TERMS OF REFERENCE AND OPERATIONAL GUIDELINES OF THE SA DEPARTMENT FOR HEALTH AND WELLBEING HUMAN RESEARCH ETHICS COMMITTEE

1. THE COMMITTEE

1.1 Purpose and scope

The SA Department for Health and Wellbeing (DHW) Human Research Ethics Committee (HREC) is responsible for providing ethical assessment of proposals initiated or conducted by SA Health staff or external researchers seeking access to SA Health data held centrally and/or clients.

The DHW HREC reviews social health, public/population health, epidemiology, data linkage and qualitative research applications. The DHW HREC does not review clinical trials. All clinical trials must be submitted to an HREC with appropriate expertise to review these applications.

The DHW HREC reviews research applications on behalf of the SA Regional Health Services, South Australian Ambulance Service (SAAS) and research conducted by the Department of Human Services. The DHW HREC also reviews proposals that require the services of SA/NT DataLink, in cases where SA Health data is being accessed and linked.

In addition, where researchers do not have an established relationship with an HREC or are located overseas, the DHW HREC is willing to review these research applications providing they fall within the scope of the DHW HREC.

The DHW HREC will comply with the principles set out by relevant National Health and Medical Research Council guidelines and all relevant state and commonwealth legislation.

The DHW HREC will provide guidance to investigators on the conduct of ethically sound human research, and information privacy standards and relevant national and local guidelines and requirements.

National Mutual Acceptance - The committee is certified with the National Health and Medical Research Council to undertake the review of multi-centre research taking place across participating jurisdictions (public health organisations) as the 'Lead' HREC in the following categories:

- public/population health research
- qualitative health research
- mental health research
- data linkage research

1.2 Terms of reference

- Receive, examine and recommend approval or rejection of research proposals initiated or conducted by SA Health staff and/or external researchers seeking access to SA Health data and/or clients. The DHW HREC will accept and review proposals from South Australian researchers/research organisations as well as those from other Australian states and territories.

- Assess proposals in accordance with the *National Statement on Ethical Conduct in Human Research (2023)* (the National Statement), *Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities*: *Guidelines for researchers and stakeholders (2018)* and the *Australian Code for the Responsible Conduct of Research (2018).* In assessing research proposals, the DHW HREC will keep confidential all information concerning the proposals and related business.

- Protect the rights and welfare of research participants and minimize the risk of harm arising from research studies involving humans.

- Provide guidance to researchers on the ethical aspects of their proposed research.

- Advance thinking and best practice in relation to ethical aspects of research and evaluation.

- Advise applicants of the ethical acceptability of the proposed research.

In assessing research proposals involving the use of personal information, the DHW HREC will determine whether the use of personal information is ethically acceptable and advise applicants accordingly. Proposals may involve access to personal information, identifying or potentially identifying data, or internal or external data sources being linked. The proposals may be either internal (within SA Health) or external.

1.3 Accountability

The DHW HREC is accountable to the Chief Executive, Department for Health and Wellbeing, through the Chief Medical Officer, Department for Health and Wellbeing.

1.4 Reporting

The HREC will provide an annual report to the National Health and Medical Research Council, in line with its responsibilities as a fully constituted HREC.

Reports will be provided to the Chief Executive DHW on at least an annual basis, and as required. The HREC will bring to the attention of the Chief Executive any issues of significant concern regarding matters within its scope of responsibility. The annual report provided to the Chief Executive will provide information on membership; number of

applications reviewed; complaints received, including complaints about review processes and outcomes; and any other information required by the Chief Executive.

1.5 Appointment of members

The Chief Medical Officer, SA Health appoints the members of the DHW HREC.

Members will be appointed in an open and transparent manner, including via direct approach, expression of interest, nomination by an existing member or by external advertisement.

Members are appointed as individuals for their expertise, knowledge and qualities, rather than in a representative capacity. They are not appointed as representatives of any organisation, community or opinion.

Prospective members will be invited to attend three meetings as an observer before formally committing to joining the DHW HREC.

Members will be provided with a letter of appointment which will include details of the length of tenure and an assurance that indemnity will be provided for the individual when they are discharging their duties as a DHW HREC member.

Appointments to the HREC will allow for continuity, the development of expertise and the regular input of fresh ideas and approaches.

All appointed members will be asked to sign a confidentiality agreement and conflict of interest statement prior to attending their first meeting.

