WOMEN'S AND CHILDREN'S HEALTH NETWORK (WCHN)

Standard Operating Procedures

HUMAN RESEARCH ETHICS AND RESEARCH GOVERNANCE

Government of South Australia

SA Health

WOMEN'S AND CHILDREN'S HEALTH NETWORK (WCHN)

HUMAN RESEARCH ETHICS AND RESEARCH GOVERNANCE

STANDARD OPERATING PROCEDURES (SOPS)

SECTION 1: BACKGROUND

1.1 DEFINITIONS

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

1) ***DTC CTG*** means the WCHN Drugs and Therapeutics Clinical Trials Group;
2) ***Executive Director*** means the Executive Director, Corporate Services, WCHN;
3) ***HREC*** means the Women's and Children's Health Network Human Research Ethics Committee;
4) ***HREC Chair*** means the Chair of the Women's and Children's Health Network Human Research Ethics Committee;
5) ***National Statement*** means the *National Statement on Ethical Conduct in Human Research* (2007 with updates);
6) ***NMA*** means the National Mutual Acceptance scheme for the ethical and scientific review of human research projects in participating Australian jurisdictions;
7) ***Reviewing HREC*** means the Human Research Ethics Committee responsible for the ethical review and approval of a research project under NMA;
8) ***RGO*** means the Research Governance Officer, WCHN;
9) ***SA Health*** means the South Australian Department for Health and Ageing;
10) ***The Code*** means the *Australian Code for the Responsible Conduct of Research* (2007); and
11) ***WCHN*** means Women's and Children's Health Network.

1.2 Research is a key and valued activity of the Women's and Children's Health Network (**WCHN**). The WCHN is committed to supporting the WCHN 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 with updates) (*National Statement*), the *Australian Code for the Responsible Conduct of Research* (2007) (**The Code**), other relevant guidelines, policies and codes of conduct. The WCHN promotes open communication between the WCHN Research Secretariat and researchers as it recognises that this facilitates greater understanding of processes and the resolution of issues. For the HREC, such communication is primarily undertaken by the Chair and the Executive Officer rather than individual HREC members.

SECTION 2: WOMEN'S AND CHILDREN'S HEALTH NETWORK HUMAN RESEARCH ETHICS COMMITTEE (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 Drug and Therapeutics Committee (**DTC**) Clinical Trials Group (**CTG**).

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*, 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 (NS 5.1.30).

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;
- 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 list of nominations, in priority order, to the Executive Director, Corporate Services, WCHN (**Executive Director**).

New members will be required to adhere to the requirements of the *WCHN Human Research Ethics and Research Governance Standard Operating Procedures* (**SOPS**) and all relevant WCHN policies and procedures regarding South Australian Department of Community and Social Inclusion (**DCSI**) Child-Related Employment Screening clearance and WCHN Confidentiality Agreements.

2.5 Tenure

The period of tenure may be for three years, with renewal for a further three years. The maximum term may be six years. 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 comment.

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 should members be unable to attend the meeting.

2.8 Reporting

The HREC Chair submits the Australian Health Ethics Committee annual report to the WCHN Chief Executive Officer for consideration and endorsement.

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

SECTION 3: DRUG AND THERAPEUTICS COMMITTEE CLINICAL TRIALS GROUP (DTC CTG)

3.1 Role and relationship to the WCHN HREC

The DTC CTG is a 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 DTC CTG 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 5.1.33 of the *National Statement,* the DTC CTG 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 DTC CTG Chair will recommend appointment of a suitable candidate, via the Executive Director, to the WCHN Chief Executive Officer.

New members will be required to adhere to the requirements of these SOPS and all relevant WCHN policies and procedures regarding DCSI Child-Related Employment Screening clearance and WCHN Confidentiality Agreements.

3.4 Co-opted members

The Chair of the DTC CTG 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 DTC CTG or other experts may be co-opted on to the DTC CTG 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 DCSI Child-Related Employment Screening clearance and WCHN Confidentiality Agreements.

