WOMEN'S & CHILDREN'S HEALTH NETWORK
RESEARCH GOVERNANCE

WCHN SITE SPECIFIC ASSESSMENT SUBMISSION GUIDELINES

Research can only commence at the Women's and Children's Health Network (**WCHN**) when both ethical approval and site governance authorisation have been granted.

Research governance considers those matters concerning the quality, safety, privacy, risk management, financial management and ethical approval of research.

WCHN research governance and site authorisation is managed by the WCHN Research Secretariat. The principal contact for research governance is:

Ms Camilla Liddy
Research Governance Officer
Women's and Children's Health Network
T: 08 8161 6688
E: camilla.liddy@sa.gov.au

In order to conduct research at WCHN you must make a Site Specific Assessment (**SSA**) submission to the WCHN Research Governance Officer (**RGO**) for research governance authorisation.

These guidelines are intended to assist researchers in making SSA submissions. There are checklists at the beginning of these guidelines to assist you in determining what documentation is required. The SSA form also includes a research governance checklist.

Every research project is different, and may require submission of documentation that is not included in the checklists. The checklists are not intended to be exhaustive and can be adapted to suit your research project.

Online resources

The WCHN Research Secretariat website contains useful information and documents that may be required for your research. Other relevant policies are available on the SA Health and WCHN intranet.

For further information about research governance for SA Health organisations, see the SA Health Research Governance website.

Other useful information regarding research can be found online, including the following:

- Australian Clinical Trials
- NHMRC
- Therapeutic Goods Administration

SSA SUBMISSION CHECKLIST - ALL RESEARCH		
1.	SSA form *Original signatures preferred. Must have at least one original signature.*	☐ YES
2.	Research agreement, if applicable (e.g., Research Collaboration Agreement) *All research agreements must be reviewed by the RGO and signed on behalf of WCHN*.	☐ YES ☐ NO ☐ Not applicable
3.	Insurance Certificate and evidence of insurance approval *Required for studies where the PI is not an SA Health employee and/or investigators are not under the direct supervision of a PI who is an SA Health employee*.	☐ YES ☐ NO – Concurrent application
4.	Curriculum Vitae of Principal Investigator	☐ YES ☐ NO
5.	HREC approval letter	☐ YES ☐ NO ☐ Concurrent HREC/SSA submission
7.	Protocol	☐ YES ☐ NO ☐ Not applicable
8.	Participant Information Sheet and Informed Consent Form	☐ YES ☐ NO ☐ Not applicable
9.	For non-WCHN staff or students, WCHN HREC Confidentiality Agreement	☐ YES ☐ NO ☐ Not applicable
10.	For non-WCHN staff or students, current DCSI Child-Related Employment Screening Check *Required if accessing identifiable information of children (under 18 years of age) or coming on site.*	☐ YES ☐ NO ☐ Not applicable

SSA SUBMISSION CHECKLIST FUNDED & COMMERCIALLY SPONSORED RESEARCH INVESTIGATIONAL PRODUCT CLINICAL TRIALS (to be used in conjunction with SSA submission Checklist – All research)		
1.	CTRA (commercially sponsored clinical trials) *Must be on Medicines Australia standard template. Any special conditions must have SEBS approval.*	☐ YES ☐ NO ☐ Not applicable (e.g., not commercially sponsored clinical trial, no agreement required for research)
2.	CTN or CTX notification information	☐ YES ☐ NO ☐ Not applicable
3.	Indemnity *Medicines Australia Form of Indemnity for Clinical Trials – Standard must be provided for all clinical trials.*	☐ YES ☐ NO ☐ Not applicable
4.	Insurance certificate (sponsor)	☐ YES ☐ NO ☐ Not applicable
5.	Insurance certificate (other institutions, as relevant)	☐ YES ☐ NO
8.	Radiation or biosafety reports	☐ YES ☐ NO ☐ Not applicable
9.	Advertising materials	☐ YES ☐ NO ☐ Not applicable

For studies that are submitted for ethical approval under NMA, there are the following additional requirements:

SSA SUBMISSION CHECKLIST – RESEARCH APPROVED UNDER NMA		
1.	Lead HREC approval letter *Must specifically mention WCHN site as an approved site.*	☐ YES ☐ NO ☐ Concurrent HREC/SSA submission
2.	CTN or CTX information in validated form.	☐ YES ☐ NO ☐ Not applicable
3.	Participant Information Sheet and Informed Consent Form, Master version.	☐ YES ☐ NO ☐ Not applicable
4.	Participant Information Sheet and Informed Consent Form, site-specific version (both clean and tracked changes versions).	☐ YES ☐ NO ☐ Not applicable
5.	Any information to be provided to study participants (e.g., participant identification cards, questionnaires, fact sheets): • Master version(s); and • WCHN-specific versions in clean and tracked changes version (if applicable)	☐ YES ☐ NO ☐ Not applicable
6.	Any advertising materials.	☐ YES ☐ NO ☐ Not applicable
7.	For investigational product (drug or therapeutic) trials, information about the investigational product, e.g., pharmacy manuals, investigator brochures, instructions for use.*	☐ YES ☐ NO ☐ Not applicable
8.	Radiation safety or biosafety reports.*	☐ YES ☐ NO ☐ Not applicable

