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HUMAN RESEARCH ETHICS AND RESEARCH GOVERNANCE

STANDARD OPERATING PROCEDURES

Government of South Australia
Women's and Children's Health Network

CREATE together

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SECTION 1: INTRODUCTION

1.1 Scope of Standard Operating Procedures (SOPS)

Paediatric research and research pertaining to women's health in the areas of obstetrics and gynaecology are key and valued activities of the Women's and Children's Health Network (**WCHN**).The WCHN is dedicated to fostering research excellence and translating the best available evidence into practice to improve the health outcomes of women, babies, children and young people.

Standard Operating Procedures (**SOPS**) have been developed for research ethics and research governance matters. They apply to WCHN researchers, external researchers who are undertaking research at a WCHN site, WCHN research ethics committee members and other staff involved in the conduct and oversight of health and medical research at WCHN. The SOPS take into account the regulations, legislation, ethical and governance principles and guidelines for the responsible conduct of research.

The WCHN is committed to supporting the Human Research Ethics Committee (**HREC**) in its ethical review of research involving humans, and the research governance of such research by its Research Governance Officer (**RGO**). It encourages awareness of the National Health and Medical Research Council (**NHMRC**) *National Statement on Ethical Conduct in Human Research* (2007, updated 2018) (***National Statement***), the *Australian Code for the Responsible Conduct of Research* (2018) (***The Code***), other relevant guidelines, policies and codes of conduct.

The WCHN promotes open communication between the WCHN Research Secretariat and researchers in order to facilitate greater understanding of processes governing research at the WCHN.

For research ethics matters, communication is primarily undertaken with the Chair HREC and the Executive Officers of the HREC and Drug and Therapeutics Committee Clinical Trials Group (**DTCCTG**). For research governance matters, communication occurs with the RGO. For research grants matters, communication occurs with the Research Grants Officer. For strategic and other research matters, communication occurs with the Director, Research Secretariat.

1.2 Definitions

Unless the context otherwise requires, the following definitions shall apply:

- ***Director*** means Director, Research Secretariat, WCHN.
- ***DTCCTG*** means Drugs and Therapeutics Committee Clinical Trials Group, WCHN.
- ***Executive Director*** means Executive Director, Corporate Services, WCHN.
- ***HREA*** means Human Research Ethics Application.
- ***HREC*** means Human Research Ethics Committee, WCHN.
- ***HREC Chair*** means the Chair of the Human Research Ethics Committee, WCHN.
- ***National Statement* means** *National Statement on Ethical Conduct in Human Research* (NHMRC 2007, updated 2018).
- ***NHMRC*** means National Health and Medical Research Council.
- ***NMA*** means the National Mutual Acceptance scheme for the ethical and scientific review of human research projects in participating Australian jurisdictions.

- ***Reviewing HREC*** means the Human Research Ethics Committee responsible for the ethical review and approval of a research project under NMA.
- ***RGO*** means Research Governance Officer, WCHN***.***
- ***SA Health*** means the South Australian Department for Health and Wellbeing.
- ***SSA*** means Site Specific Assessment.
- ***SOPS*** means the Standard Operating Procedures.
- ***The Code*** means *Australian Code for the Responsible Conduct of Research* (2018).
- ***WCHN*** means Women's and Children's Health Network Inc.
- ***WWCC*** means Department of Human Services Working With Children Checks.

SECTION 2: WCHN HREC

2.1 Role

The role of the HREC is to provide ethical review of research projects or audits, and ongoing review of any amendments to these projects, involving WCHN patients; patients' families; patient tissue (including stored tissue); patient information; or staff. In reviewing proposed research that involves drug or therapeutic substances, the HREC will receive expert advice from the WCHN DTCCTG as an advisory and recommending subcommittee to the HREC.

Researchers should be aware that the introduction of new clinical health technologies or other interventions into WCHN is undertaken by the New Health Technologies and Interventions Committee (**NHTIC**). This Committee does not consider health technology or clinical practice innovation that constitutes part of a clinical trial/research project unless by invitation of the HREC Chair, DTCCTG Chair or RGO.

2.2 Chair

The Patient Ethicist or other suitable person shall hold the position of Chair of the HREC. In the absence of the Chair, an Acting Chair will be appointed by the Chair from one of the current members of the HREC.

2.3 Membership

Minimum membership will be eight members. Membership will meet the minimum requirements of the *National Statement (Section 5.1.30)*, including:

- a chair;
- a laywoman not associated with the WCHN;
- a layman not associated with the WCHN;
- at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- a person who performs a pastoral role in a community;
- a lawyer; and
- two persons with knowledge of, and current experience in, research that is relevant to submitted research proposals.

Members may not be appointed in more than one of the above categories.

Where possible, the HREC membership will comprise:

- an equal number of men and women;
- at least one third of members who are not currently WCHN staff; and
- at least one member experienced in reflecting on and analysing ethical decision making.

2.4 Appointment of additional members

Additional members may be appointed to facilitate the work of the HREC.

When requiring new members, the HREC will call for nominations via advertisement. Following an interview process, the HREC Chair will then submit a recommendation to the Executive Director, Corporate Services.

New members will be required to adhere to the requirements of the NHMRC's National Statement and The Code, *WCHN Standard Operating Procedures* and all relevant WCHN policies and procedures including the Department of Human Services Working With Children Checks (**WWCC**), WCHN Confidentiality Agreements and Conflict of Interest Declarations.

2.5 Tenure

The period of tenure may be for three years, with renewal for a further three years.

The maximum term may be no more than six years. Ideally, no more than 40% of the membership should change in any one calendar year.

2.6 Lapse of membership

Membership will lapse if a member fails to attend three consecutive meetings without apology (unless exceptional circumstances exist). The Chair will notify the member in writing of such lapse of membership.

2.7 Quorum

A quorum will be a simple majority. Where there is less than full attendance, the Chair must be satisfied that the minimum membership listed in the section has received all the documentation and have had an opportunity to provide comments.

In addition, when a quorum has not been achieved, comments will be obtained from a sufficient number of members not present at the meeting, to make the meeting quorate. Where decisions are not quorate, the HREC Chair will seek to resolve the issue outside of the meeting or, where that is not possible, place the item on the next HREC agenda for reconsideration; and the applicant will be duly notified.

There is provision for the appointment of proxies to the HREC should members be unable to attend the meeting.

2.8 Reporting

The HREC Chair submits the HREC annual report to the NHMRC via the Executive Director for consideration and endorsement.

Monthly meetings are scheduled with the Executive Director to update the WCHN Executive on any issues of relevance to the HREC.

SECTION 3: WCHN DTCCTG

3.1 Role and relationship to the WCHN HREC

The DTCCTG is an advisory and recommending subcommittee of the WCHN HREC. Its role is to review clinical trial protocols involving a drug and/or therapeutic substance and make recommendations to the HREC on study design and safety. In addition, the DTCCTG provides review of any amendments to clinical trial protocols and ongoing safety monitoring.

3.2 Chair

The Director of Pharmacy or other suitable person shall hold the position of Chair.

3.3 Membership

Members are drawn from a pool of suitable experts with relevant pharmacological, scientific, and clinical expertise.

In keeping with Section 5.1.33 of the *National Statement*, the DTCCTG Chair will appoint membership so as to ensure the Committee has sufficient expertise in order to provide scientific review of the research that it is likely to consider.

The DTCCTG Chair will recommend appointment of a suitable candidate, via the Executive Director, to the WCHN CEO.

New members will be required to adhere to the requirements of these SOPS and all relevant WCHN policies and procedures regarding the Department of Human Services WWCC, WCHN Confidentiality Agreements and Conflict of Interest Declarations.

3.4 Co-opted members

The Chair of the DTCCTG will ensure that there are sufficient members present to provide the expertise required for the review of protocols and other matters being considered. Where necessary, members of the DTCCTG or other experts may be co-opted onto the DTCCTG to provide the required expertise. In such cases co-opted experts will be required to adhere to the requirements of these SOPS and all relevant WCHN policies and procedures regarding the Department of Human Services WWCC, WCHN Confidentiality Agreements and Conflict of Interest Declarations.

3.5 Reporting

The DTCCTG will provide a written report to the HREC for each protocol reviewed.

The DTCCTG will provide a copy of its minutes to the WCHN Drug and Therapeutics Committee (**DTC**).

