WSLHD RESEARCH GOVERNANCE GUIDE

FOR THE SUBMISSION OF

ACCESS REQUEST, SITE (STE) APPLICATIONS

&

ONGOING AUTHORISATION of STUDIES

TO THE WSLHD RESEARCH GOVERNANCE OFFICE

REVISION HISTORY

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<tr>
<th>Date</th>
<th>Rev No</th>
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<td>July 2018</td>
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<td>January 2019</td>
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<td>April 2019</td>
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<td>Removal of Online Forms submission guidance</td>
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<td>Addition of External Researcher Information</td>
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<td>Clarification of site for research involving WSLHD Mental Health Services, Integrated &amp; Community Health</td>
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<td>Updates to requirements for Principal Investigators to be employees of WSLHD</td>
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| October 2020 | 7 | Addition of New Department for Blacktown Mount Druitt (BMD – Chair of Research)  
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Purpose and Scope

Research governance can be defined as a framework for effective oversight of research, such that it meets appropriate standards of quality, safety, privacy, risk management, financial management and ethical acceptability in the Public Health Organisation. It provides a framework for the Local Health District, hospital/facilities, managers and researchers in a shared responsibility and accountability on the conduct of the research.

More information on the role of Research Governance can be found in NSW Health policy directive PD2010_056 Research - Authorisation to Commence Human Research in NSW Public Health Organisations.

The purpose of this guide is to outline the submission and authorisation procedure to the WSLHD Research Governance Office. It is designed to assist investigators with the completion of site specific (STE), access request and ongoing site authorisation applications.

The Western Sydney Local Health District (WSLHD) Research Governance office is responsible for the review of site applications (STEs) associated with a research project that may be conducted at any of the sites within the WSLHD.

- Westmead Hospital
- Blacktown Mount Druitt Hospitals
- Auburn Hospital
- Cumberland Hospital (WSLHD Mental Health Services) – An STE application should be completed for Cumberland Hospital (WSLHD Mental Health Services) when a research project involves patient or staff located at Cumberland Hospital or receiving services from WSLHD Community Mental Health Service.
- WSLHD – Integrated and Community Health
- WSLHD – Sexual Health Centre
- WSLHD – Drug Health

A separate Research Governance application (STE) should be completed for each site, however there may be circumstances where one STE will be accepted for multiple sites within WSLHD. Please contact the Research Governance Office for further details: WSLHD-ResearchOffice@health.nsw.gov.au or 02 8890 9007.

The following guide is developed to assist in preparing your STE application for review by WSLHD Research Governance. Advice and guidance on governance applications is available. To make an appointment please contact 02 8890 9007 or email WSLHD-ResearchOffice@health.nsw.gov.au.
Completing the STE Application

The Research Ethics and Governance Information System (REGIS) is the online portal used to help manage ethics and site governance approvals of human research Projects in NSW and ACT public health organisations (PHOs) and local health districts (LHDs.) The following information should be used in conjunction with the REGIS Quick Reference Guides (QRGs) for research applicants found on the REGIS website [https://regis.health.nsw.gov.au/how-to/](https://regis.health.nsw.gov.au/how-to/).

**Project Registration**

Complete a Project Registration following the [Completing Project Registration QRG](#). The Project Registration lists all sites where the research project will be conducted at and the STE is generated from this. *Note that HREA applications which have been completed in REGIS will already have their project registration completed.*

**SSA Form**

Use the following information provided to you in conjunction with the [Site Specific Application Part 1: Completing Application & Requesting Head of Department Support QRG](#) and [Site Specific Application Part 2: Submitting Site Application after Head of Department Declaration QRG](#) to complete your SSA form and submit for review to the WSLHD Research Governance Office. The following information is provided to guide you with the information required to complete the SSA form in REGIS. To complete the form you should work through the following tabs on the left hand side of the page.