* *These are only required in instances where WCHN HREC is <u>not</u> the lead HREC. Where WCHN HREC is the lead HREC, these documents are available on the WCHN HREC files and researchers need not provide them again with their SSA submission.*

Contents

Fees

It is the responsibility of the researcher and sponsor to be aware of the current SA Health Research Ethics and Governance Fees Schedule (or its equivalent and as may be amended from time to time) (**SA Health Fees Schedule**). The SA Health Fees Schedule is located on the SA Health research website. The relevant fees contained in the SA Health Fees Schedule will be invoiced for all submissions and reviews for the duration of the research.

Researchers involved with Cooperative or Collaborative Research Group (**CRG**) clinical trials may request a reduction or waiver of fees. Please address your request to the RGO and clearly explain the reasons for your request for a reduction or waiver of fees. Such a request does not guarantee that a reduction or waiver of fees will be granted and is at the discretion of the RGO.

Invoicing

For all studies that will incur fees as outlined in the SA Health Fees Schedule, details for invoicing of WCHN research ethics and research governance fees should be provided with the initial SSA submission.

Fees for the review of contracts, amendments, addition of a sub study and so on will also be charged as outlined in the SA Health Fees Schedule.

Concurrent submissions

You may submit your SSA at the same time that you apply for ethical approval from a certified Australian Human Research Ethics Committee (**HREC**). However, it is important to be aware that governance authorisation is not granted until evidence of HREC approval is provided to the RGO.

If you wish to make concurrent submissions, please make this clear in your covering letter.

Conditions of research governance authorisation

The terms and conditions of research governance authorisation are included in the authorisation letter from the RGO and are **in addition** to the terms and conditions of HREC approval.

Researchers have a responsibility to comply with reporting requirements and other conditions.

Failure to comply will have significant implications for the ongoing authorisation of the study and may have other serious consequences for the researcher(s).

For example, failure to provide an annual report within the specified timeframe or failure to ensure that all non-WCHN staff and students satisfy the WCHN Confidentiality Agreement and DCSI Child Related Screening check requirements may lead to the withdrawal of site authorisation and suspension of the study.

In the event there are other conditions of research governance authorisation, these will be detailed in the research governance authorisation letter.

Annual reporting

A condition of WCHN Human Research Ethics Committee and WCHN research governance approval is that an annual report must be provided to the RGO within 30 days of each anniversary of the initial HREC approval for the duration of the HREC approval period.

Please submit your Annual Reports on the WCHN template form available on the WCHN research governance website.

The RGO will send an email to the Principal Investigator and Site Contact Person to acknowledge and approve the Annual Report. Any further actions that may be required will be detailed in this email.

Acknowledgement of receipt

The RGO will send acknowledgement of receipt notifications via email to the Principal Investigator and Site Contact person. If any further action is required or if there are any conditions of acceptance, these will be detailed in the email.

Additional sub studies

In instances where an additional sub study is added after initial ethical approval, you must submit the sub study to the WCHN HREC for approval. The RGO must then review the sub study and authorise for it to proceed at the WCHN site.

Sub-studies which form part of a larger study will be indemnified (assuming all requirements for indemnity as outlined in this document have been met) if:

- The sub-study has been considered and approved by the HREC as part of the approval process; and
- The context of the study and supporting documentation does not vary from the initial study.

In the event that the sub-study has not been considered by the HREC as part of the approval process, ethics approval will be required together with a further review of indemnity.

National Mutual Acceptance

The National Mutual Acceptance (**NMA**) scheme is when one HREC provides approval for more than one Australian site. The WCHN HREC participates in the NMA scheme and is certified to do so as lead approving HREC. Please refer to the SA Health research website and the WCHN HREC website for further information on how to apply for ethical approval under the NMA.

In terms of research governance, there is a section on the SSA form to record the name of the approving HREC and to list the other sites involved in the study. All participating sites should be recorded in section 4, including the WCHN site.

Please ensure that the lead HREC approval letter specifically mentions that the WCHN site has been granted approval for the study.

In your SSA submission cover letter, please indicate that the study has been approved under NMA (for HREC approved studies). Also include the details of the lead HREC in the cover letter and in section 2 of the SSA form.

It is also important to consider the requirements of the lead HREC in terms of reporting and accountability. For example, the annual reporting is usually completed on the lead HREC forms and the local RGO copied in to the correspondence.

