Procedure

Research Governance: Site Specific Application

NSWHP_PR_049

1. Purpose

This Procedure is to assist NSW Health Pathology (NSWHP) researchers with preparing a research governance site specific application.

2. Scope

This Procedure applies to all Staff involved in the conduct of research in NSWHP. This includes NSWHP employees, contingent workers, students and trainees.

3. Definitions

Case Report Form (CRF): a paper or electronic document designed to record all the protocol-required information to be recorded on each participant as part of a medical study.

Chief Medical Information Officer (CMIO): a member of NSWHP's Strategic Leadership Team responsible for health informatics platform(s) required to work with clinical IT staff to support the efficient design, implementation, and use of health technology within a healthcare organisation.

Clinical Trial Agreement (CTRA): one of several key documents that govern the conduct of clinical trials. They serve as a legally binding contract between a sponsor, site, and researcher, and outline each party's responsibilities and obligations for the clinical trial (Clinical Trial Agreements).

Clinical Trial: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Clinical Trial Approval (CTA) (previously CTX): TGA's clinical trials approval (tga.gov.au/clinical-trials) to supply unapproved therapeutic goods in Australia via a clinical trial despite the therapeutic goods not being entered in the Australian Register of Therapeutic Goods (ARTG).

Clinical Trials Notification (CTN) Form: TGA's notification process when importing into and/or supply in Australia of an "unapproved" therapeutic good/s for use in a clinical trial.

Confidentiality (non-disclosure) Agreement (CDA/NDA): Is a legal contract, which should be used when sensitive information needs to be shared between two parties. It ensures that the person or organisation who gains access to sensitive information doesn't disclose it to a third party (IP Australia).

Consent Form: the document on which participants give their written consent to take part in the research.

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected (ICH Guideline Good Clinical Practice).

Human Research Ethics Application (HREA): A concise application to facilitate timely and efficient ethics review for research involving humans. The HREA assists researchers to consider the ethical principles of the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) in relation to their research.

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Human Research Ethics Committee (HREC): A committee constituted in accordance with the National Statement on Ethical Conduct in Human Research 2007 (updated 2018) to review and where appropriate approve and monitor the ethical and scientific aspects of human research.

Indemnity Agreement (IA): A written agreement that is a promise by one party to another that it will cover a loss arising from an event that happens to the other party (Australian Clinical Trials).

Institutional Biosafety Committee (IBC): An administrative and consultative body that reviews research involving hazardous biological agents, ensuring they meet safety, ethics and professional standards as well as compliance with legislation such as the Gene Technology Act (2000) and Biosecurity Act (2016) and associated regulations.

Participant Information Sheet (PIS): The participant information sheet is the document that explains the research project to potential participants and invites their participation. It is a key mechanism for ensuring that consent is active, informed and voluntary.

Principal Investigator (PI): A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team (Guideline for Good Clinical Practice).

Project Centre: is a Local Health District (LHD), a Specialty Health Network, a pillar organisation, an affiliated health organisation or other health organisation operated by NSW Health**.**

Project Registration: the first step in initiating your research project in REGIS.

Project Site: is a facility, location or service where the research is being conducted within the Project Centre's jurisdiction.

Radiation Safety Committee: An administrative and consultative body that reviews the radiation safety of all uses of ionising radiation substances.

Research: Activities that includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.

Research Agreement: The written agreement between organisations involved in a research project on the management of the research. Examples: Medicines Australia Clinical Trial Research Agreement (CRTA), NSWHP Research Collaboration Agreement, NSWHP Material Transfer Agreement (MTA).

Researcher means a person who conducts, or assists with the conduct of, research.

Research Ethics Governance Information System (REGIS): The NSW Health system to manage the ethics and governance process for human research projects conducted across NSW Health and ACT Health.

Research Governance Office (RGO): The NSWHP unit responsible for the management of applications for site authorisation and oversight of authorised research projects.

Site-Specific Application (SSA) Form (otherwise known as STE): A process used by organisations in the NSW Public Health System 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. The application helps each site assess and decide if there are resources available to effectively conduct a research project at a nominated site. It considers risks, impacts and practices at each research location. It is also referred to as a site approval (STE) in the REGIS system.

Staff means all persons who are employees of NSWHP, including full time, part time, fixed term, contingent workers and casuals who are engaged in supervisory and other research roles on behalf of NSWHP.