3.5 Reporting

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

The DTC CTG 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 AND DTC CTG

4.1 Frequency of meetings

The HREC and DTC CTG will meet once a month with the exception of January.

4.2 Applications

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

- a National Ethics Application Form (NEAF);
- a Low and Negligible Risk (LNR) form; or
- a WCHN Audit form.

NEAF and LNR applications are to be completed on 'Online Forms'. The link for the 'Online Forms' website, 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 one signed hard copy of all documentation to be submitted to it 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*. Under FOI, no personal details will be released.

4.4 Timelines of ethical review

The timelines for receipt of protocols and meeting dates for the HREC and DTC CTG are available on the HREC website.

Where possible, protocols involving a drug or therapeutic substance will be considered by the DTC CTG 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.

4.5 Timelines for 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 Distribution of documents

The meeting agenda, including protocols for the HREC and DTC CTG, 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 DTC CTG 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 DTC CTG 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.

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 Records

The Executive Officer will prepare and maintain records of the HREC and DTC CTG's activities, including agendas and minutes of all meetings, both electronically and in hard copy.

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 concerning 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' 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 DTC CTG requires further information regarding the research project from either the researcher or expert reviewer:

- 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/DTC CTG 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 DTC CTG's deliberations face to face or by telephone.
- The HREC or DTC CTG (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/DTC CTG 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 NEAF 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 DTC CTG to attend a following 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 DTC CTG 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 DTC CTG is willing to clarify matters further by face-to-face or telephone discussion.

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

Prior to attending a meeting of the HREC or DTC CTG, 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 DTC CTG for review/approval prior to implementation. Amended documents should be track changed and include an updated version number.

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 accrual 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, or face-to-face meetings 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 Operational Policy Directive (v.3 4/1/2016)*. The policy can be viewed via the HREC website or SA Health Research website.

There are two streamlined approaches for the consideration of multi-centre research ethics applications (NEAF and LNR) 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. A copy of the approval letter will also be provided to each site's Research Governance Officer.

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 Queensland, New South Wales, Victoria and South 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 Research Governance Officer 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* 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 RGO website or on 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**) review. This review is in addition to the HREC review; the SSA Form has a separate purpose and separate assessment process to the National Ethics Application Form (NEAF).

Applications for research governance review at the WCHN must be made by submitting the SSA form which is located on the 'Online Forms' website. NEAF and SSA submissions may be made concurrently, and this is encouraged by the WCHN Research Secretariat.

The RGO requires the SSA and the relevant research governance documentation for approval. WCHN SSA Submission Guidelines and Checklists are available on the WCHN RGO website to aid researchers in submitting to the RGO.

For research projects approved under NMA where the WCHN HREC is not the Reviewing HREC, as well as the standard documentation requirements, researchers are required to submit a full copy of the protocol, investigator brochure (where relevant), patient information sheets and consent form, and any other study documents approved by the Reviewing HREC along with their SSA.

The purpose of submitting research documents along with the SSA is for record keeping and monitoring and not for ethical review.

Once the RGO has reviewed the SSA and the Executive Director, Corporate Services has signed off on the SSA, the study may commence. The RGO will provide the researcher with a final approval letter authorising the study.

7.2 Site Specific Assessment (SSA)

A Site Specific Assessment (**SSA**) must be submitted to the RGO for review and approval prior to 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 Principal/ Coordinating Investigator to enable assessment of the feasibility and suitability of research projects at individual sites/institutions, including the WCHN. The Principal/Coordinating Investigator is encouraged to complete and submit the SSA form concurrently upon submission of the ethics application.

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 have been submitted with the SSA.

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 then recommend the study to the Executive Director for final authorisation at WCHN.

Upon satisfaction that the proposed research meets all research governance requirements for WCHN, the Executive Director may authorise the research project to commence at WCHN. The RGO will then issue a final Research Governance authorisation letter to the researcher.