All correspondence with the lead HREC must be made through the lead site Principal Investigator/Study Coordinator.

Guidance on the documents required for SSA submission for an NMA project is provided below.

Annual Reporting under NMA

For research approved under the NMA, annual reports are usually submitted to the lead HREC on the lead HREC specific forms via the lead site Coordinating Principal Investigator/Study Coordinator. Where WCHN HREC is the lead HREC, annual reporting information for all approved sites is provided to the WCHN RGO on the WCHN Annual Report form. Where WCHN HREC is not the lead HREC, the Annual Report form of the lead site must be completed and submitted via the lead site Coordinating Principal Investigator/Study Coordinator and the RGO must be copied in on the Annual Report submission.

Additional sub studies under NMA

For studies conducted under NMA where WCHN HREC is not the lead HREC, the lead HREC must review and approve the additional sub study. The RGO must then be provided with the lead HREC approval letter and copies of all approved documents, including any amended Participant Information Sheets and Consent Forms that require localisation for the WCHN site in clean and tracked changes versions. The sub study may not be conducted at WCHN until the RGO provides authorisation for the sub study.

Amendments or new research documents under NMA

When any amendments are made to the protocol, Participant Information Sheet and Informed Consent Form, or to any other research documents, or where new documents or information is added to the research the following steps must occur:

1. Amended documents or new documents are submitted to the lead HREC for approval.
2. Lead HREC grants approval.
3. Copy of the lead HREC approval letter and all lead HREC-approved documents (amended or new) are provided to the RGO for approval.
4. For any document that has been amended, the RGO is provided with:
    a. Approved Master version (if applicable); and
    b. Amended version in clean and tracked changes format.
5. For any document that has a site specific version (for example, participant information sheets, flyers, advertising material, brochures, changes in recruitment target), the RGO is provided with:
    a. Approved Master version; and
    b. Site specific version in clean and tracked changes format (if applicable).
6. WCHN RGO notifies site of acknowledgement and approval.

Any amended or new documents must be approved by the RGO prior to their implementation and use at the WCHN site.

Documentation for SSA submission

An SSA submission will not be accepted without all necessary and available documentation being included in the initial submission.

If only the SSA Form is submitted and no other regulatory/governance documents accompany that submission, the SSA form will not be considered until the supporting documentation is also provided.

A covering letter should be included with your submission documentation. The covering letter should as a minimum detail the research title, HREC reference numbers, the documents submitted (including version numbers and dates), site contact details and invoicing contact details. Please refer to the checklists for guidance on what documentation will be required to support your SSA submission.

SSA form

There are two types of SSA form:

1. SSA form for all research (**Full SSA**); and
2. SSA form for Low Negligible Risk research (**LNR SSA**).

All applications for SSA must be made on the South Australian SSA form generated from the Online Forms website.

Some of the information about the study that is required for the SSA form can be populated from the National Ethics Application Form (**NEAF**). The NEAF is the form that is required for HREC submissions.

Please refer to the User Manual or help icons in the Online Forms system for assistance with completing the SSA form. Please contact the RGO if you have any queries about the sections contained in the SSA form.

The RGO requires the SSA form to have original, wet ink signatures. If you are unable to provide original signatures for any reason then please inform the RGO at the time of submission. For example, if you have signatures from interstate sites or from multiple sites and only have PDF versions then please advise the RGO of this in your covering letter. Generally, the RGO will accept PDF versions of signatures if a valid reason is provided and at least one signature on the SSA form is an original. It is the responsibility of the researcher to ensure that the original signed versions are securely stored at the originating site.

Study personnel

Please indicate who will be the 'site contact person' for the study. This is often the Principal Investigator. However, the site contact person does not need to be an investigator. For example, for clinical trials the lead Study Coordinator can be the contact person for the site rather than the Principal Investigator.

The details of all staff that are working on the research at WCHN as investigators must be included on the SSA form.

The experience and training for all staff involved in the study, not just the Principal Investigator, must be documented in the research personnel section of the SSA form. You need not list every staff member or person performing research-related procedures. However, you must advise that all

persons involved in the research have experience in the relevant area and will receive appropriate and adequate training in research-related procedures. For Investigators and Study Coordinators, please advise that they have received training in principles of the International Council for Harmonisation (ICH) Good Clinical Practice (GCP) (if applicable).

It is important to list any non-WCHN staff and students who are working on the study and to detail their involvement in the study in the SSA form (e.g., in the research personnel or study details section). It is a South Australian legislative and WCHN policy requirement that only non-WCHN staff and students who are listed in the SSA form and who have provided the RGO with both a WCHN HREC Confidentiality Agreement and a current DCSI check may be authorised to be involved in the research and access identifiable WCHN patient information.

Non-WCHN staff and students

Non-WCHN staff or students are not authorised to perform any acts in relation to the study at the WCHN site that would involve access to identifiable WCHN patient data without the RGO reviewing and approving a WCHN HREC Confidentiality Agreement and a current DCSI Check.