3.6 Quorum

A quorum will be half the members.

SECTION 4: MEETING PROCESS AND APPLICATIONS TO HREC / DTCCTG

4.1 Frequency of meetings

The HREC and DTCCTG will meet once a month with the exception of January. For exceptional circumstances, members will consider applications outside of these times.

4.2 Applications

Depending on the research that is being proposed, applications may only be submitted using:

- a Human Research Ethics Application (**HREA**);
- a Low and Negligible Risk (**LNR**) Ethics Application; or
- a WCHN Audit form.

HREA and LNR applications are to be completed on 'Online Forms', or other research management system (**RMS**) utilised by the Research Secretariat. The link for the 'Online Forms' website (or other RMS), the audit application and

further information on HREC requirements is available on the WCHN HREC website.

The HREC requires both an electronic PDF submission via email and two ink-signed hard copies of all documentation to be submitted for review.

4.3 Freedom of Information requests

The HREC has a register of applications made to the HREC. The register is not a confidential document.

Electronic and/or hard copies of research protocols and other study documents are held in HREC files in the WCHN Research Secretariat.

Whilst it is the general practice of the HREC to treat applications as confidential and not disclose them to persons outside the HREC and the WCHN Research Secretariat, there may be circumstances where applications are made available to other persons. Examples of disclosure are when an application is subject to release by law or a request for information is made under the *South Australian Freedom of Information (**FOI**) Act 1991*.

4.4 Submission dates for ethical review

The submission dates for receipt of protocols and meeting dates for the HREC and DTCCTG are available on the HREC website.

Where possible, protocols involving a drug or therapeutic substance will be considered by the DTCCTG before being considered by the HREC.

Protocols received after the closing date will be held until the next meeting.

Applications will be acknowledged by email as soon as possible after their receipt. To assist follow up by researchers, the email advice will include the WCHN HREC reference number which needs to be included in all correspondence.

4.5 Ethical review of multi-centre research

The HREC Chair may determine that there is insufficient expertise on, or available to, the HREC to permit an adequate scientific and ethical review of a proposal, or that the HREC is not able to review a proposal in a timely manner (e.g. the meeting agenda for the HREC meeting has reached capacity).

In such cases, the HREC will advise the researcher as soon as practicable in order that the protocol can be submitted to another lead HREC or an expert review obtained where possible.

4.6 Preparation and distribution of agendas

Agendas are developed by HREC/DTCCTG Executive Officers in conjunction with the HREC/DTCCTG Chairs. The meeting agenda, including protocols for the HREC and DTCCTG, will be distributed to all members one week before the meeting.

4.7 Presentation of applications for ethical review

Agenda documents are uploaded to *Filegator*, which is a 'cloud' based programme, for HREC and DTCCTG members to download onto their devices. The relevant Chair introduces the application and opens it up for discussion at the meeting.

4.8 Absences

If the Chair of either the HREC or DTCCTG is unable to attend a meeting or is on leave, the relevant Chair will appoint a proxy Chair from the membership. There is provision for proxies should members be unable to attend the meeting.

On occasions, a DTCCTG meeting may need to be rescheduled, necessitating that applications are considered out-of-session by e-mail.

To ensure compliance with NHMRC guidelines, members are requested, via the agenda, to provide any comments or concerns on agenda items in writing to the HREC Executive Officer prior to the meeting. Comments from absent members are considered at the meeting and are filed with the minutes.

4.9 Minutes and records

The HREC/DTCCTG Executive Officers will prepare and maintain records of the HREC/DTCCTG activities, including minutes of all meetings, both electronically and in hard copy format. The minutes will be checked by the relevant Chair prior to distribution and will be ratified at the next meeting by committee members.

4.10 Attendance, as observers, of people other than members or researchers at HREC meetings

As a general rule, observers are not permitted at HREC meetings. Requests to attend meetings should be directed to the Chair of the HREC. If permitted to attend, observers will be required to sign a Confidentiality Agreement.

SECTION 5: DECISION PROCESS

5.1 Outcome determination

Decisions will be reached by consensus in keeping with the requirements of the *National Statement*, and other relevant NHMRC documents.

Any concerns that HREC members have regarding applications or amendments should be expressed during meeting discussions. If these concerns cannot be satisfactorily answered by those present, and if agreement cannot be reached, the researcher/s can be invited to the next meeting in order to clarify any concerns.

5.2 Protocol decision

The HREC may approve a protocol outright, approve it 'subject to', request further information before making a decision, or reject a protocol. Decisions regarding the approval or rejection of a protocol will be recorded in the minutes and the investigator will be notified in writing within two weeks of the decision. Exceptions to this timeframe may result from exceptional circumstances such as staff absences from the WCHN Research Secretariat.

5.3 Decision delays

When a decision is delayed because the HREC or DTCCTG requires further information regarding the research from either the researcher or expert reviewer the following will be ensured:

- The reasons will be recorded in the minutes and in the letter of advice to the chief investigator.
- To ensure that there is a 'paper trail', responses from the investigator to the HREC/ DTCCTG must be by letter or email (responses may take the form of clarifications, agreement to protocol modifications, appeal against modification, etc). However, to facilitate the process, the Chair or Executive Officer may also clarify the HREC's or DTCCTG's deliberations face to face or by telephone.
- The HREC or DTCCTG (in the case of studies involving a drug or therapeutic substance) will decide whether the investigator's response should be considered at the following meeting or whether authority will be delegated to the Chair to consider the response.
- If the response is to be considered by the full committee this will be recorded in the minutes and conveyed to the researcher.

- If authority is delegated to the Chair, the Chair may approve the protocol or may decide the response will be considered at the next HREC / DTCCTG meeting.

5.4 HREC decision within 60 calendar days of the 'clock start' from the HREC closing date

The HREC aims to provide a final decision on all LNR and HREA applications it has considered within 60 calendar days. The clock is stopped for periods in which the HREC is waiting on requested information from researchers.

5.5 Expert review

Experts may be invited to assist in the review of an application. Before a research application is sent to an expert reviewer, a completed *Confidentiality and Declaration of Conflict of Interest Agreement Form for Expert Reviewers, Consultants, Observers and Researchers* must be submitted to the HREC's Executive Officer.

It is the responsibility of the expert reviewer to identify and disclose any direct or indirect conflict of interest relating to a research application.

5.6 Attendance at meetings by researchers when an issue cannot be resolved

When a matter cannot be resolved at the meeting, researchers may be invited by the HREC or DTCCTG to attend the next meeting to discuss the matter in detail and provide any clarification. A researcher may also make a request to attend a meeting in order to provide any clarifications.

The Chair or Executive Officer of the HREC or DTCCTG will contact the researcher to invite them to attend the meeting and to clarify the matters that have not been resolved. A formal letter will also be sent to confirm unresolved matters and to include a reminder that the Chair of the HREC or DTCCTG is willing to clarify matters further by face-to-face or telephone or video conferencing discussion.

Researchers may request, verbally or in writing, to attend the HREC or DTCCTG meeting. The Chair of the HREC or DTCCTG may clarify the reasons for the request, but wherever possible will facilitate such a request.

Prior to attending a meeting of the HREC or DTCCTG, a researcher may be required to sign a *Confidentiality and Declaration of Conflict of Interest Agreement Form for Expert Reviewers, Consultants, Observers and Researchers*. It is the responsibility of the researcher to identify and disclose any direct or indirect conflict of interest relating to a research application.

5.7 Amendments

All amendments must be submitted to the relevant HREC or DTCCTG for review/approval prior to implementation. Amended documents should be track changed and include an updated version number and date.

5.8 Chair delegated authority

The HREC Chair has been delegated authority by the HREC to approve certain submissions, including, but not limited to the following types of amendments:

- Addition of new titles (e.g. to match a grant application) to the protocol approval which do not change the scope of the study.
- Notification that participants have completed their involvement in a study.
- Minor changes to advertisements which are in keeping with study aims.
- Minor non-substantial modifications to questionnaires/surveys.
- Substitution of tests, questionnaires, formulas which are deemed to be more appropriate when a test has already been approved.
- Modifications to the recruitment process providing it is not a vulnerable group.

- Advice that the study has met its recruitment targets.
- Study closure visit.
- Administrative letters.
- Press releases.
- Letters to parents, where the protocol has previously been approved.
- Minor changes to inclusion/exclusion criteria.
- Extra data reviews.
- Minor clarification of protocol and safety monitoring.