1.6 Membership

The core membership of the DHW HREC is in accordance with NHMRC guidelines. The core membership comprises:

- A Chairperson
- Two people who bring a broader community or consumer perspective and who have no paid affiliation with SA Health
- Two people with current research experience that is relevant to research proposals to be considered at the meetings they attend
- A person with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional
- A person who performs a pastoral care role in the community
- A qualified lawyer, who may or may not be currently practicing and, where possible, is not engaged to advise the institution on research-related or any other matters.

In addition to the above membership, wherever possible, membership will also include:

- An individual with knowledge of research and health ethics.

No individual may represent more than one of the categories listed above at any individual meeting but may fill a different category at a separate meeting, so long as all minimum membership categories are represented at each meeting.

Additional members may be appointed to ensure the DHW HREC has the expertise required to assess the proposals regularly submitted to it for consideration.

The DHW HREC has established a pool of members to draw on as needed.

As far as practicable, HREC membership will ensure each meeting has a diverse membership, including gender diversity.

All newly appointed members will receive a letter of appointment and a formal induction package, plus copies of the National Statement, and the *Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders 2018 document.*

Members may be asked to participate in relevant specialised working groups as required.

Observers are allowed to attend meetings at the discretion of the HREC Chair for the purpose of induction/training. Observers will be required to sign a confidentiality agreement and will have no voting rights.

1.7 Chair and Deputy Chair

The Chief Medical Officer appoints the Chair and Deputy Chair.

In the absence of the Chair, the Deputy Chair shall perform the role and duties of the Chair.

The roles and responsibilities of the Chair are:

- To chair the meetings of the DHW HREC meetings.
- To chair sub-committee meetings of the DHW HREC.
- To ensure matters referred to the DHW HREC are addressed and that outcomes and decisions are accurately recorded.
- To ensure the guidelines for the operation of the DHW HREC are adhered to.
- To ensure research proposals are considered in an effective and timely manner.
- To provide information for briefings and other advice as requested by the Chief Executive on human research ethics issues.
- To be the signatory for ethics approval letters.

1.8 Sub-committees of the HREC

A sub-committee of the HREC may form out of session to review a range of matters, including the following:

- Lower risk ethics submissions.
- Responses to matters raised by the full committee.
- Submissions deemed suitable for out of session review, including lower risk applications, as determined by the National Statement.
- Response to complex proposals with significant issues that require in-depth consideration by members with expertise prior to full consideration by the committee.
- Consideration of matters that need to be expedited due to timing issues associated with the commencement of the project.
- Clarification of matters pertaining to an ethics application that needs to be discussed in person with the principal investigator and/or project staff (or delegates).

The sub-committee will generally comprise the Chair (or Deputy), Executive Officer, and at least one other member.

The Executive Officer of the HREC will provide relevant material to the sub-committee for consideration. The sub-committee may either deliberate via email or in person.

Based on the discussion and views of the sub-committee, the Chair or Deputy Chair, will either make a determination regarding the application, or refer it back to the full committee for a decision. All decisions will be recorded either in the minutes, or the 'out of session' items as an appendix with the minutes of the next meeting.

1.9 Expert advice

The committee or Chair may request the advice of individuals who are external to the DHW HREC on ethics applications under consideration, where they possess a level of expertise that will complement the review of the committee.

The Executive Officer will retain a list of the individuals who may be approached to provide this expert review and/or advice.

Experts who are requested to review research applications will be asked to sign a confidentiality agreement prior to this review and will be indemnified in their role of providing advice to the HREC.

The HREC must be satisfied that the expert/s do not have a conflict of interest in relation to the project under consideration.

1.10 Confidentiality

Members of the DHW HREC will treat and keep confidential all information and documents which relate to business considered by the committee.

Members are required to sign a confidentiality agreement. All new members will receive a copy of this confidentiality agreement upon their appointment to the committee.

Members will be asked to sign a confidentiality agreement at the start of each calendar year to re-state their agreement to the maintenance of confidentiality.

1.11 Tenure

Members are appointed for a term of three years and may be reappointed for subsequent terms by the Chief Medical Officer, DHW.

A member may resign from the DHW HREC at any time upon giving notice in writing to the HREC Chair.

1.12 Lapse of membership

Membership will lapse if a member fails to attend three consecutive meetings of the DHW HREC without apology 24 hours prior to the meeting unless exceptional circumstances exist. The Chair will notify the member of such lapse of membership in writing.

