g. study design, analysis, recruitment, etc.]* | [name][position][unit/dept][org][address] Ph. xxxxxxxxxxEmail: xxxxxxxxxx@xxxxxxxxxx*[Role e.g. study design, analysis, recruitment, etc]* |

# Sub- Investigator(s):

|  |  |
| --- | --- |
| [name][position][unit/dept][org][address] Ph. xxxxxxxxxxEmail: xxxxxxxxxx@xxxxxxxxxx*[Role e.g. study design, analysis, recruitment, etc.]* | [name][position][unit/dept][org][address] Ph. xxxxxxxxxxEmail: xxxxxxxxxx@xxxxxxxxxx*[Role e.g. study design, analysis, recruitment, etc.]* |
| [name][position][unit/dept][org][address] Ph. xxxxxxxxxxEmail: xxxxxxxxxx@xxxxxxxxxx*[Role e.g. study design, analysis, recruitment, etc.]* | [name][position][unit/dept][org][address] Ph. xxxxxxxxxxEmail: xxxxxxxxxx@xxxxxxxxxx*[Role e.g. study design, analysis, recruitment, etc.]* |

**OTHER PERSONNEL**

|  |  |
| --- | --- |
| [name][position][unit/dept][org][address] Ph. xxxxxxxxxxEmail: xxxxxxxxxx@xxxxxxxxxx*[project role, e.g. advisors, contributors, etc.]* | [name][position][unit/dept][org][address] Ph. xxxxxxxxxxEmail: xxxxxxxxxx@xxxxxxxxxx*[Role, e.g. study design, analysis, recruitment, etc.]* |

# INTRODUCTION

The introduction is a very brief overview of study (~250 words). The introduction should be concise but sufficient to orientate the reader to the main purpose of the study, how it will be conducted and its expected benefits. It is a structured sketch of the study that will provide an overview before examining the details. It is placed at the head of the protocol but is often written after the protocol itself is completed.

# BACKGROUND

The most important aspect of a research proposal is the clarity of the research problem.

This is an opportunity to convince the reader (or reviewer) of why the study needs to be done (and deserves funding or ethical approval). Keep this brief and to the point (approximately two A4 pages). The following key points may be used as a guide:

* Conduct a comprehensive literature search (Cochrane, Medline, Embase and other databases relevant to your area of study).
* Discuss the importance of the topic (public health and/or clinical importance and impact on individuals/community; incidence, prevalence, mortality and morbidity).
* Critically appraise the relevant literature and discuss the state of current knowledge on the topic (including deficiencies in knowledge or gaps that make the study worth doing).
* Indicate how the research question has emerged and fits logically with the above.
* Outline your approach to address the research question.
* Explain how your study will contribute to existing research and benefit other individuals or the wider community.

Discussion should be clear and logical that demonstrates you are fully conversant with the ideas presented and can grasp their methodological implications. Aim to be concise and present only key sources rather than an exhaustive list of cited references (limit to approximately 20-25 key papers). The literature review should logically lead to the statement of the aims of the proposed project.

NS reference: Chapter 3.1, Element 1

# AIM OF STUDY / RESEARCH QUESTIONS

Your aim(s) should arise from your literature review and state what the study hopes to accomplish.

Your focused research question(s) may need to be further refined as one or more study objectives. The study objective(s) should be single and quantifiable statement(s) that will allow you to answer your research question(s).

*E.g. The objective of this study is to determine if socioeconomic status is associated with excess childhood asthma in Istanbul.*

NS reference: Chapter 3.1, Element 1

# HYPOTHESIS *(for quantitative studies)*

Hypotheses are more specific than objectives and amenable to statistical evaluation. Your primary hypothesis is your statement of the hypothesised effect on the primary outcome measure. A hypothesis is worded very simply and written as ‘testable’ statements. Your experimental results will prove or disprove your hypothesis. Hypotheses are generally stated in the null form (Ho) as they have their basis in inferential statistics. Rejecting the null hypothesis increases our confidence, with a given level of probability, that there is a relationship between the variables being studied. However, a classic scientific hypothesis includes both a null and alternative (Ha) hypothesis.