All non-WCHN staff or students must provide the RGO with a signed WCHN HREC Confidentiality Agreement. If the research involves children under 18 years of age, a current Department of Communities and Social Inclusion Child-Related Employment Screening check (**DCSI Check**) may be required. Further information and forms are available on the WCHN research website.

These requirements apply to all non-WCHN staff or students identified in the SSA submission. It also applies to all non-WCHN staff or students who wish to work on the study at any time in the future.

For example, and to avoid doubt, these requirements extend to:

- any monitors, Clinical Research Associates (**CRA**) or other non-WCHN personnel working on the study in any capacity who have access to identifiable WCHN patient information.
- any monitors, CRAs or other non-WCHN personnel working on the study in any capacity who are at any time on-site at a WCHN facility for research related purposes. An exemption can be sought for those non-WCHN staff and students who are on-site but not in a position to access any identifiable data.
- any researcher or research group who wishes to access WCHN data for the purposes of creating a registry and who can at any time access identifiable WCHN patient data. In this instance, every person who is non-WCHN staff or student must satisfy the above requirements if they can *at any time* access identifiable WCHN patient data.

If you wish to apply for an exemption or exception to these requirements, please contact the RGO. The decision to grant an exemption or exception to these requirements is made by the WCHN Human Resources Department. It is not a decision that is within the ambit of research governance.

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.

For further information, refer to the WCHN Research Governance website, the *Children's Protection Act 1993* (SA) and the *Children's Protection Regulations 2010* (SA). The relevant WCHN policy is available to WCHN employees on the WCHN intranet.

Changes to study personnel

There may be instances where new study personnel are added to a study, or existing study personnel are removed. For example, you may wish to conduct testing that requires experts or someone has left the institution and is no longer involved in the study.

The RGO must be notified of all changes in study personnel.

When a Principal Investigator is changed, the WCHN HREC (or the lead HREC if a study approved under NMA) must also be notified.

If you wish to add non-WCHN staff and students in the future, a separate email application must be made to the RGO. In some instances, this application may require a WCHN HREC Confidentiality Agreement and, where applicable, a current DCSI check.

No changes to study personnel are to be implemented prior to receiving authorisation from the RGO and approval from the relevant HREC.

Credentialing

All medical staff are expected to be currently credentialed at WCHN or a South Australian hospital service.

Credentialing information can be accessed through SA Health PCs if you have an SA Health HAD login. Please contact the RGO if you are unsure how to access this information, or contact the applicable Human Resources department.

Access to information and data - Data Custodian

You are not authorised to access any data or data systems without the approval of the WCHN Data Custodian.

Research that requires access to SA Health or WCHN information systems must be approved by the WCHN Data Custodian. The RGO will arrange for the WCHN Data Custodian to review all relevant studies once ethical approval has been granted.

The WCHN Data Custodian is Ms Sacha Gower, A/Director of Health Informatics, Performance, Planning & Outcomes (**HIPPO**), WCHN. No other individual or head of department may sign the SSA form as Data Custodian.

It is important that you provide an adequate summary of your research and identify all patient data systems that are to be accessed for your research and all means of accessing WCHN patient information, including how potential participants are identified in the screening process, and whether you intend to access information from electronic medical records and/or paper-based medical case notes.

Do not mark the SSA form Data Custodian signature page as being 'not applicable' even if you believe it is not applicable. Instead, leave the Data Custodian signature page blank. Only the WCHN HREC (if the reviewing HREC), RGO and Data Custodian may determine if Data Custodian sign off is not applicable.

Unlike the Full SSA form, the LNR SSA form does not automatically include a Data Custodian signature page. For the LNR SSA form you must select from a drop down list of options that the Data

Custodian signature is required. This selection incorporates the Data Custodian page into the SSA form.

You are not authorised to access any data or data system (including electronic and paper medical records) that is not listed on the SSA form.

If you do not list a data system in the SSA form and you access data from that data system for the purposes of your research then you are in breach of the terms and conditions of your SSA authorisation. This could lead to withdrawal of research governance authorisation of your research or further serious consequences.

For example, you are using HOMER to access information about the number of WCH patients admitted with a certain disorder. You are also cross-referencing patient laboratory test results on OACIS to see if they are eligible for inclusion in your study based on a particular test result. However, in the SSA form you have only listed OACIS as a means of information gathering for your research. Therefore, you may only use OACIS for your research and not HOMER. If you do use HOMER to identify research participants then you are in breach of the terms and conditions of authorisation for your research. This breach is very serious particularly as it concerns unauthorised access to identifiable WCHN patient data. You are still in breach of WCHN research governance authorisation even if you use HOMER for clinical purposes. This is because you are accessing HOMER for research purposes (i.e., to identify potential research participants).

