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 (SOP)

SECTION 1: BACKGROUND

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 HREC in its ethical review of research involving humans and the research governance of such research by its Research Governance Officer. It encourages awareness of the National Health and Medical Research Council (NH&MRC) *National Statement on Ethical Conduct in Human Research (2007)*, the *Australian Code for the Responsible Conduct of Research (2007)*, other relevant guidelines, policies and codes of conduct. The WCHN promotes open communication between the HREC and researchers as it recognises that this facilitates greater understanding of the HREC's processes and the resolution of issues. 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 or audit projects, and ongoing review of any amendments to these projects, involving patients, patients' families, patient tissue (including stored tissue), patient information and/or WCHN staff. In reviewing proposed research that involves drug or therapeutic substances, the HREC will receive expert advice from the 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 from one of the members of the HREC.

2.3 Membership

Minimum membership will be eight members. Membership will meet the minimum requirements of the NH&MRC *National Statement on Ethical Conduct in Human Research (2007)*, 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
- 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, there will be:

- an equal number of men and women;
- at least one third of members should not be staff of WCHN;
- at least one member experienced in reflection on and analysing ethical decision making.

2.4 Appointment of additional members

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

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

New members will be required to adhere to the requirements of the *WCHN Human Research Ethics and Research Governance Standard Operating Procedures* regarding Department of Community and Social Inclusion (DCSI) Police Checks 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 Membership has received all the documentation and have had an opportunity to comment.

In addition, when a quorum has not been achieved members will be asked to ratify the minutes outside of the HREC meeting. In this instance, appropriate members will be selected from non-attending members and will be of a sufficient number to reach quorum. In those cases where the minutes are not ratified, the 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.

2.8 Reporting

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

The Chair of the HREC submits an annual report to the WCHN Clinical Safety and Quality Committee.

Monthly meetings are held with the Executive Director Corporate Services to update the 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. The DTC CTG's role is to review clinical trial protocols involving a drug and/or therapeutic substance and make recommendations to the WCHN 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.

When requiring new members, the DTC CTG 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.

New members will be required to adhere to the requirements of the *WCHN Human Research Ethics and Research Governance Standard Operating Procedures* regarding Department of Community and Social Inclusion (DCSI) Police Checks 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 or other experts may be co-opted on to the DTC CTG to provide the required expertise. In such cases co-opted experts will adhere to the requirements of the *Standard Operating Procedures* regarding Department of Community and Social Inclusion (DCSI) Police Checks and WCHN Confidentiality Agreements.

3.5 Reporting

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 be submitted using:

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

NEAF and LNR applications are to be completed on ‘Online’ forms. The link for ‘Online’ forms, the audit application and further information on the Committee’s requirements is available on the WCHN HREC’s website.

All applications are to be submitted in hard copy to the WCHN HREC and, if a drug or therapeutic substance is involved, to the DTC CTG.

4.3 Freedom of Information requests

The WCHN 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 Human Research Ethics files in the Research Secretariat.

Whilst it is the general practice of the HREC to treat applications as confidential and not disclose them to persons outside the ethics committee 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 WCHN HREC's 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 the proposal, or that the HREC is not able to review the 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

A hard copy of each application is sent to each HREC member and DTC CTG member (when there is a drug or therapeutic substance involved). The 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 no provision for proxies should members be unable to attend the meeting.

Members are requested, via the agenda, and to ensure the HREC complies with NH&MRC guidelines, to provide any comments or concerns on agenda items in writing to the HREC's 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 (2007)* and other relevant NH&MRC documents.

Any concerns that members of the HREC 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 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 has delegated authority to the Chair to approve the following types of amendments; this list is subject to change and hence is not definitive:

- 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 Research Secretariat.