*e.g. H0: Asthma prevalence rates are not different among children from low and high socioeconomic groups in Istanbul.*

*HA: Asthma prevalence rates are different among children from low and high socioeconomic groups in Istanbul.*

# STUDY DESIGN

State the design of the research (e.g. randomised controlled study, cross-sectional survey, prospective or retrospective cohort/case-control, observational, focus groups/interviews, action research).

Whatever the study design, you need to ensure that you provide the reader with a clear statement and description of your proposed design. You may also explain why the particular study design has been chosen in preference to other possible designs (i.e. justification for choice of study design).

NS reference: Chapter 3.1, Element 1

# STUDY SETTING/LOCATION

The location of where the study will be conducted (e.g. Neonatal Intensive Care Unit, Riverland Region). You need to mention whether the study is going to be a single-centre study or a multi-centered study (i.e. conducted in more than one location).

1. **Sites**

Include all organisations involved in the study, that are governed by SA Health (e.g. where the participants will be recruited, where any datasets are being received from, where the data will be stored, who is initiating the research etc.).

Example:

* SA Department for Health and Wellbeing
* Lyell McEwin Hospital, SA
* SA Ambulance Service
* Port August Hospital, SA

NS reference: NS5.5.6

# STUDY POPULATION AND SETTING

You need to describe the population that will be targeted to participate in the study. It is important to outline:

* The population the participants will be drawn from
* All aspects of participant selection
* The total number and number within any subgroups

If you are undertaking quantitative research, this section also describes how one can be certain that the results from your sample population can be generalised to the target population of interest. If your research is qualitative, describe what makes the selection of this particular population and site sound, in terms of its interest, richness, diversity, likelihood of success etc. Also, you need to describe the way in which you will sample for participants (typical case, snowball, theory-based etc.)

NS reference: Chapter 3.1, Element 2

# ELIGIBILITY CRITERIA

Inclusion and exclusion criteria are standards that you have set determining whether a person may or may not be allowed to enter your study. They are used to identify appropriate participants and to ensure their safety.

*NS reference: Ns1.4a*

1. **Inclusion criteria**
* E.g. Asthma-related hospital admission
* E.g. Admitted between \*\*/\*\*/\*\*\*\* and \*\*/\*\*/\*\*\*
* E.g. Ages =>18 years
* E.g. English speaking
1. **Exclusion criteria**

Provide details of participants that will be considered ineligible to participate and justification for their exclusion. These criteria are not always clinical in nature, aiming principally to accommodate participants in a safe and ethical manner. Criteria may include:

* circumstances that interfere with the participant’s ability to give informed consent (diminished understanding or comprehension, or a language other than English spoken and an interpreter unavailable),
* contraindications to the study treatment(s)/procedure(s),
* taking certain concomitant medication(s), or conditions that interfere with a patient's ability to comply with all treatment(s)/procedure(s) or follow study guidelines.
* E.g. Ages <18 years

# STUDY OUTCOMES

1. **Quantitative**
2. **Primary Outcome**

The primary outcome should be the most important and clinically relevant outcome (e.g. clinical, psychological, economic, or other) of the study. This is the measure used to answer your study aim. However, it is also the outcome used to calculate study sample size and power and test the primary research hypothesis. Generally, no more than 1-2 primary outcome measures are pre-specified. Primary outcome measures may be measured in various ways such as:

* binary (e.g. caesarean/no caesarean, blood loss ≥500mL/blood loss <500mL);
* continuous (e.g. weight - kg, blood loss - mL);
* ordinal (e.g. pain - mild, moderate, severe);
* time to event (e.g. survival)
* counts (e.g. number of infections, number of events occurring).
1. **Secondary Outcome(s)**

Secondary outcome(s) are measures of additional or less important research interest. They may include additional clinical, psychological, economic, or safety outcomes (e.g. treatment related side effects/adverse events). However, as these endpoints are not used to calculate study power and sample size it is often not possible to draw robust conclusions from the results.