You are not authorised to access any information about WCHN patients in a particular manner if you do not list the method of access on the SSA form.

If you do not list a means of accessing WCHN patient data in the SSA form and you access data from a WCHN patient information source for the purposes of your research then you are in breach of the terms and conditions of your SSA authorisation. This could lead to withdrawal of research governance authorisation of your research or further serious consequences.

For example, you are conducting research into a group of patients that attend a certain WCH clinic. You wish to approach patients from this clinic to participate in your research. You are going to get a list of names of patients who attend the clinic from the WCH department. You will then use this list of names to determine who to contact for your research. Therefore, you must include in your SSA form that you are using the particular clinic patient list to recruit from and identify how and from whom the list of names will be provided to the researcher. As this is identifiable WCHN patient information, you are required to have the approval of the WCHN Data Custodian prior to obtaining WCHN patient information. If you do not include this information in your SSA form and/or do not obtain approval from the WCHN Data Custodian then you are not authorised to access the information.

You can only recruit participants in the manner(s) listed in the SSA form.

Only WCHN sites, services, departments, divisions or other places or means of participant recruitment that are specified in the SSA form are authorised for recruitment. If you recruit outside of these then you are in breach of the terms and conditions of research governance authorisation.

If you do not list a means or method of recruiting participants in the SSA form and you recruit participants in that manner, you are in breach of the terms and conditions of your SSA authorisation. This could lead to withdrawal of research governance authorisation of your research or further serious consequences.

For example, in the SSA form you have identified that participants will only be recruited from OACIS results. However, you also plan to recruit from list of patients who attend a clinic at Women's and Children's Hospital. WCHN patient names are identifiable patient information (even if you are not given any other details). If you use the clinic list to recruit from and you have not included this in your SSA application then you are in breach of your research governance authorisation. If you wish to use clinic lists to recruit from, then you must include in your SSA form all of the clinics and referral sources from which you will receive this information. It is sufficient to state that you will be receiving clinic lists 'on referral from Women's and Children's Hospital [specify clinic name] clinics' rather than listing the names of specific referrers.

Access to specific de-identified data sets or systems

If you wish to discuss how you can access data systems or to seek approval to access certain data sets for your research, then you must contact the Data Custodian to seek approval. This process is separate to the research governance processes. For example, if you wish to perform a WCH case note audit or require a de-identified data set from WCHN data systems then you must contact the WCHN Data Custodian to arrange approval of the process and supply of the information.

If you have made, or intend to make, such a request please include details of this in your SSA form.

Research versus clinical use of WCHN data

Even if you access WCHN data for clinical purposes, **you must still apply for WCHN Data Custodian approval for any research that accesses patient information from SA Health or WCHN data systems**. This is because the data will be used for *research* purposes, which is separate to clinical purposes.

For example:

1) You intend to recruit participants from your department's clinics. If you are recruiting participants from the clinic list, then the identifiable patient data (for example, patient names on the clinic list, medical records) is being accessed for research purposes as well as for clinical purposes. Therefore, you must have WCHN Data Custodian approval to use the clinic list to recruit from and you must indicate on the SSA form that you will be using the clinic list for recruitment of research participants.

2) You have access to OACIS for your usual clinical practice. For your research you wish to screen for potential patients using parameters from OACIS (e.g., admission details, laboratory results, radiology reports). Accessing data from OACIS to screen for research means that you are using an SA Health data system for research purposes. Therefore, you must advise on the SSA form that you will be using OACIS for screening/recruitment and the WCHN Data Custodian must provide approval for this use of the data system.

3) You are enrolling participants into a clinical trial that is using local laboratories for blood testing. You have access to OACIS as part of your clinical practice and will use OACIS to access the laboratory results for your participants. Therefore, by accessing research protocol-required laboratory test results on OACIS you are using OACIS for a research purpose. Accordingly, on the SSA form you must include OACIS on the list of SA Health data systems that will be used for the research and the WCHN Data Custodian must approve this use of the data system.

Researchers must adhere to the WCHN requirements relating to non-WCHN staff or students who request access to identifiable data for the research (see 'Non-WCHN staff and students' section above).

Clinical trials information

As of 1 July 2015, the Therapeutic Goods Administration of Australia (TGA) requires all Clinical Trial Notifications (**CTN**) to be submitted via their online submission portal. It is the responsibility of the study sponsor to submit the application and pay the submission fee. **A CTN form must not be submitted to the TGA online portal until both ethical approval and research governance authorisation have been granted**.

In some circumstances, WCHN will agree to act as 'sponsor' for research or clinical trials. A researcher must apply to the RGO in order for WCHN to agree to act as CTN sponsor. In the event WCHN agrees to act as sponsor, any relevant agreements must be in writing to clarify the obligations

WCHN undertakes in its role as sponsor for a particular study and to determine how the TGA submission fee will be paid by the group or reimbursed to WCHN (as the case may be). We also require researchers to provide all relevant information to be entered into the online CTN form and to provide the RGO with a copy of the TGA notification letter as soon as practicable.