<table>
<thead>
<tr>
<th>Part A: Project-Wide Information</th>
<th>The project wide information is auto-populated from the information provided during the project registration or ethics application created in REGIS. You should review this information to ensure it is correct.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part B: Site Team</td>
<td>List all investigators who will be working on the project at the site nominated in the STE application. <strong>DO NOT</strong> list investigators who will not be physically attending the site to perform research activity as this may delay the processing of your application. You should also nominate an administrative contact for the project in this section. The administrative contact will receive the same notifications and correspondence as the site Principal Investigator.</td>
</tr>
<tr>
<td><strong>Part C: Departments and Services</strong></td>
<td>In this section you will need to nominate the department where the research will be conducted in, and any departments which may be required to provide support to the project. Once the department is selected the individual nominated to provide their support will auto populate. These details cannot be changed. You will also be required to provide information regarding the resources (financial/non-financial) you request the department to provide.</td>
</tr>
<tr>
<td><strong>Part D: Recruitment, Records, Tissue and Data</strong></td>
<td>In this section you will be asked to provide information around the recruitment of participants, requirements for access to records and tissue samples for your project.</td>
</tr>
<tr>
<td><strong>Part E: Site Costing and Funding</strong></td>
<td>In this section you will be required to provide information regarding financial costs to the site associated with the project, non-financial costs associated with the project and any funding (commercial company, research grant, departmental) to be used to cover these costs.</td>
</tr>
<tr>
<td><strong>Part F: Attachments – Site Specific Documents</strong></td>
<td>In this section you are required to upload any documents which require consideration by the WSLHD Research Governance Office. Use the Submission Checklist included in this document to assist you. <strong>Note:</strong> for STE applications which have had their ethics application performed within REGIS all documents submitted as a part of this ethics application will be available to the RGO for review.</td>
</tr>
<tr>
<td><strong>Part G: Declaration</strong></td>
<td>The declaration is performed by the site principal investigator and indicates that the information provided in the SSA form is correct.</td>
</tr>
</tbody>
</table>

**Complete SSA**

Once all sections of the SSA form are complete you can complete the SSA within the Part G: Declaration tab. **Note:** Completing the SSA does not automatically submit your application to the WSLHD Research Governance Office. After complete SSA is selected the application will be sent to the nominated Head of Department of the departments listed in Part C of the application.
Submitting the STE Application to the WSLHD Research Governance Office (REGIS)

Once all Head of Department and/or Head of Supporting Department decisions have been made against your application a REGIS system notification email will be sent to the site Principal Investigator (and administrative contact if nominated in Part B.) These decisions are now ready for review by the Principal Investigator prior to submitting the application to the WSLHD Research Governance Office. For guidance on how to review head of department decisions and submit to the WSLHD Research Governance Office refer to the Site Specific Application Part 2: Submitting Site Application after Head of Department Declaration QRG.

Eligibility Review (REGIS)

Once your application has been submitted to the WSLHD Research Governance Office it will undergo an initial eligibility check against the following WSLHD Research Governance Minimum requirements;

- The Principal Investigator listed on the SSA must be an employee of WSLHD.
- All Declarations of Support have been made against your STE application in REGIS.
- HREC Approval listing WSLHD site(s) as approved study site must be provided as a supporting document with STE application (for studies with ethical approval outside of REGIS under NMA.)
- Evidence of SSA Payment Fee is included as an attached document (For Commercially Sponsored studies ONLY)

Once the initial eligibility check has been performed you will receive a system generated email advising you of the outcome of this eligibility review.

Eligible – Your application will proceed to review by the Research Governance Officer. You do not need to do anything further at this point.

Ineligible – If the application is marked as ineligible the reasons for this decision will be outlined within the email text. Use the Resubmitting an application after an ineligible notification QRG to make amendments to your application and resubmit to the WSLHD Research Governance Office.

Research Governance Review (REGIS)

Once your application is deemed eligible a review will be performed by the Research Governance Officer. The review may ask for clarification or request additional information be provided to support your application. Once the Research Governance Review has been performed the site Principal Investigator (and administrative contact if nominated in Part B) will receive a system
generated email requesting more information. The Research Governance Review document will be sent as an attachment to the system generated email from REGIS. Your responses to the Research Governance review will be through one of the two following pathways;

**Decision pending further information** – This decision is made when the RGO requires you to make changes to your application or documents. REGIS will automatically create a new version of the STE application for you to edit. You should make edits to the new version of your STE application and provide your responses to the Research Governance Review document as an attachment within your application.

**Recommendation (STE) pending further information** – This decision is made when the RGO requires more information but **NO** changes to the SSA form or documentation. You should prepare your responses to the Research Governance Review document and copy this text into the More Information form within REGIS.

Use this Research Governance Review document and the [Responding to a request for information QRG](#) for assistance on how to respond to requests for further information within REGIS. To assist in expediting your approval the reply to the Research Governance Review should be returned once it is complete, avoid incomplete responses when items are still pending.

**Research Governance Site Authorisation**

Once all items within the Research Governance Review form have been addressed your application will be referred to the CE or their delegate for consideration and approval. When approval has been granted a system generated email from REGIS will be sent to the site Principal Investigator (and administrative contact if nominated in Part B) notifying them of this approval.