1. **Qualitative**

You should describe the form that you expect your findings to take (presentation of themes, critical episode presentation, life history) and the way in which you will present these (report, papers for publication, conference presentation, feedback to participants etc.)

# STUDY PROCEDURES

This section should describe exactly what is going to happen during conduct of the study. It is preferable to use the active voice and state in the future tense (e.g. “We will randomly allocate participants to…”).

1. **Recruitment of participants**

This section should describe which potential participants will be identified/selected for recruitment (e.g. via outpatient clinic), how they will be approached, who will approach them, how consent will be obtained, how long potential participants will be given to consider participation. *[National Statement Chapter 2.2]*

Please note that research that uses de-identified datasets still needs to describe the participants in the application. This research may involve the use of information with or without personal identifiers and it may be obtained from or associated with individuals or gathered in aggregate form.

If the recruiter is in a perceived position of power, or in a dependent/unequal relationship with the participant, further information is required on how this will be managed *[National Statement Chapter 4.3]*.

You may need to justify the feasibility of recruiting the required number of participants and estimate the proportion that you would expect will agree to participate.

Finally, the period of time expected to recruit the required number of participants should be stated here.

*NS reference: NS Chapter 3, Element 2*

1. **Study procedures**

In this section you need to clearly and comprehensively describe exactly what will happen to participants once they are enrolled in your study.

Depending on the study it might include the frequency and duration of visits whether they are expected to self-complete a daily diary at home, the duration of the study or follow-up, if they will take part in a focus group, and any measurements taken at each visit (e.g. questionnaires, physical measurements, biological samples).

You should include precise details of any intervention(s) intended for each group/participant including the time each study visit (interview, questionnaire, test) will take, where it will take place, and what is involved.

You should also provide details of any follow-up and consider how you will monitor ongoing participation if applicable.

You might also describe under which circumstances participants may withdraw or be withdrawn by the investigators and how this will occur. **A schematic diagram or flow chart may be useful for this section.**

*NS reference: Chapter 3.1, Element 1*

1. **Methods of data collection**

It is essential to state how the data will be collected to assess the outcome(s) of the study (e.g. patient questionnaire, interview, focus group, medical charts, routinely collected hospital case notes, datasets/databases, biological specimens).

Describe at what point(s) of the study data collection will occur. You should make statements that justify the validity of the study measure/instrument and/or whether there will be audio recordings. If not, you will have to verify how you will ensure the validity and quality of data being collected.

Also, mention here if you are going to have one or more assessors to collect data, their level of training/experience (or how they will be trained), and if you are planning to assess inter-rater reliability (if applicable).

Does your research involve the use of Artificial Intelligence (AI)? If so, provide the following details:

* where the data are currently stored
* who is the custodian of the data source
* include the approximate size of the data set
* who is developing the AI software (the research team, third party, student etc)
* how the data will be analysed.

*NS reference: Chapter 3.1, Element 4*

1. **Access to Existing Data**

**If not applicable, this section can be removed and replaced with a N/A.**

This section includes more detailed information data being collected from databases or existing datasets. Specifically it asks for the organization holding the data, the data custodian, and the data variables.