The research governance authorisation letter will state the site name for which approval has been granted, the title of the research project, 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 (COMPLAINTS/CONCERNS AND APPEALS) SSA AND HREC DECISIONS

8.1 General

In keeping with Section 5.1(4) of the *National Statement (2007)* 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:

- Record of the complaint/concern is taken by the HREC Executive Officer.
- The complaint/concern is conveyed to HREC Chair.
- The Chair discusses 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.
- When a resolution cannot be achieved at the level of the HREC the WCHN Chief Executive Officer/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 Chief Executive Officer /delegate with all relevant material, including details of the complaint/concern.
- The WCHN Chief Executive Officer / 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 DTC CTG 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:

a. Where a proposal has been rejected, the investigator may submit a new application to the HREC, taking account of the HREC concerns. The revised application will be processed and reviewed in accordance with the HREC's usual processes; or

b. Where (a) 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 of Corporate Services will be notified by the WCHN Chair in order to discuss and resolve the issue.

Following an appeal under 8.3(b) 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 Chief Executive Officer/delegate.

The following process will be followed:

- The HREC Chair will provide the WCHN Chief Executive Officer / 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 Chief Executive Officer / 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 Chief Executive Officer / delegate;
- Two nominees of the Chief Executive Officer / 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 Chief Executive Officer / 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 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 Chief Executive Officer / 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 Chief Executive Officer / 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 Principal Investigators/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 WCHN Director, Research Secretariat.
- 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, Research Secretariat.
- When a resolution cannot be achieved at the level of the Director, Research Secretariat, the Executive Director is notified by the Director, Research Secretariat in order to discuss and resolve the issue.

The site Principal Investigator (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 Research Governance Officer.

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 Chief Executive Officer/delegate of any such complaints in a timely manner.

Following consideration and further investigation by the RGO and WCHN Chief Executive Officer/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 CEO/delegate, this should be communicated in writing to the WCHN Chief Executive Officer/delegate. In these instances, the below process will be followed:

- The WCHN Chief Executive Officer/delegate will determine if further investigation is necessary. If so, the WCHN Chief Executive Officer/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 Chief Executive Officer/delegate will notify the RGO and the PI of the outcomes of the investigation.

8.6 Code of Conduct

The HREC and DTC CTG act in accordance with the *WCHN Code of Conduct* and the *Australian Code for the Responsible Conduct of Research (2007)*.

SECTION 9: CONFLICT OF INTEREST AND CONFIDENTIALITY PERTAINING TO HREC COMMITTEE MEMBERS

9.1 Confidentiality

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

While applications are treated as confidential and are not disclosed to persons outside the ethics committee 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)*. Under FOI, no personal details will be released.

9.2 Signed declarations

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

9.3 Conflict of interest

Any member of the HREC and DTC CTG 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 Committee members may have.

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

SECTION 10: MONITORING

10.1 Background

As defined by the *National Statement (2007 with updates)*, monitoring "refers to the process of verifying that the conduct of research conforms to the approved proposal" *(NS 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 trial or may indicate the need for amendments to the trial protocol" *(NS 3.3.22).*

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 DTC CTG 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 Coordinating Principal Investigator, Principal Investigators, 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 (for New South Wales Health, Queensland Health, South Australia Health and Victorian Health Department), 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 Coordinating Principal Investigator, the site Principal Investigator, 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, extension requests, Adverse Event Reports and Serious Adverse Event reports to the HREC 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, principal investigator (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 reports, serious unexpected suspected adverse reaction reports, adverse event reports and adverse device events.
- Review reports from independent committees, e.g. a 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

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

Letter of notification of a monitoring visit

The RGO will contact the Principal Investigator 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 Principal Investigator/research team. In order to allow reasonable preparation, prior to the monitoring visit the RGO will inform the Principal Investigator of all documentation or information that will be considered by the RGO at the monitoring visit.

