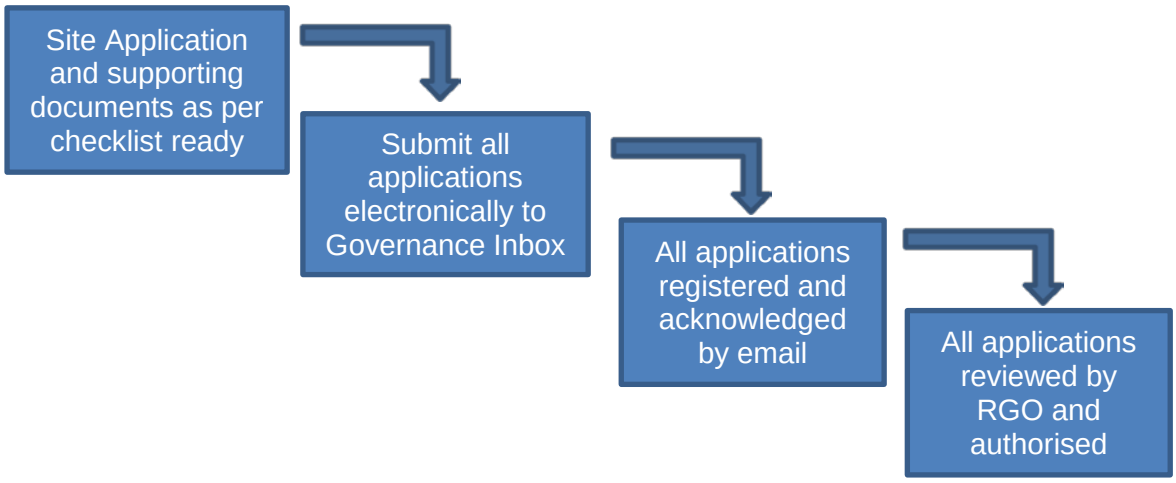
RESEARCH GOVERNANCE SUBMISSION GUIDELINES

PROCEDURE ©

DOCUMENT SUMMARY/KEY POINTS

- These guidelines are intended to assist with the compilation of all documents required for the assessment of site specific applications for Human Research across SCHN
- They are a quick reference guide for submitting a Site Specific Application (SSA) for high-risk NEAF projects, Low and Negligible Risk (LNR) projects and Access Requests
- **Advice and guidance on governance applications is available.**
  To make an appointment, please contact (02) 9845 3011 or the Governance Inbox: SCHN-Governance@health.nsw.gov.au
- Submission Process Overview (may be conducted in parallel with Ethics Submission)



This document reflects what is currently regarded as safe practice. However, as in any clinical situation, there may be factors which cannot be covered by a single set of guidelines. This document does not replace the need for the application of clinical judgement to each individual presentation.

Approved by:	SCHN Policy, Procedure and Guidelines Committee	
Date Effective:	1st December 2016	**Review Period**: 3 years
Team Leader:	Manager	**Area/Dept**: Research Governance

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- Key Points:
  - Completing the SSA Form
  - Completing the LNRSSA Form
  - Completing your Access Request Form
  - Clinical Trials
  - Declarations
  - Submitting the Application
  - Associated Links
  -

CHANGE SUMMARY

Update November 2016

New Sydney Children's Hospitals Network Guidelines

Updated from local: Guide_SCHN_Submission guidelines for NEAF applications_May 2014

READ ACKNOWLEDGEMENT

All Research Governance Office staff members at SCHN should read and acknowledge they understand the contents of this document.

All SCHN Staff conducting human research projects at an SCHN Site should read and acknowledge they understand the contents of this document.

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1 Purpose and Scope

"Research projects to be conducted at sites under the control of NSW Public Health Organisations, whether they have undergone full or expedited HREC review, must undergo site specific assessment before authorisation can be granted by the Chief Executive or their delegate." NSW Health Policy Directive Research - Authorisation to Commence Human Research in NSW Public Health Organisations

The Sydney Children's Hospital Network (SCHN) Research Governance office is responsible for the review of all types of site-specific applications (SSAs) associated with a Human Research project that may be conducted at any of the six (6) sites within the SCHN.