*NS reference: Chapter 3.1, Element 4*

|  |  |
| --- | --- |
| **Name/Description of data** | **Flinders Medical Centre Medical Records** |
| **Data Custodian** | Flinders Medical Centre |
| **Agency Type** | State *(/ State / Commonwealth / Private Sector)* |
| **Data Collection Format** | Identifiable (identifiable / re-identifiable / non-identifiable) |
| ***Variable*** | ***Justification*** |
| *Patient\_ID* |  |
| *Name* |  |
| *Date of Birth* |  |
| *Address* |  |
| *Surgeon* |  |
| *Age at time of surgery* |  |
| *Ethnicity* |  |
| *Smoking History* |  |

|  |  |
| --- | --- |
| **Name/Description of data** | **Integrated South Australian Activity Collection (ISAAC)** |
| **Data Custodian** | SA Department for Health and Wellbeing |
| **Agency Type** | State *(State / Commonwealth / Private Sector)* |
| **Data Collection Format** | re-identifiable (identifiable / re-identifiable / non-identifiable) |
| ***Variable*** | ***Justification*** |
| *Patient\_ID* |  |
| *Hospital* |  |
| *Postcode* |  |
| *Date\_Of\_Death* |  |
| *Age\_At\_Admission* |  |
| *Indigenous\_Status* |  |
| *Country\_Of\_Birth* | Country of birth is a required statistic in reporting the demography of the study population. |
| *Admission\_Date* |  |
| *Principal\_Diagnosis* |  |
| *Marital\_Status* | Marital status is a required statistic in reporting the demographic of the study population. |
| *Employment\_Status* |  |
| *Pension\_Status* |  |
| *Admission\_Category* |  |

|  |  |
| --- | --- |
| **Name/Description of data** | **SA Deaths Registry** |
| **Data Custodian** | SA Attorney General's Department |
| **Agency Type** | State *(State / Commonwealth / Private Sector)* |
| **Data Collection Format** | re-identifiable (identifiable / re-identifiable / non-identifiable) |
| ***Variable*** | ***Justification*** |
| *Age at Death Age* |  |
| *Date of Death* |  |
| *Cause of Death 1A* |  |
| *Cause of Death 1B* |  |
| *Cause of Death 1C* |  |
| *Cause of Death 2A* |  |

1. **Data Linkage Management**

Data linkage allows for the identification of distinct entities between

datasets. If data linkage is occurring in your study, specific detail is required on how the linkage will occur including who will manage the linkage (e.g. SA-NT datalink, AIHW) and how participants’ privacy and confidentiality will be protected, if not already described under heading ‘Study procedures’.

Consider how your findings account for any limitations arising from your choice of datasets/databases or from missing data?

 Consider how will you manage any risk that linking databases of non-identifiable data could subsequently result in the individuals being identified?

The HREC encourage including a flow diagram which depicts the data linkage process.

*NS reference: Chapter 3.1, Element 4*



1. **Safety considerations**

The safety of research participants is foremost. You will need to provide adequate information on how the safety of research participants will be ensured, drawing attention to any relevant sections of the *National Statement*. This can include procedures for recording and reporting serious adverse events and their follow-up. Remember that even administering a research questionnaire or conducting an interview may have adverse psychological effects on susceptible individuals. Also keep in mind that your research may have impacts on whole populations; you need to consider whether the findings of your research may harm communities if they are reporting inappropriately.

Safety considerations also apply to the safety and wellbeing of researchers (for example, if they are doing home visits, if they are working with dying patients, mental health patients, etc.).

1. **Data monitoring**

This section includes information on the personnel and processes of person or groups monitoring the study, study monitors to audit study conduct, any stopping and discontinuation rules and handling of adverse events/serious adverse events.

1. **Protocol Deviations**

This section is relevant to all research applications, please consider the response accordingly.

Example text provided as a guide, customize as needed:

A protocol deviation is any noncompliance with the study protocol, GCP, or HREC requirements.

The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be implemented promptly.

The principal investigator will use continuous vigilance to identify and report deviations within 72 hours of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the approving HREC(s) and site Research Governance Officer(s).

1. **Unexpected or Serious Adverse Events**

This section is relevant to all research applications, please consider the response accordingly.

Example text provided as a guide, customize as needed:

An unexpected adverse event is an unforeseen harmful, unpleasant or undesirable response, reaction or outcome experienced by a research participant or researcher. Such incidents may include unanticipated physical, psychological, emotional, cultural, financial or legal harm. It may also include where an unexpected event has occurred which may potentially harm participants, researchers, or the study organisation.