Monitoring Visit

Monitoring visits will be conducted by the RGO. The monitoring visit will involve the RGO meeting the Principal Investigator 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, Serious Adverse Events Reports and Annual Progress Reports.
- All Research Governance correspondence including WCHN Research Governance authorisation letter, Principal Investigator Curriculum Vitae and/or credentialing, and requirements for non-WCHN study personnel such as DCSI Child-Related Employment Screening clearances 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 Principal Investigator with a letter outlining the findings. This letter may include recommendations from the RGO to the Principal Investigator about issues to be addressed and actions to be completed.

The Principal Investigator will be expected to respond to the required actions in a timely manner. It is the responsibility of the Principal Investigator 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 Principal Investigator. 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 Principal Investigator 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, Research Secretariat or delegate to review the report and file an appeal. In the letter the Principal Investigator 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 Principal Investigator.

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

If required, the Principal Investigator will need to attend a meeting before a panel. The Panel will comprise of independent members who will give the RGO, the Principal Investigator 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. 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

As a minimum requirement all Serious Adverse Events (SAEs), Serious Unexpected Suspected Adverse Reactions (SUSARs), Adverse Events (AEs) and Adverse Device Events (ADEs) must be reported and monitored as outlined below:

- Researchers will immediately notify the HREC Chair of any SAEs, SUSARs, AEs or ADEs at this site, or at another site if it impacts upon, or potentially impacts upon, the conduct or safety of the study at the WCHN.
- SAEs, SUSARs and AEs will be reviewed by the DTC CTG and HREC Chair.
- Device adverse events (ADEs) will be reviewed by the HREC.
- The HREC will acknowledge all SAEs, SUSAR reports, AEs and ADEs.

In addition to the monitoring responsibilities described above, multi-centre studies involving a drug or therapeutic device must have a Data Safety Monitoring Board (DSMB) or equivalent to advise the HREC and DTC CTG in relation to SAEs, AEs, ADEs, and SUSARs.

It is the responsibility of the principal investigator to report all AEs, ADEs, SAEs and SUSARs associated with the study to the HREC and all other sites at which the research is being conducted for multi-centre research.

It is the responsibility of each institution at which the study is being conducted to assess any AEs, SAEs, ADEs, SUSARs and make a determination as to the continuance of the study at their site.

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 suspension of 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 DTC CTG 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 Principal Investigator 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 its Executive Director Corporate Services. 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 Principal Investigator and/or Coordinating Investigator of the suspension or withdrawal of ethical approval.
- The WCHN HREC will inform the site Principal Investigator and/or Coordinating Investigator of any subsequent decisions.
- In multi-centre research projects in which the WCHN HREC did not review the protocol, it requires that it be immediately advised 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 Principal Investigator must suspend all appointments and recruitment and follow the direction of the HREC.

In multi-centre trials, the site Principal Investigator is to immediately inform the Co-ordinating Principal Investigator and Chief Investigators 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 Coordinating Principal Investigator or site Principal Investigator must notify the RGO of the withdrawal of ethical approval and any conditions imposed by the Reviewing HREC.

SECTION 12: CHARGING OF FEES FOR ETHICAL AND GOVERNANCE REVIEW

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**) studies (including CRG 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* (Fee Schedule). The Fee Schedule applies to all SA Health public health institutions. The Fee 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 *SA Health Research Ethics and Governance 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 (HREC AND DTC CTG)

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

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

SECTION 14: COMMUNICATION WITH RESEARCH 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 projects.

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.

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

SECTION 15: HREC / DTC CTG RECORDS

15.1 Retaining of data

Researchers' records and the records of the HREC and the DTC CTG are to be retained for 30 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 researcher/s 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 DTC CTG records

Both hard and electronic copies of agendas and minutes for the HREC and DTC CTG 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. emails).

15.3 Database

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

- Imports data directly from the 'Online Forms' website (e.g. NEAF, LNR 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).

SECTION 16: TRAINING FOR HREC / DTC CTG

16.1 Training of HREC and DTC CTG members and relevant administrative staff

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

HREC members will be provided with educational material in the form of journal articles and/or other documents with each 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 DTC CTG are provided with the *National Statement (2007)*, 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 DTC CTG before formal commencement and are advised on proceedings by the relevant Chair during and after the meeting.