Members may seek leave of absence from the HREC for extended periods.

1.13 Liability coverage

SA Health indemnifies members and expert advisors when they are acting in good faith for the purposes of discharging their roles as committee members and advisors.

1.14 Remuneration

The Chair is remunerated for their time preparing for meetings, reviewing correspondence following meetings and attending to out of session work.

Community members are remunerated at $35 per scheduled hour for meeting attendance and preparation time fees for one hour per meeting at $35 per hour when HREC papers are 300 pages or less or two hours per meeting when HREC papers are 301 pages or more. This is in accordance with the *SA Health Sitting Fees and Reimbursement for External Individuals*.

All members can be reimbursed for legitimate expenses incurred in attending committee meetings or in otherwise carrying out the business of the HREC, such as travel and parking expenses.

1.15 Training

Throughout their tenure, members will be given the opportunity to attend conferences and workshops relevant to the work and responsibilities of the HREC. Reasonable expenses for these activities will be covered by DHW, at the discretion of the Chief Medical Officer, DHW.

2. OPERATING PROCEDURES

The committee will perform its functions according to the procedures outlined in this document. All committee members will be provided with copies of the operational guidelines and the *National Statement on Ethical Conduct in Human Research* (2023) and *Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders 2018.*

The DHW HREC will conduct its business at regular meetings. On some occasions, as determined by the Chair, the committee may attend to business out-of-session via e-mail, phone or video conference, or through a sub-committee.

2.1 Management of the committee

The Office for Research, SA Department for Health and Wellbeing, will provide executive support to the DHW HREC.

2.2 Statement of compliance

The activities of the DHW HREC will be monitored by the NHMRC to ensure its compliance with the National Statement and other relevant documentation and guidelines. The DHW HREC will meet its reporting obligations as specified by the NHMRC.

2.3 Meetings

The DHW HREC will meet monthly, with the exception of January when no meeting will be held. Additional meetings of the full committee may be held at the discretion of the Chair. The HREC will not meet if no new proposals are submitted for review.

A schedule of meetings shall be prepared annually, to be circulated to guide applicants of timeframes. A copy of meeting and submission dates will be included on the SA Health HREC website.

Attendance at a meeting by members may be in person or via video conference link.

Members who are unable to attend a meeting are asked to contribute prior to the meeting through written to the Executive Officer or Chair. The comments received from absent members will be tabled at the meeting, and these comments considered as part of the review of a proposal.

Each proposal will be assigned two lead reviewers, who will be required to provide a written report 24 hours prior to the meeting and present the report verbally at the meeting.

The agenda shall be distributed by the Executive Officer to all attending members of the DHW HREC enough in advance to enable members to be fully informed (as specified by section *5.2.4* of the National Statement).

If notification is received that a member is unable to attend the meeting, another member from the same membership category may be asked to attend and all paperwork will be provided to them.

Additional or urgent business may be put before the meeting at the discretion of the Chair.

The quorum for the DHW HREC will be the minimum requirement as per the National Statement, section *5.2.5.*

Where there is less than full attendance of members from the minimum membership categories at a meeting, the Chairperson must be satisfied that the views of the members who are not present have been received and considered by all members of the HREC participating in the meeting before a decision is made.

2.4 Conflict of interest

Any member of the DHW HREC who has any actual or potential personal, financial, professional or institutional interest, in a proposal or other related matter considered by the committee, should as soon as possible declare such interest, in accordance with Chapter 5.6 of the National Statement. The DHW HREC will make a determination regarding the nature of the conflict at the beginning of each meeting and will advise the member of the role that he/she may play in relation to the review of the proposal.

In cases where the conflict of interest is considered to be significant, the member will be asked to leave the meeting while the protocol is being discussed but may be invited to stay briefly to clarify any issues surrounding the protocol. Upon completion of discussions the member is to return to the meeting. All declarations of interest shall be recorded in the minutes.

2.5 Review of applications

2.5.1 Submission of applications

Applications must be submitted to the DHW HREC two weeks prior to the meeting date. Late applications will not normally be considered until the following meeting.

Applications to the DHW HREC must be submitted electronically through the Research GEMS portal using the Human Research Ethics Application (HREA) form.

All ethics applicants must ensure their application is complete and fulfils the requirements outlined in the submission checklist document, available on the SA Health HREC website and through the Executive Officer.