These sites are:

1. The Children's Hospital at Westmead (CHW)
2. Sydney Children's Hospital, Randwick (SCH)
3. Newborn Emergency Transport Service (NETS)
4. Bear Cottage
5. The Children's Court Clinic
6. NSW Pregnancy and Newborn Services Network (PSN)

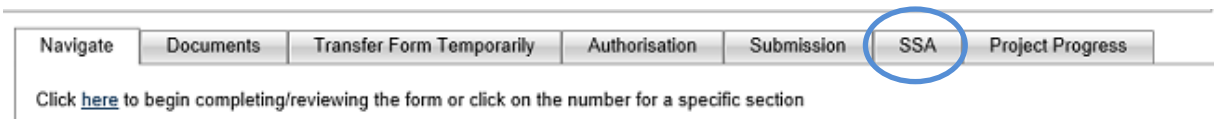
Generally a separate Research Governance application (SSA) must be completed for each site although there may be some circumstances where one SSA will be accepted for multiple sites within the Network. Please contact Research Governance for further details: governance inbox: SCHN-Governance@health.nsw.gov.au or 02 9845 3011

To complete a site specific application (SSA) you must have first completed:

1. A National Ethics Application Form (NEAF); OR
2. A Low and Negligible Risk Research Application Form (LNR Application Form)

Access these forms: www.ethicsform.org/au/SignIn.aspx

1. Login and select your NEAF or LNR application
2. Select the SSA TAB to complete your SSA



There are three (3) types of SSA documents:

1. Site Specific Assessment (SSA): required if you have completed a NEAF
2. Low and Negligible Risk Research Site Specific Assessment Form (LNR SSA): required if you have completed an LNR Application Form
3. Access Request Form: required if you have completed a NEAF or LNR Application Form and only wish to access data, samples or advertise your project at a SCHN site and you are not employed at SCHN.

Each type of document will be covered in more detail in the following sections. Please contact the Research Governance Office prior to completing if you are unsure of the most appropriate form.

2 Abbreviations and Definitions

1. Abbreviations

CHW	The Children's Hospital at Westmead
CTN	Clinical Trial Notification
CTX	Clinical Trial Exemption
CTRA	Clinical Trial Research Agreements
HREC	Human Research Ethics Committee
IAF	Invoicing Authorisation Form
ICH-GCP	International Conference on Harmonisation – Good Clinical Practice
LNRSSA	Low and Negligible Risk Site Specific Application
NMA	National Mutual Acceptance
NEAF	National Ethics Application Form
NETS	Newborn and Paediatric Emergency Transport Service
PI	Principal Investigator
PSN	Pregnancy and Newborn Services Network
RGO	Research Governance Officer
SCH	Sydney Children's Hospital
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TGA	Therapeutic Goods Administration

2. Definitions

Clinical Trial

Interventional research involving a drug/device trial, radiation therapy, surgery, treatment or diagnostic procedure and studies associated with ongoing activities relating to trials that have been conducted. This may include observational research and evaluation of a trial, developing a registry and other post-marketing surveillance activities.

Clinical Trial Notification (CTN) Scheme

Trial sponsor notifies the TGA of their intention to conduct a clinical trial using an unapproved therapeutic good.

Clinical Trial Exemption (CTX) Scheme

TGA reviews information about the product and decides whether or not to approve the proposed Usage Guidelines of the product.

Clinical Trial Research Agreements (CTRAs)

The NSW, Qld, Vic and SA Health Departments (the SEBS States), together with Medicines Australia, have developed four standard CTRAs.

Governance Inbox

SCHN-Governance@health.nsw.gov.au

Lead HREC

Local HREC accredited by the Director-General of the NSW Department of Health to conduct ethical and scientific review of human research on behalf of the NSW public health system in the categories of: (a) clinical trials/interventional clinical research; and/or (b) general research.

National Mutual Acceptance (NMA)

In 2013, NSW Ministry of Health in conjunction with the corresponding government health agencies in Queensland, South Australia, and Victoria (the 'participating jurisdictions') agreed to implement a scheme of National Mutual Acceptance (NMA) of single ethical review (by a lead HREC) of multi-centre clinical trials conducted in each participating jurisdiction's public health organisations. In December 2015, the scope of NMA was expanded beyond clinical trials to all human research.

Principal Investigator (PI)

The individual who takes responsibility, according to ICH-GCP, for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the research project for site authorisation.

Research Governance Officer

The individual appointed within the Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of authorised research projects.

Research protocol

Document that details the objectives, design, methodology, statistical considerations and organisation of a research project.

Site

Facility, location or service where the research is being conducted.

Site authorisation

Authorisation granted by the Chief Executive or their delegate of the Public Health Organisation for the commencement of a research project.

Site-specific assessment (SSA)

Mechanism used by Public Health Organisations to ensure that the proposed research project complies with minimum governance requirements, and to consider whether the research should be conducted and supported at the proposed site.