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

SECTION 17: RESEARCH MISCONDUCT

It is a SA Health requirement that WCHN has a written procedure concerning complaints or allegations of research misconduct. Any such complaint or allegation must be investigated appropriately with due sensitivity and consideration.

The WCHN's procedure for managing complaints/allegations of research misconduct is outlined in the *WCHN Code of Conduct for Research* (updated 2014) and applies to managing complaints and allegations of research misconduct and breaches of the *Australian Code for the Responsible Conduct of Research (2007)* within WCHN, and any persons involved in the conduct of research at WCHN sites.

Research misconduct includes the following:

- Fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting the results of research, and failure to declare or manage a serious conflict of interest.
- An avoidable failure to follow an approved research protocol, particularly where this failure may result in unreasonable risk or harm. It also includes the wilful concealment or facilitation of research misconduct by others.

Research misconduct does not include:

- Honest differences in judgement in the management of the research project, and may not include honest errors that are minor or unintentional.

Should the complaint or allegation be substantiated by compelling evidence, appropriate disciplinary action will be pursued by the WCHN. Any disciplinary action should be determined by the WCHN's CEO or delegate, and be consistent with the nature of the misconduct.

The WCHN has the responsibility to devise an appropriate documented process, as reflected in the *WCHN Code of Conduct for Research,* in the process of investigations making sure it is consistent with the requirement of the *Australian Code (2007).*

SECTION 18: LIABILITY COVERAGE

18.1 Liability of HREC and DTC CTG members

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

18.2 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 Ageing'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 Principal Investigator 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 from time to time.

SECTION 19: ADDITIONAL REQUIREMENTS FOR NON-WCHN RESEARCHERS AND RESEARCH STAFF

All non-WCHN students and researchers are required to provide a valid DCSI Child-Related Employment Screening 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 requirements is required by South Australian legislation and WCHN policy. Failure to adhere to these requirements will lead to very serious consequences.

19.1 Police Checks

WCHN requires a DCSIChild-Related Employment Screening clearance (**DCSI check**) 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 DCSI check must be sighted by the RGO.

19.2 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 (**Confidentiality Agreement**) and submit it to the RGO (research projects) or RHEC (audits). It is also a requirement that all non-WCHN staff joining the research study/audit after its commencement sign and submit a Confidentiality Agreement to the RGO (research projects) or the HREC (audits).

The Principal Investigator 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 Site Specific Assessment form, or original audit application, and must be provided before research governance authorisation/ethical approval is granted.

Please note that 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.

This requirement relates to current and future students and non-WCHN staff on the research project/audit. If the students and non-WCHN staff on this research project are subsequently involved on other ethically approved research projects, a

Confidentiality Agreement must be signed for each specific research project/audit and sent to the RGO/HREC.

19.3 Curriculum Vitae

A current copy of the Principal Investigator's CV (Curriculum Vitae) 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.

SECTION 20: 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.

20.1 Clinical Research Trial Agreements (CTRA)

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) must be approved by the Southern and Eastern Border States (SEBS) review committee.

20.2 Other Agreements.

All Agreements including Multi-Institutional Agreements, Collaborative Agreements, Non-Disclosure Agreements, Research, License, Services, 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 legal review and inform the researcher of the process and the outcome of the review.

SECTION 21: APPLICATIONS UNDER THE CLINICAL TRIAL NOTIFICATION (CTN) SCHEME OR CLINICAL TRIAL EXEMPTION (CTX) SCHEME

Sponsors must not submit a CTN to the TGA until they have received both ethical approval and research governance authorisation at WCHN.

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 22: REVIEW AND ENDORSEMENT OF STANDARD OPERATING PROCEDURES

Standard Operating Procedures will be reviewed and endorsed by the Director of the WCHN Research Secretariat, the Chair of the WCHN HREC and the WCHN Research Governance Officer on an ongoing basis.

Updated: July 2016