If arrangements are not already in place and your collaborative or cooperative research groups wish to request that WCHN be sponsor of your study for CTN purposes, please place a request with the RGO. Making a request that WCHN be the CTN sponsor of your study does not guarantee that WCHN will accept this role.

More information is available on the TGA website and in the Australian Register of Therapeutic Goods.

Where WCHN is not the sponsor, we require the sponsor to complete and validate (but not submit) the online CTN form and provide a copy of this validated form to the RGO.

Once site authorisation has been granted and the sponsor has submitted the CTN form, the RGO must be provided with a copy of the submitted information and the TGA notification letter as soon as practicable.

Please contact the RGO in the first instance if you are submitting a CTN form, have any queries about the CTN submission process, or to discuss options for your study.

WCHN requirements

The CTN form 'Approving Authority Details' for WCHN are as follows:

Name of approving authority:	Women's and Children's Health Network Inc. ABN 64 021 748 126
Approving authority contact:	Mr Philip Robinson
Position:	Executive Director, Corporate Services WCHN
Contact phone:	08 8161 7348
Contact email:	Philip.robinson@sa.gov.au

If the WCHN HREC is the reviewing HREC, the details are:

> **HREC Name:** Women's and Children's Health Network Human Research Ethics Committee
> **HREC Code:** EC00197

Insurance and indemnity

Recently, a review was undertaken in relation to granting SA Health indemnity for research projects and clinical trials. As a result, SA Health Legal Governance and Insurance Services (**LGIS**) will no longer be responsible for reviewing indemnity for research projects and clinical trials. This review will now be undertaken by the site Research Governance Officer (**RGO**).

In summary, the changes are:

1. SA Health employees conducting a research project in the capacity of their employment with SA Health are **automatically covered by SA Health insurance** where approval from a SA Health HREC or NMA HREC has been obtained.

2. For research projects sponsored by a third party, including commercially sponsored clinical trials, the sponsor must supply evidence of its insurance cover. A sponsor's insurance cover must indemnify the local site, investigator and research staff, and participants involved in the research project. For all commercially sponsored clinical trials, the Medicines Australia Form of Indemnity for Clinical Trials – Standard must also be submitted to the RGO.

3. For research projects conducted by non-SA Health employees at a SA Health organisation that involves SA Health patients, staff, resources or data to support the research project, the PI must provide appropriate insurance documentation on behalf of the non-SA Health organisation. Appropriate insurance documentation includes current insurance certificate/s and written insurance approval from the non-SA Health organisation for the research project. These requirements include research projects conducted by staff and students of academic and research institutions. Where applicable, the RGO must be provided with current insurance certificates in the initial submission. It is the responsibility of the researcher to ensure that the RGO is provided with updated certificates of insurance as they are renewed.

All documentation (if any) should now be provided to the RGO with your Site Specific Assessment (**SSA**) submission.

Any requests for indemnity received by LGIS will be returned with a request that the e-mailer contact their site RGO to obtain indemnity.

If LGIS has already approved your research project (i.e., before 13 January 2016), please provide a copy of the LGIS approval email to the RGO.

Guidance documentation

a) The SA Health Research Governance Policy Directive has been updated.

b) A guidance document (*Insurance Services Guide: Indemnity Insurance for Research Projects/Clinical Trials*) and process flow chart (*LGIS Research Trials Flowchart*) have been developed by LGIS, a link to which is available on the SA Health Research Governance website and the WCHN Research Governance website. As these documents may change over time, please ensure that you check the website before submitting a SSA to the RGO.

c) The South Australian SSA form has been updated to incorporate a declaration by the Principal Investigator. If you have already submitted an SSA form on the superseded version, the RGO will review the indemnity arrangements if all relevant insurance documentation (if any) is included with your SSA submission.

Please contact the RGO if you have any queries about this process.

Biosafety and radiation safety

All research that involves biosafety or radiation must comply with the relevant requirements.

For example, research involving protocol-specified (i.e., over and above standard of care) medical imaging procedures involve radiation. In these circumstances, the RGO must be supplied with a radiation safety report that has been reviewed and approved by the WCHN HREC (or by the lead HREC for NMA studies where WCHN HREC is not the lead HREC). The Medical Imaging Department should also endorse the study and sign the SSA form as a supporting department.

For studies conducted under NMA, the RGO will accept lead HREC-approved biosafety or radiation safety reports from the lead site.

Investigational drugs - Pharmacy

For any research involving investigational products (drug or therapeutics) or non-investigational products (drug or therapeutics), the SSA form must be signed by the WCHN Pharmacy Department. This indicates that the WCHN Pharmacy Department are aware of the research and have agreed to manage, store, handle or dispense the pharmaceutical product(s) (as may be required).