It is recommended that each ethics application undergoes a peer review process by a person independent of the project team, in accordance with the expectations outlined in the *Australian Code for Responsible Research Conduct.* Details of this review should be outlined in the application form and copy of the peer review report provided with the application.

Each application submitted to the DHW HREC must adhere to the requirements stipulated in the National Statement and the *Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders 2018*, and other relevant ethical guidelines and standards, as applicable.

In determining whether or not these proposals are ethically acceptable, the DHW HREC examines compliance with confidentiality and privacy requirements, and standards for research ethics established by the National Health and Medical Research Council through the National Statement, the *Ethical conduct in research with Aboriginal and Torres Strait Islander peoples and communities: Guidelines for researchers and stakeholders 2018*, and other relevant ethical guidelines and standards.

Each application submitted to the DHW HREC must obtain evidence of 'in-principle' support from the relevant area/ organisation. This includes the appropriate evidence of support from relevant data custodians. It is the responsibility of the Coordinating Principal Investigator (CPI) to obtain and provide these approvals, either by email (for non-DHW data sets) or the Research GEMS Site Specific Assessment (SSA) form (for DHW-held data sets).

The HREC may consider the views of another properly constituted HREC in relation to a research protocol.

Applications involving Aboriginal and Torres Strait Islander participants

Ethics applications involving research on an Aboriginal or Torres Strait Islander community will be reviewed by the DHW HREC. However, approval will be subject to review and approval of the application by the Aboriginal Health Research Ethics Committee (AHREC) of South Australia.

The South Australian AHREC reviews all research applications where the focus is on a topic of disease/health burden identified as being of specific concern to Aboriginal or Torres Strait Islander people (based on 4.7.6 of the National Statement). In addition to a research application having been submitted to and reviewed by the DHW HREC, proposals are required to be submitted to the AHREC if:

- The experience of Aboriginal 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 Torres Strait Islander people; or
- Where it is proposed to separately identify Aboriginal and Torres Strait Islander people in the results; or
- The information has an impact on one or more Aboriginal or Torres Strait Islander communities; or
- The geographic location of the research is such that a significant number of the population are likely to be Aboriginal or Torres Strait Islander origin (based on 4.7.6 of the National Statement; or
- Where terms such as 'resilience', 'well-being', 'cultural safety', and 'language and culture' are used in the description and design of the project indicating that the project has important health implications for Aboriginal or Torres Strait Islander people; or
- Aboriginal and Torres Strait Islander health funds are a source of funding.

Student applications

All student applications must be submitted by the principal supervisor as the Coordinating Principal Investigator (CPI) and not the student. The student should sign the application as an associate researcher however the supervisor must be listed as the CPI.

Incomplete applications

Incomplete applications will generally be returned to the applicant for completion. However, minor omissions may, at the discretion of the Executive Officer, be remedied by the applicant within a specific timeframe if possible.

The Executive Officer will acknowledge receipt of the proposal and will advise of the date of the committee meeting at which the proposal will be reviewed.

2.5.2 Fees for ethical review

A fee structure applies within the SA public health system for the review of research ethics submissions (new applications and amendments). Not all submissions are invoiced, and applicants should review the SA Health Research Ethics and Governance Fees Schedule available on the SA Health HREC webpage.

2.5.3 Expedited review of lower risk applications

Members of a sub-committee of the DHW HREC may be requested to review low risk applications out-of-session, either via email or in person.

Members will be allocated to a sub-committee through a roster system to review low risk applications. Two to three members, including the Chair or Deputy Chair will be part of a sub-committee. All members are expected to participate in sub-committee reviews.

Applicants will be required to still submit a protocol through the Research GEMS portal. Applications deemed to be lower risk by the Chair or Deputy Chair of the HREC after reviewing the project will be assigned to the sub-committee. Research with the potential for physical or psychological harm will generally not be considered for an expedited review method. This includes research exploring sensitive personal or cultural issues.

The timing associated with this review will be dependent upon the workload of the sub-committee but should be within two to three weeks.

All review outcomes low risk applications will be reported at the next full meeting of the committee via the Out of Session items document.

2.5.4 Decision making

The DHW HREC will endeavour to reach a decision concerning the ethical acceptability of a proposal by general agreement. Any significant minority view (i.e., two or more members) will be noted in the minutes.

After the initial review of a proposal, the committee may choose to delegate to the Chair or Deputy Chair and nominated members the authority to approve the proposal between meetings.