TGA means the Australian Therapeutic Goods Administration.

4. Procedure

Depending on the type of research activity there are two research governance application pathways, these being:

1. **Site specific application (SSA)** (Section 4.1) (via NSW Health's REGIS)

2. **Access request application** (Section 4.3) (via Access Request Form NSWHP_SD_048)

4.1. SSA overview

The SSA is a site governance process (separate to ethical review) completed at any time after the ethics application has been submitted in REGIS. It helps each site decide if there are resources available to effectively conduct a research project at a nominated site.

a) At Project Registration in REGIS 'NSW Health Pathology' must be listed as the Project Centre where a NSWHP staff member is a listed investigator.

b) The Project Site will either be:

- NSW Health Pathology – site (Clinical Laboratory Services or Forensic and Analytical Science Service), or
- NSW Health Statewide Biobank (Biobank only)

c) If you are unsure of the names of the Centre or Site/s your project will be conducted at, please discuss with the NSWHP RGO (NSWPath-RGO@health.nsw.gov.au). Please note: an incorrect selection can delay your application process.

d) There are no submission deadlines for NSWHP SSA review. Submissions are reviewed on a rolling basis in order of submission via NSW Health's Research and Ethics Governance Information System (REGIS).

e) All applications must be submitted via REGIS at https://regis.health.nsw.gov.au/. Please refer to the relevant Quick Reference Guides for Research Applicants on the website for information about making a submission via REGIS.

f) Ineligible applications may be returned, and an automatic email reply will be sent out to the PI.

g) To assist the Department Head (in REGIS) to support your application you MUST consult with and obtain written approval (via email) from the relevant line manager (i.e. Clinical Director, Local Pathology Director, Branch Director etc) PRIOR to submitting your site-specific application (SSA) via REGIS. The Department Head will consult with the relevant line manager to satisfy the scientific value of the project and stated impact on the department.

h) At Part C Departments and Services the relevant Department Head must be listed on the REGIS SSA application under 'Department'.

i) If NSWHP data is being accessed or used, the NSWHP Authority for Data Provision must be added as:

- 'NSWHP – Clinical Services – Data' (Chief Medical Information Officer); or
- 'NSWHP – Forensic and Analytical Science Service – Data (Director, Forensic and Analytical Science Service) or
- 'Biobank – Data (Director of Biobanking)

j) If the data requested is to be disclosed outside of NSWHP a Disclosure of Information (DOI) and Confidential Undertakings agreement will be required, signed by the:

- CMIO for de-identifiable data
- Chief Executive (CE) for identifiable data.

k) Currently NSWHP's RGO is only able to review SSA submissions under the REGIS scheme listing 'NSW Health Pathology' as the Project Centre.

4.2. Application and Documentation

Please refer to SSA Checklist (NSWHP_SD_049) for an overview of the documentation required for submission.

4.2.1. SSA Form

a) The following sections of the SSA Form must be completed in REGIS:
   - Part A: Project-Wide Information
   - Part B: Site Team
   - Part C: Departments and Services
   - Part D: Recruitment, Records, Tissue and Data
   - Part E: Site Costing and Funding
   - Part F: Attachments – Site Specific Documents
   - Part G: Declaration

   Note some of elements of the form will automatically be populated from information entered at Project Registration or in relation to the ethics application.

b) The PI in the SSA Form must be a NSWHP staff member.

c) At Part B 'Site Team' include in your submission investigators who;
   - will require access to the site for any research related purpose specific to the project AND/OR
   - will require access to confidential site information or data.

d) The PI MUST seek approval in writing (via email) from the relevant line manager (i.e. Clinical Director, Local Pathology Director, Branch Director etc.) PRIOR to completing the REGIS application.

e) The line manager approval should be uploaded into REGIS at Part F Attachments as part of the submission.

f) At Part C 'Departments and Services' the PI must add their own Department Head and any other Department Head that the research may impact.

   Department Heads include:
   - Director of Operation/s,
   - Director Forensic and Analytical Science Service,
   - Director of Biobanking

g) If access to medical records is required, the Authority for Data Provision must also be added as a Department Head.