All dispensing must be performed through WCHN Pharmacy Department, unless otherwise approved by the Director, Pharmacy, WCHN.

In the instance that a research group or researcher prepare or otherwise handle pharmaceutical product, the RGO must have written confirmation of approval from the Director, Pharmacy, WCHN for the specific processes that the group or researcher may undertake.

Funding arrangements and financial oversight

All funding related to the study must be accurately reported in the SSA form. This applies to all research for which funds are held or managed external to WCHN, including SA Pathology and universities. The information provided in this section is crucial to research governance review.

If there is no funding for the study, please indicate how you will be undertaking the research. For example, detail any in-kind support of WCHN staff or any resources or equipment that will be used.

Every box must be completed. Where there is no funding, please enter 'not applicable' rather than leave the box blank.

All financial arrangements must be authorised and the SSA form signed by the relevant Director of Finance (or delegate) or Business Manager.

If the funds are being held in a non-WCHN cost centre such as SA Pathology or at a university then the appropriate financial/business manager must approve the study and sign the SSA form.

Head of Department endorsements

Any division or department that is involved in the research must endorse the research being conducted in their department and must sign the SSA form. This includes departments that are actively involved in the research. It may also include departments that are not actively involved, but will experience some impact from the conduct of research (for example, participants will be recruited from the department).

All relevant Divisional or Department Heads must sign the SSA form.

It is a conflict of interest for any person who is listed on the SSA form as an Investigator, whether as the Principal Investigator or Associate Investigator, to also provide endorsement as the Head of Department. In instances where the Head of Department is an Investigator, the endorsement and SSA form signature must be provided by the next highest level of authority. For example, where a Department Head is also the Principal Investigator, the Divisional Head must provide endorsement.

Data Custodian

The RGO will arrange for your research project to be reviewed by the WCHN Data Custodian once ethical approval has been granted (see above). No other individual may sign the Data Custodian section of the SSA form.

Please ensure that the Data Custodian signature page is included in LNR SSA forms.

Final authorisation

Final authorisation for the research is provided by the Executive Director, Corporate Services WCHN. The 'Final authorisation' page must be left blank on all SSA forms.

Participant information

Please provide the RGO with the WCHN-specific Participant Information Sheets and Informed Consent Forms (**PISIC**).

For NMA studies, the lead HREC will review and approve the participant information, including all PISIC. You must provide to the RGO the Master PISIC and WCHN-specific PISIC for review and authorisation. The WCHN-specific PISIC must be provided to the RGO in a clean version and also with tracked changes (tracked changes from the Master version).

The use of WCHN, SA Health or other such logos must be approved by Media and Communications, Women's and Children's Health Network. Approved logos are available for download from the WCHN intranet website. You do not need to seek separate approval if you use these logos as their use has already been approved by Media and Communications, WCHN.

Research agreements

If your study involves an agreement between WCHN and any other party, then this agreement must be submitted to the RGO for review. This includes any confidentiality disclosure agreements, research collaboration agreements, data sharing agreements, or contracts. These agreements need not adhere to a specific format and can be based on local templates of other institutions or organisations.

WCHN is the entity that can enter into research agreements. Individual SA Health researchers are not authorised to enter into or sign research agreements on behalf of WCHN.

These types of agreement generally require independent legal review prior to being signed on behalf of WCHN. The RGO will arrange legal review on your behalf as and when required. Where fees are chargeable, the appropriate fee will be charged as outlined in the SA Health Fees Schedule.

The 'Institution' (or however it may be referred to or defined) is always 'Women's and Children's Health Network Inc. ABN 64 021 748 126'. To expedite review, please ensure that the details of the 'Institution' are inserted exactly as follows:

Name of Institution:	Women's and Children's Health Network Inc.
Address:	72 King William Road, North Adelaide SA 5006
ABN:	64 021 748 126

Please ensure that you provide all relevant supporting documents (if any) when you submit an agreement to the RGO. For example, some agreements may be made under a 'head agreement', in which case the RGO needs a copy of the head agreement. Others may refer to a 'funding agreement', in which case the RGO needs a copy of the funding agreement.

If an agreement is signed in counterparts then we will require a copy of every signature once the agreement has been signed by every party. We will usually accept a PDF version of the signed document in this instance.

Any future amendments, variations or other such agreements relating to the main agreement may incur the Contract Review Fee in accordance with the SA Health Fees Schedule. This must be considered in any initial budget negotiations. Where fees are chargeable, we also expect to see in the contract a clause to the effect that all HREC and research governance fees will be paid in accordance with the SA Health Research Ethics and Governance Fees Schedule (or its equivalent) as may be amended from time to time.