5.9 Communication with researchers

The HREC encourages open communication with researchers to facilitate an understanding of the HREC's processes and views on the deliberation of protocols. Communication may be by telephone, email, letter, face-to-face or video conferencing with the HREC Chair or Executive Officer or by attendance at a HREC meeting.

Responses to correspondence, where full HREC consideration is not required will be within 10 working days of receipt of the correspondence. Exceptions to this timeframe may result from exceptional circumstances such as staff absences from the WCHN Research Secretariat.

SECTION 6: ETHICAL REVIEW OF MULTI-CENTRE RESEARCH

6.1 General

The HREC adheres to the *SA Health Research Ethics Policy Directive (v3.2 – 16 July 2020)*. The policy can be viewed via the HREC and/or SA Health's research websites.

There are two streamlined approaches for the consideration of multi-centre research ethics applications based upon the mutual recognition of ethical review by other NHMRC certified HRECs, including:

- SA Health Single Ethical Review Model
- National Mutual Acceptance (**NMA**) Model

6.2 SA Health Single Ethical Review Model:

The WCHN will accept the ethics approval of the lead SA Health HREC for all multi-centre research taking place within the SA Health public health system, excluding audits.

In general, the lead committee will be located at the SA Health institution of the Chief Investigator/Principal Investigator (**CI/PI**). However, the following qualifications apply:

- Research involving Aboriginal and/or Torres Strait Islander people will require additional ethics review by the South Australian Aboriginal Health Research Ethics Committee (**AHREC**).
- Where the primary research participants are children / young people and the WCH site is involved, the WCHN HREC will be the lead.
- Where the primary data being used is held centrally by SA Health, the SA Health HREC will be the lead.

Where the WCHN HREC is the lead HREC, it will notify the Coordinating Principal Investigator (**CPI**) of the outcome of the review. The letter of approval will list the SA Health sites for which ethical approval has been given.

6.3 National Mutual Acceptance (NMA) Model

The WCHN HREC will accept the outcomes of a single ethics and scientific review of the lead NHMRC certified public health organisation HREC in the Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria and Western Australia as outlined on SA Health website.

The WCHN HREC is certified by NHMRC to conduct the single ethical and scientific review of multi-centre human research projects under NMA for the following categories:

- clinical trials phase I, II, III, IV
- clinical trials drugs and devices
- clinical trials surgery
- clinical trials other
- clinical interventional research other than clinical trials
- population health and/or public health
- qualitative research
- mental health
- paediatric research
- other health and medical research:
  - women's health
  - genetic studies
  - oncology
  - tissue banking

The following categories of clinical trials are excluded from single review process in South Australia:

- Phase 0 and 1 Clinical Trials
- Clinical trials involving South Australian Aboriginal and Torres Strait Islander participants, for which all applications will need to be reviewed by the Aboriginal Human Research Ethics Committee in addition to a Certified HREC.

Researchers should check the requirements of every jurisdiction in which they intend to conduct research approved under NMA.

If the WCHN HREC is the lead HREC, it will notify the CPI of the outcome of the review. It is the CPI's responsibility to notify the outcome of the WCHN HREC review to each of the other public health organisations where the project is to take place, via the RGO associated with the site/s.

SECTION 7: RESEARCH GOVERNANCE

7.1 General

Research governance is concerned with the quality, safety, privacy, risk management, financial management and ethical acceptability of research. The *SA Health Research Governance Policy Directive (V3.2 – 30 July 2020)* outlines the research governance requirements that apply to researchers and institutions involved in the conduct and administration of health and medical research in the South Australian public health system. The policy can be viewed via the WCHN Research Governance website or the SA Health Research website.

Before a research project may commence at WCHN, it must undergo a research governance review, also known as Site Specific Assessment (**SSA**). The SSA review is in addition to the HREC review and is undertaken by the Site's RGO.

Applications for research governance review at the WCHN must be made by submitting the SSA form which is located on the 'Online Forms' website. HREA

and SSA submissions should be made concurrently to assist in timely approval, and this is encouraged by the WCHN Research Secretariat.

Upon completion, the SSA form and relevant supporting documentation should be emailed to the RGO for review. WCHN SSA Submission Guidelines and Checklists are available on the WCHN Research Governance website to aid researchers in submitting applications to the RGO.

Once the RGO has reviewed the SSA and the Executive Director has approved the SSA, the RGO will provide the researcher with a final approval letter authorising the study and the study may then commence at WCHN.

7.2 Site Specific Assessment (SSA)

A SSA must be submitted to the RGO for review and approval prior to the commencement of any research at the WCHN. This includes all single site studies and multi-site studies regardless of whether or not the WCHN HREC has provided the ethical review for the study.

The SSA form is to be completed by the PI/CI to enable assessment of the feasibility and suitability of research projects at individual sites/institutions, including the WCHN. The PI/CPI must complete and submit the SSA form concurrently upon submission of the ethics application to assist in timely approval.

The RGO will review the SSA and will consider areas relevant to the research including, but not limited to:

- the availability of local resources to support the conduct of the project at the institution;
- whether relevant approvals have been sought and obtained to enable the project to occur (e.g. Department/Facility where the project is to be conducted);
- whether the project meets site specific administrative, financial and governance requirements; and
- whether other relevant documents are required.

The WCHN requires the submission of relevant documentation to accompany the SSA for approval. The WCHN SSA Submission Guidelines and Checklists will assist researchers in determining the documentation requirements for their research project.

7.3 Research Governance Approval

Once the RGO is satisfied with the SSA and accompanying documents, the RGO will recommend the study to the Executive Director for final authorisation at WCHN. The RGO will then issue a final Research Governance authorisation letter to the researcher, including the WCHN SSA reference number which needs to be included in ongoing correspondence with the RGO.

The research governance authorisation letter will state the site name for which approval has been granted, the title of the research project, the WCHN SSA reference number and the conditions of authorisation, which are in addition to those conditions listed in the HREC approval letter. Only upon receipt of the letter may the research project commence at WCHN.

SECTION 8: GRIEVANCE PROCESS – SSA/HREC DECISIONS

8.1 General

In keeping with Section 5.1.4 (c) of the *National Statement*, the WCHN HREC takes complaints/concerns by participants and researchers seriously and uses

them as an opportunity to facilitate general improvements in the conduct of research and review.

8.2 Complaints/concerns by participants

Complaints/concerns from participants include, but are not restricted to, the conduct of researchers, or the review process of the WCHN HREC. The process for addressing any complaints/concerns is as follows:

- A record of the complaint/concern is taken by the HREC Executive Officer.
- The complaint/concern is conveyed to the HREC Chair and/or RGO.
- The Chair and/or RGO discuss the complaint/concern with the researcher and participant or participant's family where appropriate.
- Serious complaints/concerns are reported to the HREC.
- Complaints/concerns are resolved co-operatively between the participant, researcher and HREC Chair and/or RGO.
- When a resolution cannot be achieved at the level of the HREC, the WCHN CEO/ delegate is notified by the HREC Chair in order to discuss and resolve the issue.
- In these cases, the HREC Chair will provide the WCHN CEO/delegate with all relevant material, including details of the complaint/concern.
- The WCHN CEO/delegate will determine if further investigation of the complaint/concern is necessary. If so, a panel will be established to consider the complaint/concern.

8.3 Complaints/concerns/appeals by investigators regarding HREC decisions

Where the HREC or DTCCTG rejects a research proposal outright on ethical grounds, makes an unfavourable decision about a component of the research proposal, or fails to reach a decision about the ethics of a research proposal, the investigator has the following rights:

- Where a proposal has been rejected, the investigator may submit a new application to the HREC, taking account of the HREC's concerns. The revised application will be processed and reviewed in accordance with the HREC's usual processes; or
- Where the above does not apply, the investigator may lodge a written appeal with the HREC Chair specifying the grounds of the appeal.
    - The complaint/concern will be conveyed to the WCHN HREC Chair.
    - The Chair will discuss the complaint/concern with the investigator.
    - Serious complaints/concerns will be reported to the WCHN HREC.
    - Complaints/concerns will be resolved cooperatively between the researcher and HREC Chair and/or Committee.
    - When a resolution cannot be achieved at the level of the WCHN HREC the Executive Director will be notified by the WCHN Chair in order to discuss and resolve the issue.