Sponsor

The company, institution or organisation, body or individual that takes overall responsibility for the conduct of a clinical trial and usually initiates, organises and supports the clinical trial.

Therapeutic good

Broadly defined as a good which is represented in any way to be, or is likely to be taken, for therapeutic use (unless specifically excluded or included under Section 7 of the Therapeutic Goods Act 1989). Therapeutic use means use in or in connection with: preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; influencing inhibiting or modifying a physiological process; testing the susceptibility of persons to a disease or ailment; influencing, controlling or preventing conception; testing for pregnancy; or replacement or modification of parts of the anatomy.

3 Completing the SSA Form

Helpful Hint:

The numbering below corresponds to the numbering in the SSA Form itself.

Set up your investigators in the "contacts" field of the "online forms" website prior to completing the "investigator" field in the NEAF and SSA forms. This will enable you to click and drag into your NEAF application and associated SSA, rather than re-typing into each form. This will also be saved for the next time.

1. Some fields in the SSA e.g. Short Title, Project Title in Full, Project Summary, will be auto-populated from your NEAF
    - **i.** Research Governance Officer Jurisdiction:

      Sydney Children's Hospitals Network (Randwick and Westmead)
    - **ii.** Name of the HREC reviewing the research project:
        - E.g. If using the SCHN HREC, it is currently coded as:
            - EC00130 – The Sydney Children's Hospitals Network Human Research Ethics Committee
        - If the study is only operating at sites within the Network, HREC approval must be sought from an accredited paediatric HREC
        - If the study will be conducted at multiple sites within Australia, Australian accredited HREC approval from interstate may be accepted.
            - The National Mutual Acceptance (NMA) Scheme has a Memorandum of Understanding signed by NSW, VIC, QLD, SA and ACT and allows single HREC Review by a Lead HREC of any research project to be conducted at any Public Health Organisation. Discussions are still underway to include WA, TAS and NT in the future.

2. The site name:
    - **i.** CHW
    - **ii.** SCH
    - **iii.** NETS
    - **iv.** PSN
    - **v.** Bear Cottage
    - **vi.** Children's Court Clinic

3. Research personnel at this site:

   i. List all the investigators/project personnel involved at the SCHN site and contact person for the research project at this site

   ii. Students who are involved on site or will have access to identified data **must** be listed.

   iii. Supporting information required:

   - When submitting your project for review, a summary CV must be provided for all investigators listed on an SSA form. The Research Governance Office keeps soft copy CVs in an electronic file so please check with the Research Governance Office before submitting your CVs if it is already on file. Your CV must be no older than 2 years.
   - Evidence of employment is reviewed by the Research Governance Office for insurance cover:
     - All SCHN staff are indemnified by the Treasury Managed Fund (TMF) for "approved" research activities upon receipt of SSA authorisation.
     - Honorary and Visiting Medical Officer's must have signed a TMF contract of coverage. An honorary position is only available to medical staff.
   - All non-SCHN employees such as students who will be on site for the project, have participant contact or access to personal health records must provide evidence of insurance coverage from their employer/university. This can be attached to the SSA form upon submission to the Governance Inbox.
     - NB: USYD and UNSW - evidence of insurance has been provided by these Universities to the Research Governance Office, however evidence that the project forms part of the student's coursework must be provided.
     - This evidence may be in the form of the University supervisor sign off or University HREC approval if applicable.
   - Access to site by non SCHN employees
     - All non-SCHN personnel must also be screened by Staff Services to obtain approval for 'access to site'. An ID badge will be issued once all "contingent worker" screening requirements have been completed by Workforce

       (eg criminal record check, working with children check, vaccination details and ID).
     - Please contact Workforce Services on:

       schn-recruitment@health.nsw.gov.au; (02) 9845 2730

       for further information regarding this process.

- The Governance Office requires a photocopy of your SCHN ID badge or written confirmation (email) from Workforce that you have been screened. The researcher will not be able to commence the project on site until this is confirmed.
- Authorisation may be delayed if Workforce clearance is not supplied.