A serious adverse event is any untoward medical or psychological occurrence that results in death, is life threatening, requires inpatient hospitalisation or prolongation of existing hospitalization, or results in persistent of significant disability or incapacity.

The principal investigator will use continuous vigilance to identify and report adverse events within 72 hours of identification of the event to all approving HRECs and relevant Research Governance Officers.

# DATA ANALYSIS

1. **Quantitative**
2. **Sample size and statistical power**

A sample size or power calculation should be performed. This calculation is used to estimate the number of participants required to answer your primary study hypothesis with an accepted power. Conversely, it also allows you to estimate what power can be achieved with a limited number of participants. This number is calculated by specifying the magnitude of the effects that are expected (i.e. informed and clinically significant), variability of the measurements and the acceptable degree of type I and II errors. You need to specify the assumptions made for the calculation. It is recommended that you consult with a statistician for this section. Also keep in mind the estimated recruitment rate and whether you need to adjust for anticipated non-responders and losses to follow up.

1. **Statistical methods**

The statistical methods used for the study objectives/hypotheses (e.g. t-test, chi-squared, multivariate modeling) must be sufficiently detailed. If conducting a randomized controlled study, you should state whether methods will include an “intention to treat” (ITT) analysis, per protocol analysis, or both. An ITT analysis is preferred as it compares all participants in the groups to which they were originally randomly assigned (despite withdrawal, treatment failure or cross-over). Consultation with a statistician is strongly recommended.

1. **Qualitative**

The analysis strategy adopted in qualitative research will relate to the type of study being conducted and the theoretical framework guiding the study. In this section you should describe briefly your guidelines for managing data, your analytical framework (e.g. content, thematic, phenomenological, discursive), and how you will identify patterns and themes in your data.

1. **De-identification**

Researchers must maintain high standards of privacy in the data it releases.

The most obvious factor to consider in the likelihood of identification is the presence of obvious identifying variables in the data, such as a name, date of birth or street address. Even with the absence of such variables the following factors need to be considered:

***Motivation to attempt identification*** – Consider whether an individual or organisation would receive any tangible benefit (malicious or otherwise) from identification of individuals in the dataset.

***Level of detail disclosed by the data*** – The more detail included, the more likely identification becomes. Where the dataset contains multiple variables for the same record-subject, identification could be made through the combination of those variables.

***Presence of rare characteristics*** – If there are rare or remarkable characteristics for a record-subject the chances of identification are increased. For example, a 19 year old girl who is widowed is likely to be noticeable in the data.

Researchers should describe how they reduce the risk of re-identification, the following document can be used as a guide: *[*[*Privacy Committee of South Australia Privacy and Open Data Guideline*](https://data.sa.gov.au/sites/default/files/Toolkit/Privacy-and-Open-Data-Guideline.pdf)*]*

The term ‘de-identified information’ is used in privacy legislation and associated guidelines. De-identified information may be re-identifiable or non-identifiable, depending on the process used to de-identify the information and depending on the point of reference.
Information may identify an individual even if provided anonymously due to the context in which the information is given or its association with other pieces of information.

Information can also identify an individual by inference (e.g. where other participants, colleagues, peers and family might be able to infer the identity of a participant even if others couldn’t).

Information may identify a non-participating individual due to the context in which the information is given (such as a medical record) or its association with other pieces of information.

*NS reference: Chapter 3.1, Element 4*

# DATA HANDLING AND RECORD KEEPING

1. **Data Collection and Management Responsibilities**

Data collection is the responsibility of the research staff of [research institution] under the supervision of the Principal Investigator. The Principal Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

Provide details regarding the type(s) of data capture that will be used for the study. Specify whether it will be paper or electronic, distributed or central, batched or ongoing processing, and any related requirements. Indicate expectations for time for submission of case report forms (CRFs).