Following an appeal under 8.3 above, if the appellant considers the HREC has not followed due process or remains unsatisfied with the decision, they may choose to lodge an appeal with the WCHN CEO/delegate. The following process will be followed:

- The HREC Chair will provide the WCHN CEO/delegate with all relevant material, including details of the appeal; material reviewed by the HREC; and the outcome/decision of the ethical review process.
- The WCHN CEO/delegate will determine if further investigation of the appeal is necessary. If so, a panel will be established to consider the appeal.

The panel will include the following members:

- The WCHN CEO/delegate;

- Two nominees of the WCHN CEO/delegate (not members of the HREC);
- At least one nominee with relevant expertise in human research ethics; and
- Expert(s) in a discipline of research related to the project under consideration.

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

The WCHN CEO/delegate will notify the HREC and the appellant of the outcome of the investigation. Possible outcomes include:

- The appeal is dismissed; or
- The appeal is upheld and the panel makes a recommendation to resolve the issues based on the findings of the panel. The panel does not have the authority to approve an ethics application, but may choose to refer an ethics application to an independent ethics committee for re-review.

If the panel or WCHN CEO/delegate requests that a second ethical review is required as a recommendation of the investigation, an alternative SA public health system HREC (where possible) with suitable expertise and no prior involvement in the matter will be invited to undertake this review.

The panel or WCHN CEO/delegate cannot reverse the final determination of the second HREC review. Any recommendation or decision of the panel will be final.

8.4 Complaints/concerns/appeals regarding research governance/SSA matters

Complaints/concerns from PIs/researchers include, but are not restricted to, non-authorisation of the SSA without due consideration of all relevant information, appealing the final decision by the WCHN RGO of the SSA assessment process, or the SSA review process.

The process involves:

- Record of the complaint/concern is taken by the WCHN RGO.
- The complaint/concern is conveyed to the Director.
- The Director discusses the complaint/concern with the researcher.
- Serious complaints/concerns are discussed with the WCHN HREC Chair.
- Complaints/concerns are resolved co-operatively between the researcher, the RGO and the Director.
- When a resolution cannot be achieved at the level of the Director, the Executive Director is notified by the Director in order to discuss and resolve the issue.

The site PI may appeal the final decision of the SSA review where a decision has been made to not authorise a SSA, if he/she considers the decision has been made improperly or without due consideration of all relevant information. The PI may also lodge a formal complaint about the SSA review process, where the PI considers the process has been unsatisfactory.

In both instances, the PI should outline their concerns in writing to the WCHN RGO.

The PI may resubmit or amend their SSA application to meet any requirements outlined by the RGO. This application will be assessed according to the usual processes of the RGO and within a reasonable timeframe.

Where a complaint has been lodged, the RGO will notify the WCHN CEO/delegate of any such complaints in a timely manner.

Following consideration and further investigation by the RGO and WCHN CEO/ delegate, the PI will be notified in writing of the outcomes of the investigation including any further action to be taken to resolve the complaint.

If the PI remains dissatisfied with the outcomes of any further action by the RGO and/or WCHN CEO/delegate, this should be communicated in writing to the WCHN CEO/delegate.

In these instances, the below process will be followed:

- The WCHN CEO/delegate will determine if further investigation is necessary. If so, the WCHN CEO/delegate will establish a panel to consider the matter.
- The panel will be constituted as stipulated by the *Research Governance Policy Directive*, SA Health.
- The panel will allow the RGO and the PI the opportunity to make submissions.
- The WCHN CEO/delegate will notify the RGO and the PI of the outcomes of the investigation.

8.6 Code of Conduct

The HREC and DTCCTG act in accordance with the *Australian Code for the Responsible Conduct of Research (2018)*.

SECTION 9: CONFLICT OF INTEREST & CONFIDENTIALITY

9.1 Confidentiality

Information submitted to the HREC and DTCCTG will be treated as confidential by all members of the HREC and DTCCTG and any expert reviewers.

While applications are treated as confidential and are not disclosed to persons outside the HREC and WCHN Research Secretariat, there may be circumstances where applications are made available to other persons. Examples of disclosure are when an application is subject to release by law or a request for information is made under the *South Australian Freedom of Information (FOI) Act (1991)*.

9.2 Signed declarations

Members of the HREC and DTCCTG are asked to sign a *Confidentiality and Declaration of Conflict of Interest Agreement* form prior to serving on the HREC and DTCCTG. Members will sign a new *Confidentiality and Declaration of Conflict of Interest Agreement* form on re-appointment to the HREC and DTCCTG.

9.3 Conflict of interest

Any member of the HREC and DTCCTG who has an actual or potential financial or otherwise (personal, professional, or institutional) conflict of interest in an agenda item, should at the beginning of the meeting or beforehand declare such an interest. The Committee will make a determination regarding the nature of the conflict on a case by case basis.

The member will leave the room while the agenda item is being considered, but may remain in the meeting room for a period of time necessary to answer any questions that HREC members may have.

All declarations of conflicts of interest, and the absence of the member concerned, will be recorded in the HREC and DTCCTG minutes.

SECTION 10: MONITORING OF RESEARCH BY INSTITUTION

10.1 Background

As defined by the National Statement, monitoring "*refers to the process of verifying that the conduct of research conforms to the approved proposal*" (*Chapter 5.5*). In addition, monitoring includes the review of the safety of research projects via the assessment of adverse and serious adverse events, and

by the review of relevant developments or findings in the field of research in which the study is being conducted which may "*impact on the continued ethical acceptability of the research or that may indicate the need for modification to the project*" (*Section 5.5.6 (d)*).

On behalf of WCHN, both the WCHN HREC and RGO monitor research projects involving patients, patients' families, patient tissue (including stored tissue), patient information and/or WCHN staff. The DTCCTG will assist the HREC/RGO with monitoring research projects involving drugs or therapeutic substances.

In addition to the responsibilities of the WCHN HREC and RGO for monitoring research, researchers and sponsors have an obligation to ensure that the research they are involved in is monitored appropriately. The CPI, PI and research personnel are best placed to directly monitor the conduct of the research and appropriately follow up matters that impact research participants, or which may affect the safety and ethical acceptability of the project.

Under the National Mutual Acceptance System (including Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria and Western Australia Health Departments), the monitoring responsibilities pertaining to multi-centre clinical trials are outlined in the *National Mutual Acceptance Single Ethical Review of Multi-centre Clinical Trials Monitoring and Reporting Tables*, that can be viewed on the SA Health website. These tables summarise the monitoring responsibilities for the CPI, the site PI, the Reviewing HREC and the RGO.

10.2 Monitoring responsibilities of the institution

All research approved by the WCHN HREC will be monitored, including clinical trials, observational studies, clinical audit activities and public health research projects. The level of monitoring will depend on the nature of the research including the level of risk, project complexity and the broader ethical, research governance, legislative and regulatory requirements that underpin the research.

The HREC/RGO monitoring activities enhance current monitoring activities by researchers to ensure that the research conforms to the approved study protocol.

Researchers are required to submit Annual Progress Reports, Final Reports and Extension Requests to the HREC/RGO for all ongoing approved research projects.

The WCHN has the responsibility for monitoring the conduct of research (including clinical trials) that has received site approval through a range of mechanisms, including but not limited to:

- Review of progress and annual reports to ensure the research is being conducted in accordance with conditions of ethics and governance approval and other relevant frameworks, policies and requirements.
- Review of SSA amendments where changes are proposed to the research that may impact the institution's capacity to support the research.
- Review and consideration of advice provided by the lead HREC, PI (or trial sponsor as applicable for clinical trials) that may impact the ethical and scientific acceptability of the study at the institution, including safety related issues.
- Review progress reports from researchers on an annual basis.
- Review Serious Adverse Event (**SAE**) reports, Serious Unexpected Suspected Adverse Reaction (**SUSAR**) reports, Adverse Event (**AE**) reports and Adverse Device Effect (**ADE**) reports etc.
- Review reports from independent committees, e.g. Data Safety Monitoring Board (**DSMB**).

It is the responsibility of the researcher to provide the relevant documentation to the HREC/RGO for review.

10.3 Monitoring procedure of the institution

All authorised, ongoing research projects conducted at WCHN will be monitored by the RGO.

Letter of notification of a monitoring visit by institution

The RGO will contact the PI to arrange a mutually suitable time for the monitoring visit. The monitoring visit will be scheduled at a time that allows reasonable preparation by the PI/research team.