*You may not commence a project at your site until you receive formal authorisation from the Research Governance Officer.*

Research Governance site authorisation of a project is ongoing provided a progress report that has been approved by the lead HREC is submitted to the Research Governance Office annually.

**Completing an Access Request Form (performed outside of REGIS)**

An Access Request Form should be submitted to the Research Governance Office when a project requires access to WSLHD participants, tissue or data but the study is not conducted at WSLHD site/s. Examples of an access request application include;

- Participant recruitment through posters, leaflets, handouts, and letter of invitation but not recruitment through direct contact with potential participants or enrolment;
- Distribution of surveys and questionnaires through staff of the Public Health Organisation but not collation and analysis of responses at that Public Health Organisation; and
- Access to data or tissue held at the Public Health Organisation but not processing or analysis at that Public Health Organisation.

The Access Request form (titled Alternative Access Request form) can be downloaded from


Follow the instructions on page 1 of the downloaded form to assist with completing the form. Note that these instructions also provide guidance on the supporting documentation which must be provided with your Access Request application.

If you are unsure whether your project meets the requirements of an access request application contact the Research Governance Office on 02 8890 9007 or email WSLHD-ResearchOffice@health.nsw.gov.au.

**Submitting your Application to the WSLHD Research Governance Office**

All types of Research Governance submissions may be submitted at any time, there are no closing dates or submission deadlines. All submissions must be electronically received through REGIS. Electronic signatures are accepted on all submission documentation (including research contracts) therefore there is no requirement to submit hard copies of documents. If you require wet ink signatures on research contracts you must provide the number of hard copies you require to the Research Office after you have been issued a 4 digit research office number.
Research Governance Ongoing Site Authorisation (performed outside of REGIS)

It is a requirement of Research Governance site authorisation that any amendments to a research project or reports on the conduct of a research project which may affect the ongoing site acceptability are submitted to the Research Governance Office. Any changes to study documentation to be used at WSLHD site/s must also be submitted to the Research Governance Office for authorisation.

These submissions are currently managed outside REGIS. All submissions for Research Governance Ongoing Site Authorisation should be emailed to the Research Office inbox WSLHD-ResearchOffice@health.nsw.gov.au for review and subsequent authorisation. All submissions for ongoing site authorisation must be accompanied by the WSLHD Research Governance Ongoing Site Authorisation Form. Your submission may be subject to the WSLHD Research Governance Ongoing Site Authorisation fee. Please refer to the WSLHD Research Office Fee Policy for more information.

WSLHD Research Governance Requirements

Research Personnel (REGIS STE Part B: Site Team)

Principal Investigator

The Principal Investigator nominated on the SSA application must be an employee of WSLHD. Principal Investigators at WSLHD site/s are required to oversee the conduct of the research at the site and take overall responsibility for the day-to-day conduct of research project at WSLHD site/s. More information on the responsibilities of the Principal Investigator can be found in the NSW Health Policy Directive GL2011_001 Research Governance in NSW Public Health Organisations. WSLHD staff should familiarise themselves with the responsibilities of being the Principal Investigator at WSLHD before agreeing to take on this responsibility.

In some circumstances it may be appropriate for a non-WSLHD employee to act as Principal Investigator for research being conducted within WSLHD. Before these applications are accepted they must be discussed with WSLHD Research Governance Office staff.
Associate Investigators

WSLHD (NSW Health) staff members are covered for civil liabilities that arise from their conduct in carrying out authorised research during the course of their employment or appointment and within their practice discipline. To ensure WSLHD staff members are covered by NSW Health insurance Research Governance ask that all WSLHD staff members working on a research project are listed on the SSA form. This includes staff specialists, registrars, JMO’s, Nursing and Allied Health staff and any ancillary staff who have a contract of employment within WSLHD. Alternatively a delegation log may be maintained for the study and this will be the responsibility of the Principal Investigator.

Student Researchers

Student Researchers are to be listed on the SSA form and appropriate supervisors (onsite at WSLHD) are to be nominated. If no supervisors are nominated the Principal Investigator is expected to assume this responsibility. Students who also perform clinical placements as a part of their coursework will be registered on ClinConnect (the NSW Health management program for clinical placements.) Students registered on ClinConnect are not required to be accredited to be onsite as an External Researcher. Students who do not perform clinical placements as a part of their coursework will be required to be accredited as an external researcher (see below.)