4. Training.

i. Will any researchers require extra training for this project?

ii. List name/role of researcher, training required, who will provide training

- E.g. GCP Training

5. Recruitment of participants.

i. Enter minimum and maximum number of participants to be recruited at the SCHN site

6. Participant details.

i. List categories of participants to be recruited and age.

ii. Please contact the Research Governance Office if any participants will be over 16 years of age at any time throughout the study and require in-hospital stay

7. What additional time and resources above routine duties will be required of the research team throughout the research project?

i. List name, department/location, additional time spent / week

ii. Non-investigators with patient contact must be listed here. For example study nurses/coordinators should be listed even if they are not investigators

8. Anticipated Start and Finish dates.

i. Only enter the dates in relation to the SCHN Site

9. Departments and services involved in the research project at this site.

i. List all departments to be involved in ANY aspect of the research project to ensure each department is aware and has the resources to support your research

ii. Each investigator involved in the project must have their department listed here in the SSA; and they must have their Department Head sign Declaration B (refer

to Section 7). If a Department Head is also an investigator, their superior (eg Clinical Program Director) must sign off on behalf of their department.

iii. Any other departments who are providing support for your research (e.g. pathology, radiology, pharmacy, data from departmental databases etc.) must also be listed on the SSA. The Department Head of each supporting department also must sign Declaration C (refer to Section 7).

iv. If you require access to patients in a Ward e.g. for blood collection / obtaining vital signs / completing surveys, even if you do not require nursing staff assistance, the Nurse Unit Manager should co-sign Declaration C

v. If you are accessing data for your project i.e. Medical Records/PowerChart, the Medical Records Manager also must sign Declaration D (refer to Section 7).

- If you have prior access to PowerChart you are still required to obtain approval from the medical records department to access PowerChart for your research project as the access is for non-clinical care purpose. Medical Records email: **SCHN-hiu@health.nsw.gov.au** and they may require sighting the Ethics Approval Letter.

10. Study Budget

i. Include details regarding any funding received and who will fund tests, drugs, and other resources required for the project.

ii. Be clear if funding is sought and not yet received and provide detail how the project will proceed if funding applications are unsuccessful.

iii. Contracts / Securing Funding

- Include with your SSA form any contracts or agreements associated with your project such as an agreement for payment of support or supply of the study drug.
  - The SCHN Chief Executive (CE) / Director of Research is the only delegate of SCHN able to execute fully an agreement on behalf of SCHN
  - The Research Governance Officer will review these documents and provide advice to the CE or delegate in relation to execution of these documents.
  - See below for commercially-sponsored Drug/Device Trials specifically

11. Site-Specific Policies

i. Refer to links in Section 9 for SCHN specific research policies

12. Clinical Trial for Device or Drug – refer to Section 6

13. Biosafety, chemical and radiation safety

i. It may be necessary to complete notification, registration or licence requirements for research involving biosafety, regulatory issues and/or radiation. If so, evidence of this is required.

ii. Projects using ionising radiation (including standard of care) must obtain approval from the local site Radiation Safety Officer: For further information please contact:

- CHW Radiation Safety Officer: Ms Nicole Willetts (02)9845 1892 nicole.willetts@health.nsw.gov.au
- SCH Radiation Safety Officer: Brent Rogers: (02) 9382 8067 Brent.Rogers@sesiahs.health.nsw.gov.au

14. Declarations – refer to Section 7

15. Finalising the SSA Form

i. When the SSA Form is complete you must press the "SUBMIT" button to finalise your form.

- A locked code will appear in the bottom right hand corner.
- PLEASE NOTE: this button does not submit the form to our office; it changes your application from draft to final.

ii. Save the PDF generated to file.

- Please refer to Section 8 for further details on submitting the application.

4 Completing the LNRSSA Form

Helpful Hint:

The numbering below corresponds to the numbering in the LNRSSA Form itself.

Set up your investigators in the "contacts" field of the "online forms" website prior to completing the "investigator" field in the LNR and LNRSSA forms. This will enable you to click and drag into your LNR application and associated LNRSSA, rather than re-typing into each form. This will also be saved for the next time.

1. Project Title and Short Title will be auto-populated from your LNR

2.

i. Research Governance Officer Jurisdiction:

- Sydney Children's Hospitals Network (Randwick and Westmead)

ii. Name of the HREC reviewing the research project:

- E.g. if using the SCHN HREC, it is currently coded as:
  - EC00130 – The Sydney Children's Hospitals Network Human Research Ethics Committee
- If the study is only operating at sites within the Network HREC approval must be sought from an accredited paediatric HREC
- If the study will be conducted at multiple sites within NSW, HREC approval from another NSW accredited HREC may be accepted.
  - The National Mutual Acceptance (NMA) Scheme is currently NOT applicable for LNR applications.
  - If the study will be conducted at multiple Australian sites you may submit the application on a NEAF for NMA review.