In order to allow reasonable preparation, prior to the monitoring visit the RGO will inform the PI of all documentation or information that will be considered by the RGO at the monitoring visit.

Monitoring visit by RGO

Monitoring visits will be conducted by the RGO. The monitoring visit will involve the RGO meeting the PI and research personnel to discuss matters relating to the research project and its conduct. The monitoring visit may include requesting various documentation and reports and any other material relevant to the research project.

The RGO may review all study-related documentation, including, but not limited to:

- The study protocol and any subsequent amendments.
- Case report forms or data collection forms.
- Data storage and data protection.
- Information given to participants including information sheets, advertisements and brochures, the procedure for obtaining informed consent and the sighting of signed consent forms.
- All ethics correspondence including ethics approval letters and amendment approval letters, SAE Reports and Annual Progress Reports.
- All Research Governance correspondence including WCHN Research Governance authorisation letter, PI Curriculum Vitae and/or credentialing, and requirements for non-WCHN study personnel such as Department of Human Services WWCC and WCHN HREC Confidentiality Agreements.
- Compliance with any conditions of approval imposed by the HREC.
- Compliance with any conditions of Research Governance authorisation.

The RGO will require an area to review the documents and access any electronic filing systems if information is stored online.

Report and findings

Following the visit, the RGO will generate a research monitoring report, communicating the findings of the visit. The report will be issued to the PI with a letter outlining the findings. This letter may include recommendations from the RGO to the PI about issues to be addressed and actions to be completed.

The PI will be expected to respond to the required actions in a timely manner. It is the responsibility of the PI to ensure any necessary changes are implemented and advised to the RGO.

In the event that the findings were incomplete, the RGO will arrange a second monitoring visit with the relevant research staff to discuss any recommendations or gaps in the monitoring visit.

A copy of the research monitoring report and letter is to be kept as part of the research records by the PI. The RGO will keep a copy on the study file and database in the Research Secretariat. The HREC Chair will be informed of the outcomes of all monitoring visits by the RGO.

Appeals

In the event that the PI does not agree with any aspect of the RGO's report or the recommendations following the monitoring visit, the Investigator has the right to respond by letter to the Director or delegate to review the report and file an appeal. In the letter the PI should state the reasons why he/she believes the Director/delegate should review the report and the grounds for the appeal.

Following receipt of this letter, the Director/delegate will independently review the RGO's report and provide their feedback and response to the PI.

Following receipt of the response to the appeal from the Director/delegate, if the PI is still not satisfied with the outcome, the matter may be referred further, and include the Chair, WCHN HREC and/or the Executive Director.

If required, the PI will need to attend a meeting before a panel. The Panel will comprise of independent members who will give the RGO, the PI and Director/delegate an opportunity to discuss the reasons and their findings.

10.4 Annual progress report and final report

All researchers are required to submit an annual report on the progress of each protocol which has been approved and a final report when the research is completed.

Both annual progress reports and final reports are to be submitted via e-mail to Health.WCHNResearchAnnualReports@sa.gov.au. The annual report is required on the anniversary of the approval date of the research.

Annual and final reports are part of research monitoring at WCHN. Following consideration by the RGO, they are provided to the HREC Chair for final review.

It is the researcher's responsibility to provide annual and final reports without reminder from the WCHN Research Secretariat. The WCHN annual report proforma is available on the HREC and RGO website.

For studies conducted under NMA, the WCHN will accept the lead site annual report and final report, on the proviso that the report contains all relevant information for the WCHN site.

Annual and final reports will be acknowledged by email.

10.5 Reporting of various types of Adverse Events

In keeping with the NHMRC guidelines on *Safety monitoring and reporting in clinical trials involving therapeutic goods (Nov. 2016)*, it is the responsibility of the sponsor (or PI) in the absence of a sponsor) for monitoring the ongoing safety of the trial/study.

The following is a summary of the safety reporting required, however, for a more comprehensive explanation refer to the NHMRC guidelines:

- If the SAE has significant adverse effects on the safety of participants or materially impacts the ethical conduct of the trial, it should be reported to the Therapeutic Goods Administration, HREC and all investigators within 72 hours.
- If the SAE requires amendments to the protocol, the HREC and all investigators should be notified within 15 days and the amended documentation should be submitted to the HREC without undue delay.
- All other SAE can be reported as part of a six monthly or annual reporting to HREC.

The notification/reporting should include an explanation as to any impact on participant safety or ongoing conduct of the study/trial.

In addition to the monitoring responsibilities described above, multi-centre studies involving a drug or therapeutic device must have a Data Safety Monitoring Board or equivalent to advise the HREC and DTCCTG in relation to SAE, SUSAR, AE and ADE.

SECTION 11: WITHDRAWAL OF ETHICAL APPROVAL

11.1 Reasons for withdrawal

The HREC has a responsibility to withdraw or suspend ethical approval of a research protocol if this is deemed necessary to safeguard the safety and welfare of participants.

Other circumstances under which consideration will be given to withdraw or suspend research are:

- If the HREC is satisfied that circumstances have arisen such that a project is not being, or cannot be, conducted in accordance with its ethical approval.
- If the HREC has reason to believe or is satisfied that a breach of the *Australian Code for the Responsible Conduct of Research* has occurred.
- If the HREC has reason to believe that a case of research misconduct has occurred.

11.2 Decision process

Where possible, prior to implementation, the HREC (and DTCCTG for studies involving a drug or therapeutic substance) will be involved in the decision to terminate or suspend a previously approved research project before the decision is made.

If this is not possible due to the urgency of the situation, the HREC Chair will consult with as many of the HREC members as possible.

The HREC Chair will inform the WCHN Executive, via the Executive Director, of all withdrawals of ethical approval which were initiated by the HREC for ethical, legal, risk, safety or other reasons.

Letters formally advising the PI of the withdrawal of ethical approval of the research project will include reasons and will advise that the decision has been endorsed by WCHN, via the Executive Director. Advice of the HREC decision will be within three working days of the decision, unless immediate notification is required for urgent safety reasons.

In the case of HREC initiated withdrawals of ethical approval, researchers will be given the opportunity to address the issues causing the withdrawal of ethical approval, including attending a HREC meeting. The research project must not re-commence at WCHN until the safety and welfare of participants is not compromised and/or all other relevant issues have been satisfactorily addressed.

11.3 Multi-centre research projects

In addition to that specified in Section 11.2:

- For multi-centre research projects in which the WCHN HREC is the Reviewing HREC, the WCHN HREC will immediately inform the site PI and/or CPI of the suspension or withdrawal of ethical approval.
- The WCHN HREC will inform the site PI and/or CPI of any subsequent decisions.
- In multi-centre research projects in which the WCHN HREC did not review the protocol, the WCHN RGO requires immediate notification of the suspension or withdrawal of research if relevant to the conduct of the study at the WCHN and of any subsequent decisions by the lead HREC.

11.4 Principal Investigator responsibilities following withdrawal or suspension of ethical approval

The PI must suspend all appointments and recruitment and follow the direction of the HREC and/or RGO.

In multi-centre trials, the site PI is to immediately inform the CPI and CI at other sites of the withdrawal of ethical approval, and any conditions imposed by the HREC. For research projects approved under NMA where the HREC is not the Reviewing HREC, the CPI or site PI must notify the RGO of the withdrawal of ethical approval and any conditions imposed by the Reviewing HREC.

SECTION 12: CHARGING OF FEES FOR REVIEWS

12.1 Charging of fees

Significant hospital funding is required to support the review of research protocols. In an attempt to alleviate these increasing demands, SA Health and the WCHN Executive has approved the charging of fees for the review of externally funded clinical trials involving a therapeutic drug or substance and for Collaborative / Cooperative Research Group (**CRG**) Clinical Trials/Non-Commercially Sponsored Clinical Trials. Presently, no other types of research project are charged a fee.

The charging of fees is outlined in the *SA Health Research Ethics and Governance Fees Schedule (April 2019)* (**Fees Schedule**). The Fee Schedule applies to all SA Health public health institutions. The Fees Schedule can be viewed via the RGO website or the SA Health Research website.

12.2 Review of fees

It is not the purpose of the Fees Schedule to hinder research, but to offset the institution's costs of meeting the demands of appropriate ethical and governance review. As such, the policy has inherent flexibility and the fees for each study are open to discussion with the RGO.