*Note that student researchers are not covered by NSW Health insurance for their research activity within WSLHD. Students are advised to consult with their university to confirm coverage for research they are working on within WSLHD. WSLHD Research Governance may request confirmation of this coverage if required.*

External Researchers

External researchers (research personnel who are not employed by WSLHD) who wish to conduct study activity at a site within WSLHD are to be accredited as an external researcher through the WSLHD Contingent Worker process. This process is managed by the WSLHD Research and Education Network (REN.) External Researchers who will be onsite at WSLHD are to be listed on the SSA form submitted to Research Governance. If you are an external researcher listed on a SSA application submitted to WSLHD you will be contacted by REN Human Resources to arrange contingent worker status within WSLHD. Any external researcher listed on a SSA application will be assumed to be coming onto site at WSLHD.

*Note that external researchers are not covered by NSW Health insurance for their research activity within WSLHD. External Researchers are advised to consult with their employer to confirm coverage for research they are working on within WSLHD. WSLHD Research Governance may request confirmation of this coverage if required.*
Honorary Research Appointments

Medical Staff (specialists, registrars, JMOs etc.) who are not employees of WSLHD who require onsite access to WSLHD site/s to perform research are required to apply for an honorary research appointment within WSLHD. For more information please contact the WSLHD Research Office directly.

STE Declarations of Support (REGIS STE Part C: Departments and Services)

Declaration by Head of department/ Divisional Director

All STE applications will require review and acknowledgement of support from the Head of Department or Divisional Director of the department the research will be conducted within. This is managed within the REGIS STE application. Once you select the department your research will be conducted in (in most cases this will be the department that the site Principal Investigator works within) the nominated individual for that department will automatically populate, this may be the Head of Department or Divisional Director depending on which department the study will be performed in. Please refer to the Site Specific Part 1: Completing Application & Requesting Head of Department Support for more information QRG. If you are unsure as to who is responsible for providing declaration of support for your department, please contact the WSLHD Research Office.

Declaration when Head of Department or Divisional Director is a member of the investigative team

In scenarios where the Head of Department or Divisional Director is a member of the investigative team the STE application will need to referred to the Chief Medical Advisor (Westmead Hospital STE) or General Manager (Blacktown Mount Druitt Hospital STE.) In these cases the following departments should be selected in Part C of your STE application;

WMD – Clinical Support Division (Westmead Hospital STE)

BMD – Chair of Research (Blacktown Mount Druitt Hospital STE)

Note the department that the Head of Department/Divisional Director has delegated authority over should not be selected in addition to the above departments. This will cause an error within REGIS and not allow the STE application to progress.

Declaration by Head of Supporting Department

You must obtain a declaration of support from any department you require support from to conduct your research – commonly referred to as a supporting department. If Research
Governance identifies a department that is supporting your research but is not listed within your STE application, this will be requested during the Research Governance review. It is important to correctly identify any supporting departments within your STE application and obtain the appropriate declarations of support to avoid delays in the authorisation of your project. Below is a summary of the departments which regularly support research within WSLHD. If your study requires support from any of the WSLHD departments below please follow the following instructions;

**Pharmacy** – All studies involving the use of a drug must be reviewed and a declaration of support provided by the hospital pharmacy at the site where the research will be conducted. In Part C of your STE application select Pharmacy as a department within the drop down menu and the nominated Head of Department will appear automatically.

**Radiology** - For any studies involving the Westmead Radiology Department Investigators are advised to contact Westmead Radiology to obtain a C-BIRD form to be completed and returned to Radiology, upload this CBIRD form as a supporting document within Part F of your STE application. Research Governance will then liaise with Radiology regarding the study and advise the investigators of any Radiology requirements (costings etc.) Please **DO NOT** select the Westmead Hospital Radiology department as a supporting department within Part C of your STE application.

For all other WSLHD sites (Blacktown Mount Druitt & Auburn) select Radiology as a department within the drop down menu and the nominated Head of Department will appear automatically.

**NSW Health Pathology** - For any studies that require support from NSW Health Pathology such as venepuncture, processing of samples, pathology testing or access to tissue held by anatomical pathology researchers are required to contact **NSWPATH-Westmead-PathologyResearchRequest@health.nsw.gov.au** to obtain a quote for services provided by NSW Health Pathology. This quote is required to be uploaded as a supporting document with your REGIS STE application and indicated NSW Health Pathology’s ability to support a research project. Please **DO NOT** select Pathology as a supporting department within Part C of your STE application.

**Nuclear Medicine** – All studies that require study participants to undergo PET scan or ultrasound must be reviewed and a declaration of support provided by Westmead Hospital Nuclear Medicine Department (for all WSLHD site/s). In Part C of your STE application select Nuclear Medicine as a department within the drop down menu and the nominated Head of Department will appear automatically.