3. The site name:

i. CHW

ii. SCH

iii. NETS

iv. PSN

v. Bear Cottage

vi. Children's Court Clinic

4. Project summary will be auto-populated from your LNR

5. Project Duration

i. Anticipated Start and Finish dates.

- Only enter the dates in relation to the SCHN Site

6. Research personnel at this site

i. List all the investigators/project personnel involved at the SCHN site and the contact person for the research project at this site

ii. Students who are involved on site or will have access to identified data **must** be listed.

iii. Supporting information required:

- Evidence of employment is reviewed by the Research Governance Office for insurance cover:
  - All SCHN staff are indemnified by the Treasury Managed Fund (TMF) for "approved" research activities upon receipt of SSA authorisation.
  - Honorary and Visiting Medical Officer's must have signed a TMF contract of coverage. An honorary position is only available to medical staff.
- All non-SCHN employees such as students who will be on site for the project, have participant contact or access to personal health records must provide evidence of insurance coverage from their employer/university. This can be attached to the SSA form upon submission to the Governance Inbox.
  - NB: USYD and UNSW - evidence of insurance has been provided by these Universities to the Research Governance Office, however evidence that the project forms part of the student's coursework must be provided.
  - This evidence may be in the form of the University supervisor sign off or University HREC approval if applicable.
- Access to site by non-SCHN employees
  - All non-SCHN personnel must also be screened by Staff Services to obtain approval for 'access to site'. An ID badge will be issued once all "contingent worker" screening requirements have been completed by Workforce

    (eg criminal record check, working with children check, vaccination details and ID).
  - Please contact Workforce Services on:

    SCHN-recruitment@health.nsw.gov.au, (02) 9845 2730 for further information regarding this process.
  - The Governance Office requires a photocopy of your SCHN ID badge or written confirmation (email) from Workforce that you have been screened. The researcher will not be able to commence the project on site until this is confirmed.
  - Authorisation may be delayed if Workforce clearance is not supplied.

7. Departments and services involved in the research project at this site.

i. List all departments to be involved in ANY aspect of the research project to ensure each department is aware and has the resources to support your research.

- Include name and position of staff member conducting the research and additional time spent / week

ii. Each investigator involved in the project must have their department listed here in the SSA; and they must have their Department Head sign Declaration B (refer to Section 7). If a Department Head is also an investigator, their superior (eg Clinical Program Director) must sign off on behalf of their department.

iii. Any other departments who are providing support for your research (e.g. pathology, radiology, pharmacy, data from departmental databases etc.) must also be listed on the SSA. The Department Head of each supporting department also must sign Declaration C (refer to Section 7).

iv. If you are accessing data for your project i.e. Medical Records/Powerchart, the Medical Records Manager also must sign Declaration D (refer to Section 7).

- If you have prior access to Powerchart you are still required to obtain approval from the medical records department to access PowerChart for your research project as the access is for non-clinical care purpose. Medical Records may require sighting the Ethics Approval Letter.

8. Research participants.

i. Enter expected number of participants to be recruited at the SCHN site

- Please contact the Research Governance Office if any participants will be over 16 years of age at any time throughout the study

9. Study Budget

i. Include estimated cost of research at the SCHN site.

ii. Include details regarding any funding received and who will fund tests, drugs, and other resources required for the project.

- Be clear if funding is sought and not yet received and provide detail how the project will proceed if funding applications are unsuccessful.

iii. Contracts / Securing Funding

- Include with your LNRSSA form any contracts or agreements associated with your project such as an agreement for payment of support or supply of research materials
    - The SCHN Chief Executive (CE) / Director of Research is the only delegate of SCHN able to execute fully an agreement on behalf of SCHN
    - The Research Governance Officer will review these documents and provide advice to the CE or delegate in relation to execution of these documents if required.

10. Declarations – refer to Section 7

11. Finalising the LNRSSA Form

- **i.** When your LNRSSA is complete you must press the "SUBMIT" button to finalise your form.
  - o A locked code will appear in the bottom right hand corner.
  - o PLEASE NOTE: this button does not submit the form to our office; it changes your application from draft to final.
- **ii.** You will need to save the PDF generated and submit to the Research Governance Office electronically via email.
  - o Please refer to Section 8 for further details on submitting the application.

5 Completing your Access Request Form

Helpful Hint:

The numbering below corresponds to the numbering in the Access Request Form itself.

Set up your investigators in the "contacts" field of the "ethics form" website prior to completing the "investigator" field in the Access Request form. This will enable you to click and drag into your application, rather than re-typing into the form. This will also be saved for the next time.