SECTION 13: REVIEW OF TERMS OF REFERENCE

The Terms of Reference for the HREC and DTCCTG are on the WCHN website.

The Terms of Reference and membership of the HREC and DTCCTG will be reviewed by the Chair annually and, in the event of significant change, notified to the Executive Director.

SECTION 14: COMMUNICATION WITH SPONSORS

14.1 Communication with sponsors

The nominated Clinical Trials Liaison at WCHN is the RGO. Sponsors are encouraged to contact the RGO directly to discuss all aspects of a clinical trial/research project. Sponsors may also refer to the WCHN SSA Submission Guidelines and Checklists (available on the RGO website), which provide general information regarding WCHN requirements for clinical trials and other research.

The HREC does not encourage direct communication with sponsors where it may, influence the ethical review and approval of the project. The researcher at the institution should act as an intermediary if any such communication is required.

For administrative matters, e.g. the submission of a protocol, the HREC Executive Officer may provide advice to sponsors as appropriate.

SECTION 15: HREC/DTCCTG RECORDS

15.1 Retaining of data

Researchers' records and the records of the HREC and the DTCCTG are to be retained for 33 years post study completion for paediatric records and 15 years post study completion for adult records.

In multi-centre trials where the HREC is the single ethics review body, researchers' records for interstate sites should be retained either in accordance with the *National Statement* or local State requirements.

In multi-centre research studies, where the ethics review body is not the HREC, the WCHN researchers are to retain all documentation related to the research in accordance with Item No. 6 of the State Records General Disposal Schedule No. 28.

15.2 HREC and DTCCTG records

Both hard and electronic copies of agendas and minutes for the HREC and DTCCTG will be kept in the Research Secretariat or off-site storage for archived files.

Each research study will have its own protocol identification number. A hard copy file on each research study will be kept by the HREC containing a copy of all documents submitted by the researcher and the HREC's responses, as well as any other relevant documents (e.g. e-mails).

15.3 Database

SA Health public health organisations currently use the internet-based Australian Research Ethics Database (**AuRED**) which:

- Imports data directly from the 'Online Forms' website (e.g. HREA and SSA forms).
- Tracks time taken for ethics and research governance (with clock stopping).
- Records and manages aspects of ethical review and post approval.
- Electronically stores all documentation pertaining to a research study which has been downloaded from the 'Online Forms' website (e.g. Application Forms, Investigator Brochures, Protocols, Consent Forms etc).

A new research management system is currently being procured by SA Health.

SECTION 16: TRAINING FOR HREC/DTCCTG

16.1 Training of HREC and DTCCTG members and relevant administrative staff

The WCHN is committed to ensuring that HREC members, its advisers on the DTCCTG and administrative staff receive appropriate training when it is available.

In addition, HREC members will be provided with educational material in the form of journal articles and/or other documents as appropriate on the HREC agenda for the purpose of ongoing education in the area of research ethics.

16.2 Induction of new members

New members of the HREC and DTCCTG are provided with the National Statement, updates and other relevant guidelines prior to attending any meetings following formal commencement on the HREC.

New members are invited to meet with the Chair prior to formal commencement on the HREC to discuss the review process and clarify any questions/concerns. New members may also be invited to observe one or two meetings of the HREC

or DTCCTG before formal commencement and are advised on proceedings by the relevant Chair during and after the meeting.

The Chairs of the HREC and DTCCTG act as mentors to new members and ensure that they acquire the necessary information and understanding of processes.

SECTION 17: RESEARCH FUNDING

17.1 Research support

The WCHN supports research activity within the organisation through a number of different avenues, including in-kind support. WCHN staff are encouraged to source external funds for their research.

The Women's and Children's Hospital Foundation is a key supporter of research at WCHN, funding various research project grants and a number of scholarships, fellowships and other awards. The guidelines for these awards are detailed on the WCHN Research Secretariat website.

In addition, the National Health and Medical Research Council, Medical Research Future Fund, Channel 7 Children's Research Foundation and pharmaceutical sponsors of clinical trials also fund various researchers.

17.2 Requirements for the submission of Grants / Fellowships / Scholarships

All research projects at the WCHN that are funded via grants, fellowships and scholarships, are required to obtain necessary research ethics and research governance approvals before commencing the research. Funding agreements administered by the WCHN are not permitted to commence until all required approvals are obtained.

The following requirements are essential:

- All research grant queries are to be submitted to the WCHN Research Grants Officer.
- WCHN staff must notify the WCHN Research Grants Officer of the intention to submit an application.
- WCHN staff must submit applications to the Research Secretariat for our records with a signed grant cover sheet prior to submission.
- If the WCHN staff member is also a Clinical Affiliate Title Holder with the University of Adelaide, the research grant application must meet the university deadline for submission, ensuring the University of Adelaide is named as the Administering Institution if appropriate.
- All University staff and non-WCHN staff (e.g. SA Pathology, South Australian Health and Medical Research Institute) located at the WCHN, are required to submit a copy of their application and a signed cover sheet to the WCHN Research Grants Officer for our records.
- All applications should be submitted via the Research Grants Officer following discussion with all relevant Department/Unit Heads at WCHN in areas where the research may impact to ensure support for the research.

17.3 Post Award Management

- If successful in receiving an award, all Award/Grant agreements must be forwarded to the WCHN Research Grants Officer for review.
- The Research Grants Officer will liaise with the researcher, Finance Officer/Business Manager for cost-centre set-up, University Research Offices, collaborating institutions and funding bodies regarding the Award and any final reports, project variations, schedules and general queries in relation to funds.
- A separate cost centre is usually required for each project to meet acquittal and auditing requirements.

- A WCHN Finance Officer can assist in submitting invoices to the funding body for incoming funds as outlined in the funding agreement.
- Researchers must ensure they are aware of, and comply with, all reporting requirements of the funding body. These may include milestone or annual reports, and final reports upon completion of the funding period (irrespective of whether the project is complete).
- Where financial reports (acquittals) are required, the researcher must liaise with the Research Grants Officer and Finance Officer to ensure accurate and complete information is provided.
- Funds cannot be transferred to outside parties without the necessary Collaborating Institution Agreements/Service Agreements/Material Transfer Agreements in place.

17.4 Collaborations

- Whenever there is collaboration with another institution (whether or not there is a transfer of funds) a Multi-Institution Agreement (**MIA**) is required.
- The MIA holds all parties to the original terms of the funding body, and indicates the agreed funding distribution and intellectual property processes.
- The MIA should be initiated by the lead researcher's administering institution and signed by all relevant parties.
- The WCHN Research Secretariat will review the MIA and liaise with the researcher and the University or other institution's Grants Officer as required.
- Once the MIA is finalised, the Research Grants Officer will arrange for all documentation to be submitted to the Executive Director, for approval and execution of the Agreement.

SECTION 18: PRIVACY

18.1 General

The NHMRC's National Statement Glossary defines Privacy as "*a domain within which individuals and groups are entitled to be free from the scrutiny of others*".

WCHN supports the importance of privacy and requires researchers to respect the privacy and confidentiality of patients and participants of research studies.

18.2 Privacy Act / Policies / Directives / Principles / Guidelines

All research involving the use of personal health information must abide by the *Privacy Act 1998 (Cth)*, SA Health *Privacy Policy Directive 2017 (V 2.0, 15 May 2019)* and *Information Privacy Principles* - Premier and Cabinet Circular 0012 (May 2020).

The *Privacy Act 1988 (Cth)* (***Privacy Act***) regulates the way such individuals' personal information is handled. However, this Act does not cover State or Territory government agencies, including state and territory public hospitals or health care facilities (which is covered under state and territory legislation).

In South Australia, the Circular released in May 2020 is a Cabinet Instruction that contains the Information Privacy Principles (IPPs). The IPPs regulate the way South Australian Public Sector agencies collect, use, store and disclose personal information.

The *Privacy Amendment (Enhancing Privacy Protection) Act 2012*, which commenced on 12 March 2014, introduced many significant changes to the Privacy Act.

The Australian Privacy Principles (**APPs**) are the cornerstone of the privacy protection framework in the *Privacy Act*. There are 13 APPs and they govern standards, rights and obligations around:

- the collection, use and disclosure of personal information;
- an organisation or agency's governance and accountability;
- integrity and correction of personal information; and
- the rights of individuals to access their personal information.