The initial review of the committee may result in the following decisions:

- Approved
- Approved pending response to additional information (where the applicant is required to provide additional information or make amendments to the proposal)
- Request for further information (where the applicant is required to provide additional information or make amendments to the proposal)
- Not approved – resubmission required (where there are significant issues and the applicant is required to resubmit a new application)
- Rejected.

The final decision will be approved or not approved.

All decisions of the HREC will be recorded in minutes taken by the Executive Officer. To encourage free and open discussion, particular views will not be attributed to individuals in the minutes except where a member wishes to have their opinion or objection recorded.

2.5.5 Amendments

Researchers are required to seek approval of any modification to their research protocol. Depending on the nature of the amendment, these may be:

- Considered by the Chair or delegated to the Executive Officer between meetings and the committee notified of the decision at the next meeting.
- Sent to a sub-committee of the HREC between meetings and the committee notified of the decision at the next meeting.
- Considered at the next full meeting of the HREC.

Amendments should be submitted via Research GEMS 'Notification of an amendment' form and outline the summary and justification of changes, and include 'tracked' and 'clean' copies of revised study documentation.

The Executive Officer and/or Chair will decide on a case-by-case basis which approach will be most appropriate, taking into consideration the nature of the changes and assessment of risk, impact of the changes on ethical acceptability and impact of any delays on the conduct of the project.

Progress reports must be up to date before an amendment will be considered.

2.6 Communication with researchers

The DHW HREC will support open and informal communication with researchers to improve efficiency and understanding of the ethical review process and encourage shared commitment to ethical review.

Researchers are encouraged to discuss their proposal with the Executive Officer, and where appropriate, the Chair.

In situations determined by the DHW HREC, researchers may be invited to attend a HREC meeting to discuss their application and to directly respond to any issues raised by the HREC. The attendance of researchers at HREC meetings will be at the discretion of the DHW HREC. A sub-committee may elect to meet with the researcher out-of-session.

The Executive Officer will ensure that the DHW HREC web page on the SA Health website is reviewed annually, and information is relevant and a useful medium for communication with researchers.

2.6.1 Notification of ethical acceptability

The DHW HREC will notify the applicant in writing regarding the outcome of the review of the proposal at a meeting. Applicants can expect to be advised of the outcome of the ethical review within five business days of the meeting.

2.7 Research project exemptions

As per the National Statement 5.1.15, some research projects may be eligible for

exemption from ethics review. If the study satisfies the requirements of the 'Exemption checklist and request process' as documented on the DHW HREC website, the Chair may grant an exemption.

A researcher must keep an auditable record of any research they are undertaking that is exempted from ethics review in accordance with National Statement 5.1.15. This is required to ensure that there is a record of the research where no review has been conducted.

2.8 Suspension or withdrawal of ethical approval

The DHW HREC may suspend or withdraw ethical approval if it becomes aware that a project is not being, or cannot be, conducted in accordance with the approved protocol. The DHW HREC will inform the investigator(s) and the relevant institution(s) or organisation(s) of such withdrawal, and recommend to the institution(s) or organisation(s) that the project is discontinued, suspended, or that other necessary steps are taken to minimise any risks to participants. This suspension or withdrawal of ethical approval will be in accordance with section *5.4.14 – 5.4.19* of the National Statement. The reasons for the suspension or withdrawal will be recorded in the minutes.

2.9 Monitoring of projects

Responsibility for monitoring approved projects lies with the institution under which the research is conducted and with the researchers responsible for the conduct of the research (National Statement, Chapter 5.4).

The DHW HREC may request investigators to provide information relating to the conduct of the project once it is approved. At a minimum, the DHW HREC requires applicants to provide a report of progress at least annually, and at the completion of the project.

The DHW HREC will, as a condition of approval of each project, require that investigators immediately report anything that might warrant review of ethical approval of the project, as specified by Chapter 5.4 of the National Statement.

The DHW HREC may adopt any additional appropriate mechanism for monitoring, as deemed necessary. Specifically, the Chair may, in conjunction with the relevant institution, initiate an investigation into circumstances relating to adverse events or early termination and take appropriate steps to minimize any risks to participants.

2.10 Reporting and handling of adverse events

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 hospitalization or prolongation of existing hospitalization, or results in persistent of significant disability or incapacity.