1. Project Title and Short Title

2. Name of the HREC reviewing the research project

- **i.** If using the SCHN HREC, it is currently coded as:
  - o EC00130 – The Sydney Children's Hospitals Network Human Research Ethics Committee
- **ii.** If the study is only operating at sites within the Network HREC approval must be sought from an accredited paediatric HREC
- **iii.** If the study will be conducted at multiple sites within NSW, HREC approval from another NSW accredited HREC may be accepted.
  - o If the study will be conducted at multiple Australian sites you may submit the application on a NEAF for NMA review.

3. Name of coordinating investigator

4. Facilities / Locations / Services included in this application:
   - **i.** CHW
   - **ii.** SCH
   - **iii.** NETS
   - **iv.** PSN
   - **v.** Bear Cottage
   - **vi.** Children's Court Clinic

5. Project summary
   - **i.** Please provide a brief description of the project and what you are asking of the SCHN site e.g. displaying posters, provide data/samples and the staff you would like to be involved doing this.
   - **ii.** If a non-SCHN employee is coming on site to display posters / receive data/samples screening by Workforce may be required.
     - Please contact the Research Governance Office prior to submission to discuss if this is applicable
   - **iii.** List all departments to be involved in this request.
     - Include confirmation emails from the Heads of Department that they are willing to support your access request. Email support is sufficient.
     - Include the Medical Records Manager if you are accessing data for your project i.e. Medical Records/PowerChart,
       - Medical Records may require sighting the Ethics Approval Letter.

6. Finalising the Access Request Form
   - **i.** When your Access Request is complete you must press the "SUBMIT" button to finalise your form.
     - A locked code will appear in the bottom right hand corner.
     - PLEASE NOTE: this button does not submit the form to our office; it changes your application from draft to final.
   - **ii.** You will need to save the PDF generated and submit to the Research Governance Office electronically via email.
     - Please refer to Section 8 for further details on submitting the application.

6 Clinical Trials – further information required

1. CHW drug trials are required to be reviewed by the CHW Drug Committee prior to the RGO making a recommendation about the trial. For further information please contact the Clinical Trials Pharmacist, Violet Ford – violet.ford@health.nsw.gov.au

2. Please indicate on the SSA Form if the CTN or CTX route is being used.
   i. Clinical Trial Notification (CTN)
      - For externally sponsored trials (commercial or collaborative group)
        - It is the Sponsor's responsibility to draft and submit the CTN upon receipt of all approvals. No signatures are required.
        - A factsheet, with SCHN HREC and site details, is available on the internet page to assist sponsors completing their CTN form.
        - A hard copy CTN is no longer required for these studies.
        - SCHN Governance does not require sighting of the CTN when SCHN is not the sponsor and will NOT acknowledge the CTN.
        - Upon receipt of SCHN site authorisation, the commercial (or collaborative group sponsor) will submit their CTN electronically to the TGA.
      - For internally sponsored trials (investigator initiated or collaborative group)
        - In the case where the SCHN is acting as sponsor please contact the Research Governance Office before submitting the SSA.
          - The electronic CTN must be drafted by the Principal Investigator / Study Coordinator prior to submitting the SSA.
        - Upon completion of a drafted electronic CTN and after site authorisation is granted, the research governance office will submit the CTN electronically to the TGA. Payment to the TGA will be required at the time of CTN submission ($335 per submission)

3. Indemnity and Clinical Trial Research Agreements
   i. Industry sponsored trials must include the Medicines Australia Standard Indemnity Form and Medicines Australia Standard CTRA with the SSA submission
      - For further information NSW Health Policy Directive: Clinical Trial Research Agreement for Public Health Organisations (refer to link in Section 9)

ii. If any supporting department (e.g. Pharmacy / Pathology) has its own detailed budget (more detailed than what is included in any contract / agreement) that has been acknowledged and agreed to please ensure it is also included with the submission. It can be attached with Declaration C (refer to Section 7).

iii. The legal name and ABN for use in Indemnity and Clinical Trial Agreements:

- For The Children's Hospital at Westmead (CHW)

  The Sydney Children's Hospitals Network (Randwick and Westmead) t/as The Children's Hospital at Westmead (CHW) Cnr Hawksbury Rd and Hainsworth St Westmead ABN 53 188 579 090

- For The Sydney Children's Hospital (SCH)

  The Sydney Children's Hospitals Network (Randwick and Westmead) t/as Sydney Children's Hospital (SCH) High street Randwick NSW, ABN 53 188 579 090