Health information is regarded as one of the most sensitive types of personal information. In certain circumstances, the *Privacy Act* permits the handling of health information and personal information for health and medical research purposes, where it is impracticable for researchers to obtain individuals' consent, recognising:

- the need to protect health information from unexpected uses beyond individual healthcare; and
- the important role of health and medical research in advancing public health.

To promote these ends, the Privacy Commissioner has approved two sets of legally binding guidelines, issued by the NHMRC. These NHMRC Guidelines are produced under sections 95 and 95A of the *Privacy Act*:

- Researchers must follow these guidelines when handling health information for research purposes without individuals' consent. The guidelines assist HRECs in deciding whether to approve research applications.
- Guidelines under Section 95 of the *Privacy Act* (s95 guidelines) set out procedures that HRECs and researchers must follow when personal information is disclosed from a Commonwealth agency for medical research purposes.
- Guidelines under Section 95A of the *Privacy Act* (s95A guidelines) provide a framework for HRECs to assess proposals to handle health information held by organisations for health research (without individuals' consent). They ensure that the public interest in the research activities substantially outweighs the public interest in the protection of privacy.

18.3 Consent

As outlined in the *National Statement* in Chapter 2.2, consent to participate in research must be voluntary and based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it.

Depending upon the circumstances of an individual research project, it may be justifiable to employ an opt-out approach or a waiver of the requirement for consent, rather than seeking explicit consent.

However, consent to collect, use and store a person's personal information should be obtained wherever possible. In research, the key elements of consent are:

- the participant is adequately informed before giving consent;
- the participant gives voluntary consent;
- the consent is current and specific;
- the participant has the capacity to understand and communicate their consent; and
- the consent provides authority to handle personal information in a particular way.

When collecting data, researchers should provide clear and comprehensive information about:

- the form in which the data will be stored (identifiable, re-identifiable, non-identifiable);
- the purposes for which the data will be used and/or disclosed; and
- whether they require specific, extended or unspecified consent for future research.

As participant consent forms contain identifiable data, original consent forms must be:

- filed in patients' case notes where applicable or kept in a lockable filing cabinet;
- stored in a secure office with controlled access, in the department in which the research is conducted; and
- stored separately from the collected research data for that project.

Researchers must take every precaution to prevent data being used in a way that the participants did not consent to.

18.4 Confidentiality

Researchers given access to confidential information must maintain the privacy, confidentiality and cultural sensitivities of participants.

Confidential information must be used responsibly and only be used in ways agreed with those who provided it, or as approved by the HREC. Researchers must ensure that the privacy of participants is safeguarded at all times.

A breach of confidentiality may constitute research misconduct. A researcher must report a breach of confidentiality to the WCHN Research Secretariat as soon as it becomes known.

SECTION 19: INTELLECTUAL PROPERTY

19.1 Importance of Intellectual Property

The WCHN, through its researchers, has the potential to generate substantial intellectual property (IP) which is capable of being commercialised.

All WCHN staff engaged in research should be aware of the Government of South Australia's Intellectual Property Policy (2017) and understand that IP is an important component of research.

19.2 Management of Intellectual Property

The management and commercialisation of WCHN's intellectual property is undertaken by a lawyer with Treasurer's Instruction 10 approval.

WCHN researchers must notify the Director of any queries relating to IP before contacting the lawyer.

If IP may be generated as part of a collaboration, all collaborative partners will need to contact their research or commercialisation offices to notify them.

SECTION 20: RESEARCH MISCONDUCT

20.1 Management of Research Misconduct

The WCHN's process for managing complaints/allegations of research misconduct adheres to The *Code* and adopts the *Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research, 2018* (**The Guide**).

The Guide provides a framework to manage, investigate and resolve allegations of research misconduct and potential breaches of The *Code* as follows:

- Allegations of misconduct or breaches of The Code undergo a Preliminary Investigation by the WCHN RGO and/or Chair of the WCHN HREC as the designated Research Integrity Officers.

- The Preliminary Investigation should be completed within sixty (60) days of the initial written notification to the respondent researcher and submitted to the Director and the WCHN CEO via the Executive Director.
- If evidence of a potential breach of The *Code* is found, the respondent is informed.
- Based on the respondent's response, if the matter is deemed to require further investigation, referral of the case is made to a panel of persons (**the Panel**) including the Research Integrity Officer(s), Research Integrity Advisor(s) and, if appropriate, a Human Resources Officer.
- The Panel members' roles are defined as follows:
  - Research Integrity Officer (**RIO**) – a staff member with responsibility for management of research integrity at an institution.
  - Research Integrity Advisors (**RIA**) – a person who assists in the promotion and fostering of responsible research conduct and provides advice to those with concerns about potential breaches of The *Code*.
  - Human Resources (**HR**) Officer – a person responsible for hiring, developing and looking after the wellbeing of employees and fostering effective workplace relations.
- The Panel will undertake further review and make recommendations to the Director and the WCHN CEO via the Executive Director.
- The WCHN CEO (or delegate) must inform the respondent researcher in writing of the terms of the complaint referred to in the Investigation, the date of the Investigation and the person or persons appointed to undertake the Investigation.
- The WCHN CEO (or delegate) will provide the respondent researcher with an opportunity to respond in writing to the complaint within thirty (30) days of notification and an opportunity to make oral submissions to the Panel appointed to undertake the Investigation during the hearing of the complaint.
- The Panel appointed to undertake the Investigation must advise the WCHN CEO (or delegate) in writing of their findings and reasons for the finding which may include:
  - A finding of misconduct;
  - A finding that no misconduct occurred but serious scientific errors were discovered;
  - A finding that misconduct has not been established;
  - A finding that there is no misconduct;
  - A finding that there is no basis for the complaint.
- The WCHN CEO (or delegate) must provide the respondent researcher and the complainant with a copy of the findings and the reasons.
- Where the Panel appointed to undertake the Investigation make a finding of misconduct, the WCHN CEO (or delegate) must determine whether it is appropriate to take disciplinary action against the respondent researcher.
- Where the Panel appointed to undertake the Investigation are satisfied there is no basis for a complaint and the complaint was not brought in good faith, the WCHN CEO (or delegate) must determine whether it is appropriate to take disciplinary action against the complainant.
- If research misconduct is found to have occurred, the WCHN CEO (or delegate) shall upon the expiry of the appeal period, report the finding to any funding agency that funded the work in respect of which misconduct occurred or which is currently supporting the person found to have engaged in research misconduct, and to journals to which the research in question was reported.

- If serious scientific errors are discovered the WCHN CEO (or delegate) shall request the respondent researcher to take appropriate action.
- If the Investigation finds that misconduct has occurred, the respondent researcher may appeal the decision within fourteen (14) days of receiving a copy of the findings and the reasons. The appeal mechanism will be that which applies to other staff grievances in the WCHN and is governed by SA Health's *Health Care Act 2008 Human Resources Manual Part 3 – Grievances and Disputes*.
- All records of complaints and/or allegations of a breach of The *Code* and /or research misconduct and any related correspondence (internal and external) will be securely located within the WCHN Research Secretariat and placed on file in Human Resources as required.
- Privacy in all matters will be upheld in accordance with the Guidelines Approved under Section 95A of the *Privacy Act* and the Guidelines Issued under Section 95 of the *Privacy Act*.

Table 1: Research Misconduct - Delegation of functions

Action	Person responsible	Notification to
Preliminary Investigation	HREC Chair and RGO (as designated Research Integrity Officers)	Director and WCHN CEO via Executive Director
Panel Investigation	Research Integrity Officer, Research Integrity Advisor(s) and Human Resources Officer	Director and WCHN CEO via Executive Director
Relaying of outcome to respondent	WCHN CEO (or delegate)	Respondent

SECTION 21: LIABILITY COVERAGE

21.1 Liability of HREC and DTCCTG members

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

For clinical trials which are sponsored by a commercial company, the Medicines Australia Standard Form or HREC Indemnity Form must also be signed.

21.2 Indemnification of research studies

All research projects hosted by SA Health institutions involving SA Health or external staff and students must have appropriate insurance and indemnity. The review of insurance and indemnity for research projects and clinical trials conducted at WCHN sites will be undertaken by the RGO.