If you are not sure who to contact in the supporting department for signing of the SSA form, please contact WSLHD research governance for assistance.
Site Specific Documentation (REGIS STE Part F: Attachments – Site Specific Documents)

When a project has been approved by the Lead HREC as a multi-centre project, study master documentation will be approved which will then need to be customised for each site. When customising site specific documentation for WSLHD ensure the following requirements are met:

- The WSLHD logo is to be included on the document.
- The site contact person must be one of the investigators listed on the SSA form.
- The document footer must make reference to the site version and date and the ethically approved master version and date. i.e. WSLHD Version X dated XX/XX/XXXX based on Master Version X dated XX/XX/XXXX.
- WSLHD Research Governance Office contact details are to be inserted;

<table>
<thead>
<tr>
<th>WSLHD Site</th>
<th>Site complaints contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Westmead &amp; Auburn</td>
<td>Westmead Hospital Patient Advice and Liaison Service Phone: 8890 7014 Email: <a href="mailto:wslhd-pals-mail@health.nsw.gov.au">wslhd-pals-mail@health.nsw.gov.au</a></td>
</tr>
<tr>
<td>Blacktown Mount Druitt</td>
<td>Office of the General Manager – Blacktown-Mt Druitt Hospitals PHONE: 9881 8000 Email: <a href="mailto:wslhd-bmdhexec@health.nsw.gov.au">wslhd-bmdhexec@health.nsw.gov.au</a></td>
</tr>
<tr>
<td>Mental Health Patients</td>
<td>Mental Health Patient Liaison Officer Phone: 9840 3000 Email: <a href="mailto:WSLHD-Cumberland-MHS-PatientLiaison@health.nsw.gov.au">WSLHD-Cumberland-MHS-PatientLiaison@health.nsw.gov.au</a></td>
</tr>
<tr>
<td>Studies involving the</td>
<td>WSLHD Research Governance Office Phone: 8890 9007 Email: <a href="mailto:WSLHD-ResearchOffice@health.nsw.gov.au">WSLHD-ResearchOffice@health.nsw.gov.au</a></td>
</tr>
<tr>
<td>recruitment of WSLHD Staff</td>
<td>Members</td>
</tr>
</tbody>
</table>

There is to be no changes made to the wording contained in the ethically approved master participant information sheet and consent form. The only changes should be the site specific requirements outlined above.
Radiation Safety

Any Research that involves exposure of humans to ionising radiation must follow the requirements of the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005) (ARPANSA Radiation Protection Series no.8), which has been adopted by the New South Wales Radiation Control Act.

Radiation used in research is assessed by the LEAD HREC. It is the responsibility of WSLHD Research Governance to monitor radiation use at WSLHD site/s in consultation with the WSLHD Radiation Safety Officer. If there is a Radiation Safety report provided by the Radiation Safety Officer for WSLHD then this must be provided to Research Governance with your STE submission. This report should be uploaded in REGIS Part F: Attachments – Site Specific Documents. WSLHD Research Governance may request to review any radiation safety report reviewed by the LEAD HREC for a study and may request site investigators contact the Radiation Safety Officer to obtain a Radiation Safety Report for WSLHD. Provide as much information as possible with your submission regarding the use of Radiation within your research project to enable Research Governance to perform a thorough review in accordance with the code.

Research Contracts

WSLHD Research Governance accept electronic signatures on all research contracts processed through our office. If you require wet ink signatures you will need to provide these copies to the Research Governance office once your SSA submission has been acknowledged and is issued with a 4 digit Research Office reference number.

When is a Clinical Trial Research Agreement required?

Clinical Trial Research Agreements are required by WSLHD Research Governance for all commercially sponsored clinical trials. Ensure that the CTRA is signed by the Principal Investigator and the Sponsor prior to submission to the Research Governance Office.

Standard clinical trial research agreements have been developed by the NSW, QLD, VIC and SA Health departments in conjunction with Medicines Australia for use in clinical trial research. Templates are available on the Medicines Australia website [https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/](https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/)

Standard clinical trial research agreements have also been developed by the Medical Technology Association of Australia for use in commercially sponsored studies of medical technology. Templates are available on the Medical Technology Association of Australia website [https://www.mtaa.org.au/clinical-investigations](https://www.mtaa.org.au/clinical-investigations)
WSLHD is unable to accept any changes to these standard contracts without evidence of approval from NSW Health. Information relating to the process for requesting changes to these standard agreements is also available on the Medicines Australia website.