   Authority for Data Provision - Department Heads include:
   - NSWHP Chief Medical Information Officer (CMIO),
   - Director Forensic and Analytical Science Service,
   - Director of Biobanking

   Note: Department Heads should be approached to secure study support well in advance of their decision being requested in REGIS (at Part C). The Department Heads should consult with appropriate Clinical Directors to satisfy themselves of the scientific value of the research and veracity of the stated impact on their department.

h) If the data requested is to be disclosed outside of NSWHP a Disclosure of Information (DOI) and Confidential Undertakings agreement will be required, signed by the:
   - CMIO for de-identifiable data
   - Chief Executive (CE) for identifiable data.

i) The SSA is only submitted to the NSWHP RGO once all Department Heads (and the Authority for Data Provision if applicable) have processed their decisions for the application in REGIS.

Note: If the Department Head is an investigator, the application should be discussed with the NSWHP RGO so the decision can be escalated to their line manager.

4.2.2. Ethics approval letter from Lead HREC

a) All HREC approval letters, including any subsequent approved amendments, are required to be submitted with the SSA. The letter(s) must list all documents to be used on-site.

b) 'NSW Health Pathology' must be listed as a site on the HREC approval letter as a participant site, including the name of the Principal Investigator for the site.

4.2.3. Site Specific Participant Information Sheet and Consent Form(s) (PICF)

a) Master PICF (final clean version) and site-specific PICFs (tracked and clean) must be submitted.

b) PICFs must comply with the following requirements:

i. Ensure the correct site-specific logo is included in the PICF (e.g. page 1 & consent/withdrawal sheets).

ii. Check with approving HREC and include mandatory ethics statement.

This research has been approved by the XYZ Human Research Ethics Committee of XYZ Local Health District, Reference [insert REGIS ETH reference].

iii. Include mandatory NSWHP governance authorisation text, as per below:

The conduct of this research has been **authorised** by NSW Health Pathology to be conducted at [Name of site/location] site.

iv. For multicentre studies, the footer must have the HREC approved Master version AND the Site-specific version.

v. If applicable, the radiation statement needs to be the exact wording as per approved SVH radiation safety letter.

vi. Include NSWHP complaints section as per following:

Complaints about conduct of this research within NSW Health Pathology:
Should you have concerns about your rights as a participant in this research or a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact the NSW Health Pathology's Research Governance Office, telephone: 02 9464 4766. Email: NSWHP-RGO@health.nsw.gov.au and quote the reference number [insert STE reference number].

4.2.4. Include copies of ALL documents

a) ALL documents approved by the Lead HREC must be submitted (at Part F Attachments). As NSWHP has no ethics committee, or when ethics approval exists outside of REGIS (i.e. HREC approval outside of NSW or ACT) then ALL ethics approved documents are not automatically shared with the NSWHP RGO and therefore are best uploaded into the SSA (at Part F Attachments).

b) Both Master and site-specific versions are required of any additional documents (e.g. posters, pamphlets, data collection forms etc).

c) If applicable, a Radiation Safety Letter should be included.

Note: The site-specific logo needs to be inserted on ALL site-specific documentation. Also, if any study documents are missing in the application then the NSWHP RGO will request these be added to the application, which can delay your application process.

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4.2.5. Itemised Study Budget

a) In order to ensure that the costs of carrying out research are fully covered, and/or that the costs are transparent so that the financial implications can be appropriately assessed all research projects must outline costs and identify funding sources in the SSA under section “Site Costing and Funding”.

b) For complex projects such as Clinical Trials, a detailed project costing is required for sign-off by an appropriate finance authority (such as NSWHP’s Director of Operations as Head of Department).

c) The budget should be calculated using NSWHP Statewide Pricing Model and should clearly outline expected financial (cash) and non-financial (in-kind) contributions

d) Minimum requirements to be included in the study budget estimate are:

- **Participant-associated costs** such as pathology collection and testing fees, investigator consultation, Adverse Event (AE) reporting, drug dispensing, participant reimbursement e.g. parking, CRF data completion (Incl. query resolution)
- **Study-related costs** such as study establishment fees, attendance at research meetings, shipping/equipment, ethics or governance submission fees, pharmacy fees and research coordinator time.
- **In-kind support** such as the NSWHP employment time required to undertake activities for the project; utilisation of NSWHP equipment/facilities that do not have a direct charge involved

e) If there are any quotes or associated service agreements these should be uploaded as part of the site-specific documentation.