- For the Sydney Children's Hospitals Network (SCHN)

  The Sydney Children's Hospitals Network (Randwick and Westmead) (incorporating the Royal Alexandra Hospital for Children) ABN 53 188 579 090

iv. Signatory on behalf of the organisation: Prof Chris Cowell, Director, Research or the Chief Executive Officer in instances where the Director of Research is conflicted.

v. All contracts and indemnities must be signed by the sponsor prior to execution by the investigator and Chief Executive (or their delegate)

4. Certificate of Currency

i. This must be in Australian dollars at $20 million per occurrence.

ii. The excess must be equal to or less than $25 000 AUD.

iii. The clinical trial and Australian sponsor must be listed on the certificate and the certificate must be current.

7 Declarations

1. Declaration A – Principal and Associate Investigators

i. All investigators are required to sign this declaration as evidence of their adherence to conducting the study according to HREC Approval, The National Statement on Ethical Conduct of Research, the NHMRC Code for Responsible Conduct of Research and relevant legislation and regulations.

ii. If an Investigator is a student, the student's supervisor should sign Declaration A.

2. Declaration B – Head of Department (HOD)

i. The HOD of each of the Investigators is required to sign this declaration as evidence of their support of this research project being conducted in their department.

ii. Where an investigator is also HOD, certification must be sought from the person to whom the HOD is responsible i.e. Clinical Program Director (CPD).

iii. If the Director of Research is signing as CPD then the Chief Executive is required to sign final site authorisation.

Investigators must not approve their own research on behalf of their Department.

iv. Signing the Declaration:

- I certify that I have read the research project application named above.
- I certify that I have discussed this research project and the resource implications for this Department, with the Principal Investigator.
- I certify that all researchers/students from my Department involved in the research project have the skills, training and experience necessary to undertake their role.
- I certify that there are suitable and adequate facilities and resources for the research project to be conducted at this site.
- **My signature indicates that I support this research project being carried out using such resources.**

3. Declaration C – Head of Supporting Department

i. The HOD of ANY departments / services listed in section 7 of the LNRSSA and section 9 of the SSA (and does not have any member on the research team) is required to sign this declaration as evidence of being aware of this project and acknowledging they have the resources to be able to support its conduct.

ii. If any supporting department (e.g. Pharmacy / Pathology) has its own detailed budget (more detailed than what is included in any contract / agreement) that has been acknowledged and agreed to please ensure it is attached with Declaration C.

iii. Signing the Declaration:

- I have discussed this project with the Principal Investigator and have read the research project. I am (tick whichever applies):
  - Able to perform the investigations/services indicated, within the present resources of the Department

- Able to perform the investigations/services indicated, if the following financial assistance is provided: *(free text field to elaborate or attach the department budget / agreement)*
- Unable to undertake the investigations, services indicated, on the following grounds: (*free text field to elaborate*)

4. Declaration D – Authority for Data Provision

i. The HOD of Medical Records / Health Information Unit (HIU) (or the data custodian of an approved departmental database) is required to sign this declaration as evidence of support for access to medical records / data for research purposes.

- If the project involves accessing PowerChart, department databases, clinical notes or medical files for recruitment or lab results medical record sign-off is required.

ii. Signing the Declaration:

- I have considered this proposal and consulted the appropriate personnel and I confirm that I have seen all relevant documents that are required. The Department(s) is (tick whichever applies):
  - Able to confirm that the data services indicated will be provided, within the present resources
  - Able to confirm that the data services indicated will be provided, if the following financial assistance is provided: *(free text field to elaborate or attach department budget / agreement)*
  - Unable to provide data services indicated, on the following grounds: (*free text field to elaborate*)

5. Declarations E and F – Recommendation and Authorisation

i. These are completed following review by the SCHN Research Governance Office and Research Executive / CE

8 Submitting the Application

ALL SUBMISSIONS MUST BE ELECTRONICALLY RECEIVED VIA EMAIL TO SCHN-Governance@health.nsw.gov.au

1. To ensure you submit all supporting documents required for a complete review refer to the current Submission Checklist

   on the SCHN Research Governance Internet and Intranet. This must be submitted with your application as it will reduce any delay in authorisation of your project.

2. All types of SSAs may be submitted at any time THERE ARE NO CLOSING DATES.

   i. The email address of the person submitting the application must be a valid organisation email address i.e. **not** bigpond, gmail, optusnet, yahoo.