When is a Material Transfer Agreement required?

WSLHD Research Governance require a Material Transfer Agreement (MTA) to be in place when WSLHD is providing human tissue to an external institute for research purposes (note an external institute does not include other NSW Public Health Organisations.) For guidance on the use of a MTA or to request a copy of the MTA template please contact the Research Governance Office.

When is a Collaborative Group Agreement required?

WSLHD Research Governance require an agreement be in place between collaborating institutions when funding will be shared with WSLHD to cover costs associated with performing research within WSLHD site/s. Funding arrangements are to be outlined within the agreement and signed by all parties. Research Governance prefer the use of the Medicines Australia Collaborative or Cooperative Research Group (CRG) Research Agreement however will review other institutions standard agreements if preferred.

Indemnity for Clinical Trials

Indemnity must be provided to WSLHD for all commercially sponsored clinical trials being performed within WSLHD.

The Standard Indemnity on Medicines Australia form template without alternations to the content will be accepted. Indemnity template and compensation guidelines can be found on the following website:


The Standard Indemnity on MTAA form template will be accepted without alteration to the content. Indemnity template and compensation guidelines can be found on the following website:

https://www.mtaa.org.au/clinical-investigations

Research Contracts and indemnities are legal documents and the parties outlined within these documents must be Australian entities (hold an ABN.) The following details are to be used on all Research contracts when WSLHD is a party to an agreement.

<table>
<thead>
<tr>
<th>Name:</th>
<th>Western Sydney Local Health District</th>
</tr>
</thead>
</table>

October 2020
L. Attwood
Note the Name on Research Contracts and indemnities cannot be Westmead Hospital, Blacktown Hospital etc. This is the site not the contractual party. You must always list the name as Western Sydney Local Health District.

Insurance

Clinical Trials Insurance

For commercially sponsored or collaborative/cooperative group clinical trials, a current insurance certificate in the name of the local sponsor providing the indemnity or listing the local sponsor as a named insured must be provided with your SSA submission. Please refer to NSW Health Policy Directive - Clinical Trials – Insurance and Indemnity PD 2011_006 for more detail. The insurance certificate must state the minimum amount of $AUD20million for one occurrence and in the annual aggregate. WSLHD cannot accept insurance certificates of a lesser amount for the conduct of clinical trials at WSLHD site/s.

Investigator Insurance

Treasury Managed Funds (TMF) covers WSLHD (NSW Health) staff conduct in carrying out an authorised research project at the public health organisation in good faith, in the course of their employment or appointment and within their practice discipline. Visiting Medical Officers who have a current, signed Services Contract and Contract of Liability Coverage are covered by TMF. Further information can be found in NSW Health Policy Directive **PD 2011_066 Clinical Trials: Insurance and Indemnity**.

Fees & Finance
Research Governance Submission Fee

There is a fee for the submission of SSA applications for commercially sponsored clinical trials of $3,740.00 (includes GST) for the SSA submission. This is in line with the NSW Health policy PD 2008_030 HREC and Research Governance Fee Policy for Review of Commercially Sponsored Research. You must provide evidence of this fee payment to WSLHD Research Governance with your STE submission. Uploaded in REGIS Part F: Attachments – Site Specific Documents. Commercially sponsored submissions will not be accepted without this fee being paid. **Note there is no fee charged for investigator initiated or collaborative group SSA submissions.**

Research Cost Code

A WSLHD research cost code is a designated general funds cost code set up to manage funding received for research studies. The research cost codes are managed by the Research and Education Network with the research funds rolled over every financial year. If you need to set up a cost code for your research project please contact Research and Education Network Finance.

Infrastructure Fee

All commercially sponsored clinical trial attract a 10% infrastructure fee to the study budget. This fee is used by the Research and Education Network to provide support services for research being performed within WSLHD.

Banking Details for Funds Transfer

The following banking details and instructions for payment must be included in your research agreement.