Information should include the role in data collection, review of data, study materials, and reports, as well as retention of source documents, files, and records. Describe coding dictionaries to be used and reconciliation processes (if applicable).

If data are to be generated in one location and transferred to another group, describe the responsibilities of each party.

Indicate the roles of each party with regard to interpretation of data, plans for analysis, review of tables and listings, and plans for reporting.

Copies of the CRF will be provided for use as source documents and maintained for recording data for each case note. Data reported in the CRF derived from source documents should be consistent with the source documents or the discrepancies should be explained and captured in a progress note and maintained in the participant’s official electronic study record.

*NS reference: Chapter 3.1, Element 4*

1. **Study Records Retention**

Specify the length of time for the Principal Investigator to maintain all records pertaining to this study. The investigator should use the most conservative rule for document retention – i.e., retention should follow the rule that has the longest period.

**SA Health staff must comply with the State Records *General Disposal Schedule No. 28* which mandates retention of records for a period of 15 years from the date of project completion, unless legislated otherwise (for example asbestos related research is 30 years, some evaluation of public health programs need to be retained permanently).**

It is the responsibility of the researcher to ensure they are following legislative requirements around data retention.

Indicate where the study data will be retained, how it will be kept secure (e.g. password protection, firewall presence, two factor authentication), and exactly who will have access and to what.

Indicate after the retention period, how records will be destroyed (i.e. is there an organization policy for archiving, will they be destroyed by the research team, how? etc.).

**SA Health staff must comply with the State Records Act 1997, Freedom of Information Act,**

**Health Care Act, Mental Health Act, and other SA Health records related policy directives. Privacy requirements regarding the usage, disclosure, storage and security of a health record are referenced in the Privacy Policy Directive.**

* + **For more information, please visit** *[SA GOVERNMENT State Records Act 1997 General Disposal Schedules](https://archives.sa.gov.au/managing-information/archiving-transfer-and-disposal/disposal/general-disposal-schedules-gds)*

 *NS reference: Chapter 3.1, Element 4*

# PUBLICATION & INTELLECTUAL PROPERTY

The publication and authorship policies should be established and clearly outlined in this section. For example, for a study with multiple investigators, this section might state that an Executive Committee will be responsible for developing publication procedures and resolving authorship issues. Please refer to your specific contract grant and/or Clinical Trials Agreements if applicable.

1. **Dissemination of results to participants**

Describe how research participants will directly be informed of the study findings (also include in Participant Information Sheet if there is one).

*NS reference: Chapter 3.1, Element 6*

# ETHICAL CONSIDERATIONS

If not already addressed, You will need to consider and articulate how the quality of the technical aspects have been assured, the potential risks and proposed benefits of the study procedures, the priority of the participants’ interests over those of science or of society and how those interests will be safeguarded.

1. **Indemnity & Compensation for Injury**

Provide details of who is indemnifying the study, including specific detail on responsibility and management for liability of injury during the study...

1. **Vulnerable populations**

Information on how informed consent is to be obtained should be included. This ensures that if participants can read and understand the information they need to make an informed decision about their voluntary participation. This can include allowances for special population groups (e.g. children, Aboriginal and Torres Strait Islander, defense veterans, children) where applicable.

*NS reference: Chapter 2.2*

1. **Waiver of Consent**

If seeking a waiver of consent, justification must be given here, citing the *National Statement* section 2.3.10. Provide justification to each of the following points:

*National Statement 2.3.10*: Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that:

a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants

b) the benefits from the research justify any risks of harm associated with not seeking consent

c) it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)

d) there is no known or likely reason for thinking that participants would not have consented if they had been asked

e) there is sufficient protection of their privacy

f) there is an adequate plan to protect the confidentiality of data

g) in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)

h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled

i) the waiver is not prohibited by State, federal, or international law.

If seeking a waiver of consent for use of health information held by a *commonwealth* agency, please provide further justification citing section 95 of the Privacy Act 1988.