SECTION 6: ETHICAL REVIEW OF MULTI-CENTRE RESEARCH

6.1 General

The WCHN HREC adheres to the *SA Health Research Ethics Operational Policy (2013)*. The policy can be viewed via the WCHN HREC 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 NH&MRC certified HRECs, including:

- SA Health Single Ethical Review Model
- National Mutual Acceptance (NMA) Model – Phase II—IV clinical trials only

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 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.

If 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 Unit 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 – Phase II—IV clinical trials only

The WCHN HREC will accept the outcomes of a single ethics and scientific review of the lead NH&MRC 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 NH&MRC to conduct the single ethical and scientific review of multi-centre trials under NMA for Phases I-IV clinical trials.

The scope of NMA includes:

- Clinical interventional research involving any of the following: a drug, device, radiation therapy, or surgery.
- Treatment or diagnostic procedures and studies associated with ongoing activities relating to trials that have been conducted. This may include post trial activities such as observational research and evaluation of a trial, developing a registry and other post-marketing surveillance activities.

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

- 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.

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 (2013)* 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 HREC website.

Before a human 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.

The Research Governance Officer (RGO) requires the submission of the SSA and the relevant research governance documentation for approval.

For any studies not reviewed by the WCHN HREC, but when the WCHN is a site, researchers are required to submit a full copy of the protocol, investigator brochure (where relevant), patient information sheets and consent form 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 Site Specific Assessment (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 required 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. This includes SA Health indemnity and insurance approval, DCSI police check for child-related employment, Confidentiality Agreements, the Principal Investigator's Curriculum Vitae, Clinical Trial Research Agreement (CTRA) and Clinical Trial Notification Scheme (CTN) or Clinical Trial Exemption (CTX) Scheme forms where applicable.

7.3 Research Governance Approval

Once the RGO is satisfied with the SSA and accompanying documents, the RGO will then sign and recommend the study to commence at WCHN. The RGO will put a recommendation to the Executive Director Corporate Services for final authorisation.

Upon satisfaction that the proposed research meets all research governance requirements for WCHN, the Executive Director Corporate Services, will sign off and authorise the commencement of the research project. The RGO will then issue a final approval letter to the researcher notifying him/her of the approval being granted for WCHN.

The approval letter will state the site name for which approval has been granted, the title of the project, along with any conditions if any, in addition to the conditions listed in the HREC approval letter. Upon receipt of the letter, the study may 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 WCHN HREC Executive Officer.
- The complaint/concern is conveyed to WCHN 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 WCHN 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 WCHN HREC the WCHN Chief Executive Officer/delegate is notified by the WCHN HREC Chair in order to discuss and resolve the issue. In these cases
- The Chairperson 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 WCHN 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's concerned. 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 Chairperson 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 that 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 responsible for the HREC.

The following process will be followed:

- The Chairperson 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 of Corporate Services is notified by the Director 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 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)*, 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/s, the Principal Investigator/s, the Reviewing HREC and the Research Governance Officer.

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 Adverse Event Reports, for all ongoing approved research activities to WCHN HREC.

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 projects conducted at WCHN that have received ethical approval will be monitored by the RGO, including a monitoring visit. On a random selection, the RGO will select and monitor all projects including single site/multi-site research and clinical trials, and conduct monitoring visits.

Letter of notification of a monitoring visit

The RGO will contact the Principal Investigator by letter notifying them at least two weeks in advance of the time and date of the scheduled monitoring visit. Upon receipt of this letter, the Principal Investigator will also be provided with a Self-Assessment Checklist to assist them in preparation for the visit. This Checklist contains reference to specific information which will be sought by the RGO on the day of the visit, along with a list of project related documents to be provided by the Principal Investigator.

Monitoring Visit

The monitoring visit will involve the RGO meeting the Principal Investigator and research personnel to discuss matters relating to the research and its conduct. The monitoring visit will include requesting various documentation and reports and any other material relevant to the project.