It is a condition of approval that the DHW HREC must be notified by the investigators

of any serious or unexpected adverse events that take place while a participant is taking part in a study using the Serious Breach Reporting Form available via the Research GEMS online system and the SA Health website. Adverse events should be reported to the DHW HREC and copied to local Research Governance Officers within 72 hours.

In general, adverse events will be considered by the Chair or an executive sub-committee of the HREC who will review the adverse event and procedures the investigators have in place to manage it and determine an appropriate course of action. The appropriate course of action may include recording the adverse event on the project file; suspension or termination of ethical approval; or request for an amendment to the project.

The course of action will be communicated to the investigators in writing in a timely manner. Any reports of adverse events will be included on the agenda of the subsequent HREC meeting.

2.11 Reporting of protocol deviations

A protocol deviation is any change, divergence, or departure from the study design or procedures of a research protocol that has not been approved by the ethics committee.

It is a condition of approval that the DHW HREC must be notified by the investigators of any protocol deviations that take place as soon as possible.

In general, deviations will be considered by the Chair in the first instance, who will review the deviation and procedures the investigators have in place to manage it and determine an appropriate course of action.

The appropriate course of action may include recording the deviation on the project file; suspension or termination of ethical approval; retraining of investigators; or request for an amendment to the project.

The course of action will be communicated to the investigators in writing in a timely manner. Any reports of protocol deviations will be included on the agenda of the subsequent HREC meeting.

2.12 Complaints

2.12.1 Complaints concerning the ethical conduct of a project

A person with a complaint about the conduct of a project should bring the complaint to the attention of the Chair of the DHW HREC in the first instance, detailing the grounds of the complaint. The Chair will investigate the complaint and make a recommendation on the appropriate course of action. If the complainant is not satisfied with the outcome of the DHW HREC's investigation, then they can refer the complaint to the Director, Office for Research. All complaints received will be reported to the Chief Executive of SA Health.

2.12.2 Complaints concerning the committee's review process

A Coordinating Principal Investigator (CPI) who has a complaint about the DHW HREC's review process should bring the complaint to the attention of the Chair of the DHW HREC, detailing the grounds of the complaint. The Chair will investigate the complaint and its validity and make a recommendation to the DHW HREC on the

appropriate course of action within four weeks from the date of the appeal being lodged. If the complainant is not satisfied with the outcome of the preliminary investigation, they can refer the complaint to the Director, Office for Research. Complaints of bias or impropriety on the part of a DHW HREC member or members can be made directly to the Director, Office for Research.

The DHW HREC will only consider review of an ethical decision where, upon investigation, a complaint about its ethical review decision making process is substantiated. The DHW HREC will not conduct a review merely because an investigator is dissatisfied with the merits of an ethical decision.

The DHW HREC will comply with the SA Health Research Ethics and Governance Policy section 5.1. HREC Appeals process to review complaints.

2.13 Records

The Executive Officer will prepare and maintain a record of the DHW HREC's activities, including agenda and minutes of all meetings of the committee, in accordance with the National Statement, sections *5.2.19 – 5.2.20*.

The Executive Officer will prepare and maintain a file for each application received including a copy of the application, and any relevant correspondence including that between the applicant and the DHW HREC.

A database of all applications received and reviewed will be maintained by the Executive Officer.

Files shall be kept securely and confidentially. The retention and disposal of files will be in accordance with guidelines set by SA Health. In general, files for ethics proposals considered by the DHW HREC will remain on site until the study is completed and then State archived.

The DHW HREC will maintain a register of all the applications received and reviewed in accordance with the National Statement sections *5.2.20.*

3. RESEARCH AND DATA GOVERNANCE

The HREC will be responsible for ethical review and oversight only. Matters of research governance, including responsibility for determining whether data, resources, facilities and staff at the site at which the research is to be conducted are available, are the responsibility of the individual institutions.

The assessment of research governance within SA Department for Health and Wellbeing will be undertaken by the Office for Research. Each region/hospital has a separate Research Governance Officer who should be contacted if the research is to occur at that site.

Researchers must contact relevant data custodian/s prior to submitting an application for ethical review. The contact made with the data custodian does not constitute a review of data governance issues but is an important first step.

Researchers must also comply with the requirements outlined in the *SA Health Research Ethics and Governance Policy*, including the submission of the relevant Site Specific Application Form via Research GEMS.

4. REVISION OF THESE GUIDELINES

These guidelines will be reviewed every two years or when the NHMRC *Guidelines on Ethical Conduct in Human Research* (2023) are updated.