   - The Principal Investigator must be copied in on the submission email.
   - If your complete application exceeds 5MB, please send via multiple emails, each clearly titled in the Subject Line as "Email 1 of N", "Email 2 of N" etc.

   ii. You do not have to wait for ethics approval to submit your SSA for review.

   - Upon receipt of HREC approval, if you haven't already, refer to the submission checklist for any documents still to be submitted to the Governance inbox
   - THE HREC OFFICE WILL NOT PASS THIS INFORMATION ONTO GOVERNANCE. IT IS YOUR RESPONSIBILITY.

   iii. Electronic signatures are now acceptable for LNRSSA applications only. Please refer to Electronic Signing of Low & Negligible Risk Site Specific Applications in Research Governance policy on the Intranet.

   - Send application and attachments to Governance Inbox

   iv. Hard copies of documents required for SSAs (refer to Appendix 1) please send to:

   - Internal Mail:

     Attention: Research Governance Administrative Assistant, Research Office KRI, CHW

   - External Mail:

     Research Governance Administrative Assistant

     Kids Research Institute

     The Children's Hospital at Westmead Locked Bag 4001

Westmead NSW 2145

3. Participant information and consent forms
    - **i.** Please only provide the most recent versions that are approved by the HREC.
        - Each document must be saved according to the filename listed on the Ethics Approval Letter.
    - **ii.** If another HREC has approved the project the site version should also include the following statement at the end of the sheet:
        - This project has also been authorised to be conducted at [name of SCHN site]. If you have any concerns about the conduct of this study at this site, please do not hesitate to contact the Research Governance Officer on (02) 9845 3011.
    - **iii.** For multi-site projects, please provide:
        - The master versions approved by the HREC; and the versions (include tracked-change versions) you have adapted for the site with the appropriate site logo and investigator contact information.
        - If you wish to use the same information sheets across multi sites within the network you may use the SCHN network logo.

4. Your SSA application will be logged by the administration assistant and then reviewed in order of receipt by the RGOs. You will receive an acknowledgement of your SSA via email.
    - **i.** Timeframes for review:
        - 85% of SSAs are reviewed in accordance with state-wide Benchmarks and Standard Operating Procedures (as per AU RED clock stopping rules - 30 Calendar days).
        - 85% of LNR SSAs and access request applications are authorised within 21 calendar days (as per AU RED clock stopping rules).
    - **ii.** If you have not been contacted by a RGO within these time frames please contact the office **SCHN-Governance@health.nsw.gov.au**

5. Following initial review, if the RGO has any queries they will email the contact person on the application for further information. The RGO will follow up for a response. If no response is received and over 6 months has passed since last follow up correspondence (up to 4 follow up e-mails), the application will be withdrawn from the office one week after sending a final warning e-mail (copying PI and all investigators).
6. Authorisation Letters

i. Authorisation letters will be addressed to the local PI and sent via email to the contact person at the site. You may start your project at the site upon receipt of the email enclosing the electronically signed authorisation letter.

ii. For multi-site projects, site specific documents will be listed on the authorisation letter. All other documents will be as per the current HREC approval.

7. Fees

i. Governance review of any type of SSA may attract a fee. The invoice authorisation form (IAF) is mandatory for all applications and is available on the SCHN governance intranet site.

ii. For more information, please refer to the SCHN Fee Policy link in Section 9

9 Associated Links

- Research Governance in NSW Public Health Organisations
  http://www.health.nsw.gov.au/ethics/Documents/GL2011-001.pdf
- Fees For The Review of Ethics and Site Specific Assessment Applications
  http://chw.schn.health.nsw.gov.au/o/documents/policies/policies/2014-9044.pdf
- Delegations Manual- SCHN Policy - Section 14
  http://chw.schn.health.nsw.gov.au/o/documents/policies/policies/2013-9050.pdf
- Directorate of Clinical Operations and Department Heads
  http://intranet.schn.health.nsw.gov.au/files/attachments/311/initial-document-schn-directorate-clinical-operations_1.pdf
- Clinical Trials regulation in Australia
  http://www.tga.gov.au/clinical-trials
- Clinical Trial Research Agreements for Use in NSW Public Health Organisations
  http://www0.health.nsw.gov.au/policies/pd/2011/PD2011_028.html
- Clinical Trials - Insurance and Indemnity - NSW Health Policy Directive
  http://www0.health.nsw.gov.au/policies/pd/2011/PD2011_006.html
- Guidance to completing and using online CTN
  https://www.tga.gov.au/completing-online-ctn-form
  https://www.tga.gov.au/using-online-ctn-form