<table>
<thead>
<tr>
<th>Trading Name:</th>
<th>Western Sydney LHD (ABN 48 702 394 764)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bank Name:</td>
<td>Westpac Banking Corporation</td>
</tr>
<tr>
<td>BSB No.:</td>
<td>032 –099</td>
</tr>
<tr>
<td>Bank Account No.:</td>
<td>520829</td>
</tr>
<tr>
<td>Bank Address:</td>
<td>181 Miller Street North Sydney</td>
</tr>
<tr>
<td>Swift Code for Overseas Deposits:</td>
<td>WPACAU2S</td>
</tr>
</tbody>
</table>

**ON THE DAY OF DEPOSIT - FAX OR EMAIL DETAILS OF THE DEPOSIT YOU ARE MAKING**

<table>
<thead>
<tr>
<th>Send to:</th>
<th>AREA CASHIERS, ATTENTION: Mrs. Kim Dobson</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fax no.:</td>
<td>(02) 8890-9694</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:kim.dobson@health.nsw.gov.au">kim.dobson@health.nsw.gov.au</a></td>
</tr>
</tbody>
</table>

October 2020
L. Attwood
**Therapeutic Goods Administration**

**Clinical Trial Notification (CTN)**

The CTN scheme is a notification process where the clinical trial sponsor notifies the TGA of their intention to use an unapproved therapeutic good in a research project/clinical trial. Use of an unapproved therapeutic good includes:

- A product not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration; or
- Use of a registered or listed product outside the conditions of its marketing approval.

**Clinical Trial Exemption (CTX)**

The CTX scheme is an approval process where an application is made to the TGA for the review and approval from the TGA to supply an investigational product. The CTX scheme is currently under review by the TGA. Potential applicants are advised to contact the TGA for advice.

**Study Sponsor**

The CTN or CTX must be made by the study sponsor who may be:

- Commercial sponsor such as pharmaceutical or device company
- Collaborative/cooperative research group sponsor
- Local Health District if it is an investigator initiated trial.

**CTN Submission when external organisation is the sponsor**

A copy of the CTN submitted to the TGA must be provided as supporting documentation with the STE submission for review by the Research Governance Office. This can be provided in either draft or final format. This CTN should be uploaded in REGIS Part F: Attachments – Site Specific Documents. Investigational products cannot be supplied to WSLHD participants until the final CTN application has been received and acknowledged by WSLHD Research Governance.
CTN Submission when WSLHD is the sponsor

WSLHD investigators who require WSLHD to act as the sponsor for their CTN are advised to contact WSLHD Research Governance for advice and guidance in the early stages of planning their project. Once the SSA submission has been received by Research Governance an appointment will be scheduled between the Principal Investigator and the Research Governance Manager to complete and submit the CTN to the TGA. CTN’s on behalf of WSLHD can only be submitted by the organisation administrator for WSLHD, the Research Governance Manager. Note the CTN application attracts a fee of $360.00.

Notification of study completion at WSLHD

It is the Principal Investigator’s responsibility to ensure that the notification of the completion of a study at WSLHD is communicated to the WSLHD Research Governance Office. This notification can be made using the WSLHD Research Governance Ongoing Site Authorisation form emailed to WSLHD-ResearchOffice@health.nsw.gov.au. Note that once this notification has been received, site authorisation for the study will stop and it will be closed and archived from Research Governance records. No further correspondence regarding the study will be processed.
### Abbreviations and Definitions

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTN</td>
<td>Clinical Trial Notification</td>
</tr>
<tr>
<td>CTX</td>
<td>Clinical Trial Exemption</td>
</tr>
<tr>
<td>CTRA</td>
<td>Clinical Trial Research Agreements</td>
</tr>
<tr>
<td>HREC</td>
<td>Human Research Ethics Committee</td>
</tr>
<tr>
<td>HREA</td>
<td>Human Research Ethics Application</td>
</tr>
<tr>
<td>ICH-GCP</td>
<td>International Conference on Harmonisation – Good Clinical Practice</td>
</tr>
<tr>
<td>LNRSSA</td>
<td>Low and Negligible Risk Site Specific Application</td>
</tr>
<tr>
<td>MTA</td>
<td>Material Transfer Agreement</td>
</tr>
<tr>
<td>NMA</td>
<td>National Mutual Acceptance</td>
</tr>
<tr>
<td>NEAF</td>
<td>National Ethics Application Form</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>RGO</td>
<td>Research Governance Officer</td>
</tr>
<tr>
<td>REN</td>
<td>Research &amp; Education Network</td>
</tr>
<tr>
<td>STE</td>
<td>Site Specific Assessment</td>
</tr>
<tr>
<td>TGA</td>
<td>Therapeutic Goods Administration</td>
</tr>
<tr>
<td>WSLHD</td>
<td>Western Sydney Local Health District</td>
</tr>
</tbody>
</table>

**Access Request Review:** must be completed for research that requires support from a Public Health Organisation in the form of access to participants, tissue or data but does not involve the conduct of research at that Public Health Organisation.

**Clinical Trial:** Interventional research involving the trial of a new treatment, intervention or test as a means to prevent, detect, treat or manage carious diseases or medical conditions.