The provision of the Department for Health and Wellbeing's insurance is based on the researchers obtaining or maintaining ethical approval and ensuring that persons performing treatment or testing are qualified to perform such treatment or testing, or in the case of students, they are appropriately supervised by persons that are qualified. SA Health insurance does not include cover for deliberate breaches of confidentiality, wilful misconduct, or the misuse of information, fraud or similar risks.

The South Australian SSA form includes a declaration by the PI regarding insurance arrangements for study personnel. All relevant documentation (if any) must be included with the SSA submission.

Further information, including guidance documents, are available on the WCHN Research Governance website. Researchers are encouraged to check the information prior to submission, as these arrangements may change over time.

SECTION 22: ADDITIONAL REQUIREMENTS FOR NON-WCHN STAFF

All non-WCHN students and researchers are required to provide a valid Department of Human Services WWCC and WCHN HREC Confidentiality Agreement prior to being granted authorisation to commence research at a WCHN site.

Non-WCHN staff and students are not authorised to be on a WCHN site or access the identifiable information of WCHN patients who are children without first being granted authorisation by the RGO.

Compliance with these regulations is required by South Australian legislation and WCHN policy. Failure to adhere to these requirements will delay the authorisation of the study or result in authorisation of the study being terminated.

22.1 Working With Children Check (WWCC)

WCHN requires a Department of Human Services WWCC for non-WCHN study personnel involved in any research project or audit at WCHN that involves being on site at any WCHN site(s) and/or access to identifiable information of WCHN patients who are under 18 years of age.

A copy of the current WWCC must be sighted by the RGO or must be certified and verified by a permitted verifier prior to being submitted to the RGO.

22.2 Confidentiality Agreements

All non-WCHN researchers and auditors (and those associated with the research / audit) accessing patients, clients, WCHN staff, or any identifiable information must sign a WCHN HREC Confidentiality Agreement and submit it to the RGO (for research projects) or the HREC (for audits). It is also a requirement that all non-WCHN staff joining the research study/audit after its commencement must sign and submit a Confidentiality Agreement to the RGO (for research projects) or the HREC (for audits).

The PI of a research study/audit is responsible for ensuring that all non-WCHN staff working on the research study/audit have signed a Confidentiality Agreement and submitted it to the RGO/HREC. Signed Confidentiality Agreements may be attached to the SSA form, or original audit application, and must be provided before research governance authorisation/ethical approval is granted.

A signed Confidentiality Agreement is required for each separate research study/ audit. The RGO/HREC will not authorise a study to commence until all Confidentiality Agreements have been signed and submitted.

22.3 Curriculum Vitae

A current copy of the PI's Curriculum Vitae (**CV**) of no more than four pages is a mandatory requirement of SA Health, and must be submitted to the RGO. The CV submission is a requirement for each study undertaken by a researcher regardless of previous submissions.

No research will be authorised until the RGO has reviewed the researcher's CV and, if deemed appropriate, credentialing documents.

For researchers involved in undertaking clinical trials, evidence of Good Clinical Practice (**GCP**) training is required for all staff involved in such research.

SECTION 23: RESEARCH AGREEMENTS

Research/trials involving Clinical Trial Research Agreements (**CTRA**) or other Agreements such as Multi-Institutional Agreements, Collaborative Agreements, Non-Disclosure Agreements, Research, License, Services, and Material Transfer Agreements, are to be submitted to the WCHN RGO for review.

Individual investigators do not have the authority to sign any research agreement on behalf of WCHN. Only the relevant delegate of WCHN may sign an agreement on behalf of the institution. The WCHN delegate will only sign an agreement if it has first been reviewed via the RGO.

23.1 Clinical Research Trial Agreements

All CTRAs are to be submitted by the researcher to the RGO for review and approval prior to the research commencing at WCHN. More information about CTRA requirements at WCHN is included in the WCHN SSA Submission Guidelines and Checklists document, available on the WCHN Research Governance website.

Any amendments to the standard Medicines Australia template CTRAs (e.g., via the 'Special Conditions schedule, Schedule 4/Schedule 7) will incur delays to the execution of the document unless these amendments are first reviewed and approved by the Southern and Eastern Border States (**SEBS**) review committee.

23.2 Other Agreements

All Agreements including Multi-Institutional Agreements, Collaborative Agreements, Non-Disclosure Agreements, Research, License, Services, Data and Material Transfer Agreements, are to be submitted to the RGO for review before they are signed. Depending on the complexity of the agreement, the RGO will decide if the document requires legal review. In the event legal review is required, the RGO will arrange such review and inform the researcher of the process and outcome of the review.

SECTION 24: APPLICATIONS UNDER CTN/CTX SCHEMES

Sponsors must not submit a Clinical Trial Notification (**CTN**) or Clinical Trial Exemption (**CTX**) to the Therapeutic Goods Administration (**TGA**) until they have received both ethical approval and research governance authorisation at WCHN.

The choice of which scheme to use CTN or CTX, lies firstly with the trial sponsor and then with the HREC that approves the protocol (except for certain Class 4 biologicals).

For some Investigator-led or CRG studies, WCHN will agree to be the 'sponsor' for the purposes of submitting the CTN into the online TGA business portal and for future amendments to the CTN (if required, and including study cessation notification). The WCHN Research Secretariat (via the RGO) manages the CTN process for these research projects. Individual researchers should not create their own accounts with the TGA.

SECTION 25: REVIEW AND ENDORSEMENT OF SOPS

The Standard Operating Procedures will be reviewed by all staff of the WCHN Research Secretariat on an annual basis, including the HREC and DTCCTG Executive Officers and Research Grants Officer.

The revised document will be endorsed by the Director following review of the revisions by the Chair of the WCHN HREC and the WCHN RGO.

SECTION 26: RESOURCES

Australian Code for the Responsible Conduct of Research, NHMRC (2018) https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

Guide to Managing and Investigating Potential Breaches of the Australian Code for the Responsible Conduct of Research, NHMRC (2018) https://www.nhmrc.gov.au/sites/default/files/documents/attachments/guide-managing-investigating-potential-breaches.pdf

Intellectual Property Policy, Government of South Australia (2017) https://www.dpc.sa.gov.au/documents/rendition/South-Australian-Government-Intellectual-Property-Policy.pdf

National Statement on Ethical Conduct in Human Research, NHMRC (2007, updated 2018) https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Privacy Act 1998 (Cth), Australian Government (1998) https://www.legislation.gov.au/Details/C2014C00076

Privacy Policy Directive 2017, SA Health (V 2.0, 15 May 2019) https://www.sahealth.sa.gov.au/wps/wcm/connect/60b8550041526f138c0d8ee8f09fe17d/Directive_Privacy_30052017.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-60b8550041526f138c0d8ee8f09fe17d-lNmOOny

Privacy Principles - Premier and Cabinet Circular 0012, Government of South Australia (2020) https://www.dpc.sa.gov.au/resources-and-publications/premier-and-cabinet-circulars/DPC-Circular-Information-Privacy-Principles-IPPS-Instruction.pdf

Research Integrity and Misconduct Policy, NHMRC (May 2019) https://www.nhmrc.gov.au/about-us/resources/nhmrc-research-integrity-and-misconduct-policy

Research Ethics and Governance Fees Schedule, SA Health (April 2019) https://www.sahealth.sa.gov.au/wps/wcm/connect/cb0325004782199699fefb2e504170d4/SA+Health+Fees+Schedule%2C+April+2019.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-cb0325004782199699fefb2e504170d4-n5hNENM

Research Ethics Policy Directive, SA Health (V3.2 – 16 July 2020) https://www.sahealth.sa.gov.au/wps/wcm/connect/996102804a9942d8aa46ea7633bbffe0/Directive_Research_Ethics_v3.2.16.07.2020.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-996102804a9942d8aa46ea7633bbffe0-nejLhi2

Research Governance Policy Directive, SA Health (V3.2 – 30 July 2020) https://www.sahealth.sa.gov.au/wps/wcm/connect/0fb971004aaf196b9a0dfa7633bbffe0/Directive_Research_Governance++v3.2.+30.07.2020.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-0fb971004aaf196b9a0dfa7633bbffe0-neZdb1R

Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods, NHMRC (Nov 2016) https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

State Records General Disposal Schedule No. 28, Government of South Australia (2014 - 2025) https://archives.sa.gov.au/sites/default/files/public/documents/20141024%20General%20Disposal%20Schedule%20No.%2028%20Final%20V1_Copy.pdf

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