The research monitoring visit by the RGO could be scheduled for research projects including, but not limited to:

- Clinical Trials
- Research projects with reportable events, such as Serious Adverse Events
- Investigator-initiated studies without identified oversight by an external sponsor

- Studies triggered by receipt of a complaint in relation to conduct of research
- Multiple studies involving the one Principal Investigator
- Research projects with a duration of three or more years.
- Research projects with multiple investigators, or with several HREC protocol amendments

The research monitoring visit by the RGO will review all study-related documentation, including:

- 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 WCHN HREC correspondence including ethics approval letters and amendment approval letters, Serious Adverse Events Reports and Annual Progress Reports
- All Research Governance correspondence including Site Specific Assessment approval letter, Curriculum Vitae evidencing qualifications of investigators, and any updated DCSI Police Checks and Confidentiality Agreements
- Compliance with any conditions imposed by the HREC and/or RGO via the relevant approval letters

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 within 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 WCHN HREC 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.

Whilst the HREC will forward an annual report proforma to researchers for completion, it is the researcher's responsibility to provide the reports. The annual report proforma is also available on the WCHN HREC's website.

Annual and final reports will be acknowledged by email or letter within 10 working days of the HREC meeting at which it was considered. Exceptions to this timeframe may result from exceptional circumstances such as staff absences from the Research Secretariat.

It is the responsibility of the RGO to monitor the submission of annual/final reports and follow-up the non-submission of such reports with the Principal Investigator.

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 Chair of the HREC 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 WCHN 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 WCHN 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 WCHN 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 WCHN 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 WCHN 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 WCHN 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 WCHN HREC has reason to believe that a case of research misconduct has occurred.

11.2 Decision process

Where possible, prior to implementation, the WCHN 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 protocol before it is made.

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

The Chair of the HREC will inform the WCHN Executive, via the Executive Director, Corporate Services of all withdrawals of ethical approval which were initiated by the WCHN HREC for ethical, legal, risk or safety 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 project should not re-commence until the safety and welfare of participants is not compromised.

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.

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. The charging of fees is outlined in the *SA Health Fees Policy for the Review of Research Ethics and Governance Applications (2012).* The policy can be viewed via the WCHN HREC website.

12.2 Review of fees

It is not the purpose of the *SA Health Fees Policy (2012)* 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 Research Governance Officer.

The WCHN RGO is responsible for the fees charged for the review of research ethics applications (including any amendments) and research governance applications (Site Specific Assessments). Not all applications are subject to these fees, therefore all researchers and applicants should review the fee structure prior to submitting their ethics and governance applications.

The fee structure applies within the SA public health system and the costs are uniform across all the SA public health sites. The RGO will contact the researcher when a fee is applicable and provide information about the processing of fees.

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 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 WCHN HREC's Executive Officer may provide advice to sponsors as appropriate.

On research governance matters, including information on fees, the WCHN Research Governance 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 in accordance with *Function 6 of the SA Public Hospitals Retention Disposal Schedule (2000).*

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

In multi-centre research studies, where the ethics review body is not the WCHN HREC, the WCHN researcher/s are to retain all documentation related to the research in accordance with *Function 6 of the Records Disposal Schedule for SA Public Hospitals.*

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

The WCHN HREC uses the internet-based Australian Research Ethics Database (AuRED) which:

- Imports data directly from 'Online' forms (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 'Online' forms (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 are also 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 requirement that WCHN under the jurisdiction of SA Health 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

The South Australian Department of Health (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

It is a requirement of the WCHN that all research conducted at, or in association with, the WCHN be assessed for insurance and risk. Consequently, all applicants need to email their information sheets and consent forms to the Manager, Insurance Services at SA Health, for assessment and approval. A copy of this approval must be submitted to the RGO prior to the study being authorised to commence.

For those projects not requiring an information sheet and consent form, a description of the project should be emailed to the Manager, Insurance Services at SA Health. Following the determination, the Manager, Insurance Services will email the applicant, who must subsequently submit the approval to the RGO.