**Clinical Trial Notification (CTN) Scheme:** Trial Sponsor notifies the TGA of their intention to conduct a clinical trial using an unapproved therapeutic good or an approved therapeutic good outside of its approved indication.

**Clinical Trial Exemption (CTX) Scheme:** TGA reviews information about a therapeutic product and decides whether or not to approve the proposed usage guidelines of the product.

**Clinical Trial Research Agreement (CTRA):** Standard Research Agreements developed by Medicines Australia and the South Eastern Border States (SEBS) committee.

**External Researcher:** A member of the research team who is employed by an organisation external to WSLHD. External researchers who are required to attend WSLHD site/s to perform research activity will require authorisation by the WSLHD Research Governance Office.
**Lead HREC:** a 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.

**Multi-Centre research:** research that is conducted at more than one site within the NSW, Queensland, Victoria Western Australia or South Australian public health system.

**National Mutual Acceptance Scheme (NMA):** Australian state and territory Departments of Health have signed a Memorandum of Understanding for mutual acceptance of ethical and scientific review of multi-Centre human research projects undertaken in Public Health Organisations. Currently ACT, NSW, Queensland, Victoria, South Australia and Western Australia and participating in NMA.

**Principal Investigator:** the individual who takes responsibility 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 (RGO):** The individual appointed within the NSW Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of authorised research projects.

**Single Centre research:** Research that is conducted at one site only within the NSW public health system.

**Site:** a 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 Application (STE):** Application form used by Public Health Organisations to ensure that proposed research complies with local requirements, and to consider whether the research should be conducted and supported at the proposed site.

**Sponsor:** The company, institution or organisation that takes overall responsibility for the conduct of a clinical trial.

**Therapeutic Good:** 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 persona to a disease or ailment; influencing, controlling or preventing conception; testing for pregnancy; or replacement or modification of parts of the anatomy.
Associated Links

- NSW Health Office for Health and Medical Research

- Research Ethics and Governance Information System (REGIS)

- Australian Department of Health, Therapeutic Goods Administration, Clinical Trials

- Australian Government National Health and Medical Research Council

- Medicines Australia Clinical Trial Research Agreements

- Medical Technology Association of Australia Clinical Trial Research Agreements

- Western Sydney Local Health District Research Office Website
Submission Checklist

After reading through this document researchers are encouraged to use the below checklist to ensure they have provided all supporting documentation and completed all minimum requirements prior to STE submission to the WSLHD Research Governance Office through REGIS.

<table>
<thead>
<tr>
<th>Checklist Item</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have approval letters from the LEAD HREC for this study which cover the</td>
<td>approval of the WSLHD site listed within my STE application, and the approval of all study</td>
</tr>
<tr>
<td>approval of all study documentation to be used during the conduct of this</td>
<td>study at the site.</td>
</tr>
<tr>
<td>study at the site.</td>
<td></td>
</tr>
<tr>
<td>I have a copy of the HREA or NEAF/LNRNEAF reviewed by the LEAD HREC for my</td>
<td>study.</td>
</tr>
<tr>
<td>study.</td>
<td></td>
</tr>
<tr>
<td>I have a copy of all ethically approved documents to be used at WSLHD site/s</td>
<td>during the conduct of this study.</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>I have created <a href="#">site specific versions</a> of these ethically approved</td>
<td>documents when required meeting the WSLHD Research Governance requirements outlined in this</td>
</tr>
<tr>
<td>documents when required meeting the WSLHD Research Governance requirements</td>
<td>document.</td>
</tr>
<tr>
<td>outlines in this document.</td>
<td></td>
</tr>
<tr>
<td>I have a copy of the WSLHD <a href="#">Radiation Safety report</a> for this study</td>
<td>(if applicable.)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>I have a copy of the <a href="#">Research contracts and indemnities</a> for this study</td>
<td>(if applicable.)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>I have a copy of the <a href="#">insurance certificate</a> for this study, the insurance</td>
<td>certificate is current and provides clinical trial coverage of $20 million (if applicable.)</td>
</tr>
<tr>
<td>certificate is current and provides clinical trial coverage of $20 million</td>
<td>(if applicable.)</td>
</tr>
<tr>
<td>(if applicable.)</td>
<td></td>
</tr>
<tr>
<td>I have a copy of the <a href="#">Clinical Trial Notification</a> (draft or final)</td>
<td>submitted to the TGA for this study (if applicable.)</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>My SSA submission meets the <a href="#">WSLHD Research Governance minimum Requirements</a> outlined in this document.</td>
<td></td>
</tr>
</tbody>
</table>