Note: It is the responsibility of the Site PI to ensure that sufficient resources (e.g. financial support) are in place to conduct the research.

4.2.6. Research Agreements

a) Any research-related agreement must be reviewed by the Research Directorate (NSWPath-Research@health.nsw.gov.au) in consultation with Legal, and be approved by the relevant NSWHP Delegate before project commencement.

b) A NSWHP Research Collaboration Agreement (or similar) should be used when NSWHP is collaborating on a research project and is providing in-kind and/or financial contributions which may include the provision of services or transfer of tangible materials under NSWHP’s custodianship/ ownership to a recipient outside NSWHP for a permitted use. It defines the terms and conditions for NSWHP’s participating in the project.

c) A NSWHP Material Transfer Agreement (MTA) MUST be used when NSWHP is transferring tangible materials under NSWHP’s custodianship/ownership to a recipient outside of NSWHP for a permitted use, but where NSWHP is not providing any other in-kind or financial contributions to the project. It defines the terms and conditions governing the transfer of material from NSWHP to the recipient and includes obligations around on-supply (third party transfers).

d) A NSWHP Confidentiality (Non-Disclosure) Agreement (CDA/NDA) should be used when engaging with external research personnel that may be accessing confidential information.

e) A NSW Health Disclosure of Information and Confidential Undertakings (PD2018_001) may be required in cases where NSWHP has been contacted by a non-NSWHP entity to provide aggregate data from any of NSWHP’s Data Assets, unless the request is covered under the ‘Back to Notifier’ basis. NSWHP, as the data custodian, is required to put in place a Disclosure of Information and Confidentiality Undertaking signed by both entities.

f) Please consult NSWHP's Research Office (NSWPath-Research@health.nsw.gov.au) prior to submission for advice or a copy of an appropriate agreement template.

g) Please ensure that the correct organisation, ABN and address is stated.

4.2.7. Fee Payment Confirmation (if applicable)

Note: NSWHP currently does not charge any fees for research governance applications.

4.2.8. Contingent Worker Appointments or Consultancy Arrangements

a) This is required for any external researchers who may be coming on site and who may have contact with patients, access identifiable data, or using NSWHP resources/facilities.

b) Contingent worker appointments must be established for external investigators & all internal and external students who are entering a NSWHP facility or have access to NSWHP specimens or data.

c) Contingent worker appointments are managed through NSWHP's HR processes. Documents required include:

- NPC ID Checklist (Please include 4 forms of ID as outlined on the checklist)
- NPC Consent form
- Privacy Undertaking form
- Code of conduct signed
- Pre-Employment Health Assessment
- Model Health Declaration
- Evidence of Liability Insurance
- Confirmation of the position number or a MOC form to create a new contingent worker position number.
- Occupational Vaccination and Screening Forms 6 & 7 (*required for Category A positions only*)
- Overseas Statutory Declaration (*if applicable*)

d) Please consult with NSWHP Research Office (NSWPath-Research@health.nsw.gov.au) for further information**.**

ADDITIONAL REQUIREMENTS FOR CLINICAL TRIALS

4.2.9. Curriculum Vitae

a) A short Curriculum Vitae (CV) outlining experience related to their role must be included in the SSA for ALL site investigators.

b) It is mandatory for the Investigators and study coordinators to have completed Good Clinical Practice (GCP) training. A certificate of completion should be submitted at the end of the research project/study; this must be completed within the last 3 years.

4.2.10. Form of Indemnity

a) Medicines Australia Standard Indemnity: https://medicinesaustralia.com.au/policy/clinical-trials/indemity-and-compensation-guidelines/

b) Medical Technology of Australia Standard Indemnity: https://www.mtaa.org.au/clinical-investigations-research-agreements

c) For all indemnities given by Sponsors to NSWHP, please complete the "To" or ("the Indemnified Party") section on page one as follows:

Name: NSW Health Pathology
ABN: 49 382 586 535
Address: Level 5, 45 Watt Street, Newcastle NSW 2300

4.2.11. Clinical Trial Notification (eCTN)

a) Submit a draft eCTN in LANDSCAPE print preview for noting by NSWHPs RGO.

b) Following NSWHP's research governance authorisation, the study Sponsor must lodge the eCTN form directly to the TGA.