If the first-named investigator is not a WCHN employee, proof of indemnification from their employing institution, or university in the case of a student, should also be forwarded to the Manager, Insurance Services SA Health and subsequently on approval to the RGO.

Where the first-named investigator is not a WCHN employee, the study will still be indemnified by SA Health as WCHN is vicariously liable for the person's actions (i.e. where the named investigators include WCHN employees and non-WCHN employees). The exception to the rule is if a non-WCHN employee is to use the WCHN facility to undertake research which has no connection with WCHN. An example would be the use of a room for interview purposes only in a non-WCHN related project.

A hard copy of the approval email from the Insurance Services Unit SA Health must be submitted with the protocol to the WCHN HREC. If the approval email is not submitted, the WCHN HREC may approve the protocol subject to approval by the Insurance Services.

No research can commence until the Insurance Services Unit SA Health and WCHN HREC approval have been given.

18.3 Clinical trials

Applicants submitting clinical trials which are sponsored by a third party (e.g. drug company) must additionally email the Manager, Insurance Services SA Health a copy of the indemnification form and the insurance certificate of currency provided by the sponsor**.**

A copy of the approval from Insurance Services SA Health and original documents (indemnity, insurance certificate and agreement) must be submitted to the RGO.

18.4 Multi-centre research projects

The above requirements apply to any multi-site research involving WCHN patients, patients' families, patient tissue (including stored tissue), patient information and/or WCHN staff.

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

The following are additional requirements for non-WCHN researchers and research staff to adhere to before research ethics and research governance approval is given.

19.1 Police Checks

WCHN requires a *Department of Communities and Social Inclusion (DCSI) Police Check* for students and non-WCHN staff involved in any research project or audit on WCHN sites and/or in accessing identifiable patient information.

The WCHN requires the *Child related employment screening DCSI Police Check.* Once cleared through the DCSI Screening Unit, a copy of the valid *DCSI Police Check* is to be submitted to the RGO.

All students and/or researchers are required to provide a valid *DCSI Police Check* prior to being granted approval to commence research at WCHN sites. This requirement relates to current and future students and non-WCHN staff on the research project. If the students and non-WCHN staff on this project are subsequently involved on other projects approved by the HREC, a copy of the *DCSI Police Check* will need to be resent to 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 Confidentiality Agreement* and lodge it with the RGO. It is also a requirement, that all non-WCHN staff joining the research study/audit after its commencement sign and lodge a *Confidentiality Agreement* with the RGO.

The chief investigator of a research study/audit is responsible for ensuring that all non-WCHN staff working on the research study/audit have signed a *WCHN Confidentiality Agreement* and submitted it to the RGO. Signed *Confidentiality Agreements* may be attached to the Site Specific Assessment form, or original audit application, and must be provided before full approval is given.

Please note that a signed *Confidentiality Agreement* is required for each separate research study/audit. The RGO 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 project. If the students and non-WCHN staff on this project are subsequently involved on other projects approved by the HREC, a *Confidentiality Agreement* needs to be signed for each specific project and sent to the RGO.

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 to 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.

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. These Agreements will initially be reviewed by the RGO to determine whether there is a requirement for legal review. The RGO will liaise with the lawyer, Sponsor or Institution on behalf of the researcher to negotiate the terms of the CTRA. In the event that a legal review is required, the RGO will inform the researcher of the process and the outcome of the CTRA review.

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 by the researcher to the RGO for review. Depending on the complexity of the agreement, the RGO will decide if the document requires legal review. In the event that a legal review is required, the RGO will 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

For protocols approved by the WCHN HREC, the RGO will arrange for the WCHN HREC Chair and the Executive Director Corporate Services to sign the relevant pages of the CTN/CTX form once full ethics and governance approval has been obtained.

For protocols approved by an HREC external to WCHN, signature by the Executive Director Corporate Services will be organised on the relevant page of the CTN/CTX form after the Site Specific Assessment Form has been completed and the RGO has recommended approval.

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.