* ‘[Application of the Guidelines under Section 95 of the Privacy Act 1988](https://www.nhmrc.gov.au/sites/default/files/documents/attachments/template-application-s95.docx)’ to be submitted with your application; **OR**
* If applying to a Commonwealth HREC, you may already have completed the above form, and already had the Commonwealth HREC approve the application under the S95 guidelines, in which case you do not need to repeat the process, but do need to attached evidence that this has already occurred (e.g. a copy of the HREC approval citing reference to the S95 application).

If seeking a waiver of consent for use of health information held by a private agency, please provide further justification citing section 95a of the Privacy Act 1988.

1. **Confidentiality**

You will also need to adequately detail methods of data extraction (non-identifiable, de-identified or re-identifiable), and data management, storage and security storage (of paper hardcopies and/or electronic files).

*EXAMPLE:*

*Audio recordings taken from focus group and interview sessions will be kept for 5 years after transcription. Transcription will be de-identified.*

*Electronic data will be stored on SA Health servers in secure folders accessible to only staff of the Respiratory Medicine staff of The Queen Elizabeth Hospital.*

*Hard copy documents will be stored in a secure area of the Basil Hetzel Institute of The Queen Elizabeth Hospital, 37a Woodville Road, Woodville South, South Australia. Access is limited to staff of the Clinical Practice Unit.*

*NS reference: Chapter 3.1, Element 4*

1. **Ethical Review**

The study will be conducted in full conformance with principles of the “Declaration of Helsinki”, Good Clinical Practice (GCP), the National Statement on Ethical Conduct in Human Research (NHMRC, 2007), Australian Code for the Responsible Conduct of Research (2007) and within the laws and regulations Australia.

Ethical approval will be sought from the following HRECs:

* SA Department for Health and Wellbeing Human Research Ethics Committee
* Flinders University Social And Behavioral Research Ethics Committee
* SA Aboriginal Health Research Ethics Committee (AHREC)

Researchers should consider whether approval is required from the Aboriginal Health Research Ethics Committee (AHREC). The AHREC state that ethics approval is required from their Committee if:

* the primary research goals and questions of study are directly related to health research and well-being; and
* the experience of Aboriginal and/or Torres Strait Islander people is an explicit focus of all or part of the research; or
* data collection is explicitly directed at Aboriginal and/or Torres Strait Islander people; or
* it is proposed to conduct sub-group analyses and separately analyse Aboriginal people in the results; or
* the information, potential over-representation in the dataset or geographic location has an impact on one or more Aboriginal communities;
* Governmental Aboriginal health funds are a source of funding.

Researchers should consider whether approval is required from the Departments of Defence and Veterans’ Affairs Human Research Ethics Committee (DDVA HREC). The DDVA HREC state that ethics approval is required from their Committee if:

* Research is conducted on Defence members, ex-serving personnel or other Defence personnel, their information or tissue.
* Participants are to be recruited, either directly or indirectly, through a service provided by Defence or the Department of Veterans’ Affairs (DVA).
* Research is conducted by Defence or DVA personnel.
* Research is conducted on/in a Defence establishment.
* Research is sponsored, endorsed or funded in any part by Defence or DVA.
1. **Site/Governance Review**

In accordance with the *SA Health Research Governance Policy Directive,* Site Specific Assessment (SSA) Approval will be sought from individual public health sites where the project is being conducted, including:

* SA Department for Health and Wellbeing
* Lyell McEwin Hospital, SA
* SA Ambulance Service
* Country Health SA

# OUTCOMES AND SIGNIFICANCE

It may be of value to reiterate the potential benefits of answering the research question and conducting the project. This section restates the justification for the study in terms of the anticipated results. It may be important to specify the implications of the potential results and how the results of this study may inform future research or policy makers.

*NS reference: Chapter 3.1, Element 6*

# REFERENCES

1. ….
2. ….
3. ….
4. ….
5. ….
6. ….
7. ….