Upon receipt of any amendments, variations or similar documentation, an invoice will be generated and forwarded to the nominated contact for invoices in instances where the fee is to be charged.

If you wish to have this fee reduced or waived, a written request must be made to the RGO prior to submitting the documentation. This request does not guarantee that a waiver of fees will be granted and is at the discretion of the RGO.

Separate to the SSA process, it is important to be aware of the requirements of the Research Grants Officer, WCHN for any research that has funding attached to it. There are reporting requirements relating to any research grants or funding that you have applied for, regardless of whether your application was successful or not. If you have any questions about research grants or are unsure if you should notify the Research Secretariat about your funding, please contact the Research Grants Officer, WCHN:

Ms Katherine McPhail
Research Grants Officer
Women's and Children's Health Network
T: 08 8161 8175
E: Katherine.Mcphail@sa.gov.au

Clinical Trials Research Agreements (CTRA)

All commercially sponsored trials require a CTRA to be signed on behalf of WCHN.

It is the responsibility of the study sponsor to ensure the CTRA is in the correct form. We accept the Medicines Australia template CTRA (**Template CTRA**). Any amendments to the Template CTRA must be identified and a tracked changes version of the CTRA provided to the RGO.

All amendments to the Template CTRA and also any clauses included in the 'Special Conditions' Schedule to the CTRA must have Southern and Eastern Border States review committee (**SEBS**) approval for use in South Australia. More information and an application form can be found at the SA Health website.

Evidence of SEBS approval should be included with the submission. Any CTRAs that are amended or have clauses inserted into the 'Special Conditions' schedule and do not have SEBS approval prior to SSA submission may attract the 'Contract Review Fee' in accordance with the SA Health Fees Schedule.

Care must be taken to ensure that the correct version of the Template CTRA is used. For example, there is a standard CTRA for sponsors, for sponsors using an Australian Contract Research Organisation to act on their behalf, and for Cooperative/Collaborative Research Groups.

Institution

On the CTRA cover page, the details of the 'Institution' must be inserted exactly as follows:

Name of Institution:	Women's and Children's Health Network Inc.
Address:	72 King William Road, North Adelaide SA 5006
ABN:	64 021 748 126

Please review all regulatory documents to ensure that these details are correctly recorded. In the event the Institution details are not correct the CTRA must be amended which will delay research governance authorisation.

Future amendments

In the event the CTRA is amended at any time after its initial approval, where fees are chargeable the Contract Review Fee contained in the SA Health Fees Schedule will be invoiced to the sponsor.

Budgets and finance

It is important to consider the SA Health Research Ethics and Governance Fees Schedule when negotiating a budget and determining what to include in the budget. We require the budget/finance clauses to be drafted in such a manner as to allow the WCHN Research Secretariat to invoice for any and all fees in accordance with the SA Health Fees Schedule (or its equivalent) both in its current form and as may be amended from time to time. If the CTRA does not include such a clause then we will request that CTRA be amended to include it. Please ensure such a clause is included in order to avoid delays in obtaining research governance authorisation.

Execution of the CTRA

It is the responsibility of the study sponsor to ensure that the CTRA provided with the submission is in final, executable form. We prefer that the CTRA has been executed by the sponsor and by the Principal Investigator prior to final authorisation. At least three wet ink signed copies must be provided to the RGO. One copy will be retained for the research governance files.

Only in extenuating circumstances will the RGO accept an unsigned CTRA at the time of final authorisation (for example, where obtaining a signature may delay the SSA submission for a few weeks). In this instance, this should be mentioned in the SSA submission covering letter. One wet ink fully executed CTRA must be provided to the RGO prior to obtaining final authorisation for the study to commence at WCHN.

The RGO will arrange for the CTRA to be executed on behalf of the Institution (WCHN) once all SSA submission documents are in order and any research governance queries have been resolved.

Indemnity

All commercially sponsored studies must provide a Medicines Australia Form of Indemnity for Clinical Trials based on the Medicines Australia template. It is our preference that this is executed on behalf of the sponsor prior to SSA submission. If a sponsor has not signed the indemnity form prior to SA submission, the RGO must be provided with an executed copy prior to final SSA authorisation.

The details of the 'Indemnified Party' must be inserted exactly as follows:

> **Women's and Children's Health Network Inc. ABN 64 021 748 126** of 72 King William Road, North Adelaide South Australia 5006

In accordance with the Medicines Australia template form requirements, please insert all of the required details. This includes the Indemnified Party (as above), clinical study number (i.e., protocol identifier), full protocol title, identification of the Participants (select only from the two options provided) and the name of the Principal Investigator. While it is the responsibility of the sponsor to draft the indemnity form, delays can be avoided by identifying any incorrect or incomplete details prior to SSA submission.

The RGO will arrange for the Indemnity to be executed on behalf of the Institution (WCHN) once all SSA submission documents are in order.