Note: the eCTN application I.D. will be outlined in the RGO authorisation letter.

c) Once the TGA has acknowledged the eCTN, both the TGA acknowledgement and a PDF

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copy of the lodged CTN must be re-forwarded to the RGO for acknowledgement.

d) For non-NSWHP Sponsored clinical trials, it is the external Sponsor's responsibility to lodge the eCTN directly with the TGA. The NSWHP PI should forward the TGA confirmation the PDF copy of the lodged eCTN to NSWHP's RGO as soon as possible.

4.2.12. Certificate of Insurance

a) For commercially sponsored clinical trials, a copy (evidence) of the Sponsor's certificate of insurance must be submitted as part of the SSA. The insurance must:
   - include on the certificate of currency the full, legal name of the Australian entity acting as a Sponsor, as a named insured.
   - include a minimum insurance amount of $20 million AUD per any one occurrence (project) and in the annual aggregate (per year).
   - be current and detail the period of insurance.
   - detail the type of insurance; 'professional indemnity', 'product liability' (or equivalent) and include clinical trials cover.

*Note: A copy of the NSWHP insurance certificate is **not required** for investigator-initiated single NSWHP site projects.*

4.3. Access Request

a) Access request review is used when the project involves one or more of the following:
   - participant recruitment through posters, leaflets, handouts, and letter of invitation but not recruitment through direct contact with potential participants or enrolment (both of which require a SSA); or
   - distribution of surveys and questionnaires through staff of the Public Health Organisation but not collation and analysis of responses at that Public Health Organisation (which requires a SSA).

b) The Research Governance Officer has the discretion to request that the application is submitted for site specific assessment if they consider that the project involves the conduct of research at a site.

c) The Coordinating PI must complete and submit to the RGO the following documentation:
   i. The Institution's Access Request Form (e.g. NSWHP's Access Request Form NSWHP_SD_048)
   ii. a copy of the HREC letter of approval;
   iii. a copy of the HREA Form;
   iv. a copy of all documents to be distributed through the facilities, locations or services within the PHO;
   v. written confirmation of support from relevant heads of the facilities, locations and services that will provide the access such as; staff members who agreed to put up posters, hand out leaflets and letter of invitations to potential participants of your research project and heads of department/managers who agreed to distribute questionnaires or surveys to staff by e-mail.

d) For access to Local Health District (LHD) data or tissue, applications can be made via an Access Request. Please check with the local LHD RGO to confirm application form/process.

e) For non-NSWHP applications to access NSWHP data, a data application can be made to NSWHP's RGO using Data Request Form (NSWHP_F_055)

f) For non-NSWHP applications to access NSWHP tissue, please contact the local NSWHP research service coordinators or NSWHP Research Office (NSWPath-Research@health.nsw.gov.au).

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5. Roles and Responsibilities

The summary of the roles and responsibility of NSWHP, Site/Department Head (managers) and researchers in relation to effective research governance is found in the Research Governance Framework (NSWHP_CG_013).

While there are separate roles and responsibility assigned to NSWHP, managers and researchers it is acknowledged that research is enhanced through a partnership approach among all those interested in, or undertaking, research within NSWHP

6. Legal and Procedure Framework

For a detailed overview and the links to all policies, procedures, guidelines and supporting documents governing research in NSWHP, please go to:

- NSWHP Delegations Manual (NSWHP_CG_001)
- Research Governance Framework (NSWHP_CG_013)
- Research Publication Authorship, Affiliation and Acknowledgements (NSWHP_PD_026)
- Research Code of Conduct (NSWHP_PD_032)

7. Review

This policy will be reviewed by 1/07/2023.

8. Risk

Risk Statement	This SSA guideline will improve NSWHP's governance over research and **set standards to improve research quality and safeguard the public**. It will enhance ethical and scientific quality, promote good practice, reduce adverse incidents, prevent poor performance and misconduct.
Risk Category	Community Expectations

9. Further Information

For further information, please contact:

Guideline Contact Officer	Position: Research Governance Officer
	Name: Andrew Harre
	Telephone: 02 9464 4766
	Email: NSWPath-RGO@health.nsw.gov.au

10. Version History

The approval and amendment history for this document must be listed in the following table.

Version No	Effective Date	Approved By	Approval Date	Procedure Author	Risk Rating	Sections Modified
1.0	07/10/2021	Chief Executive	22/09/2021	Amanda Koegelenberg	Minimal	New Procedure