

Guidance Document:

Research Agreements

SWD26/64741

Research Ethics, Governance and Integrity Unit (REGIU)

Version 1.1, 19 September 2026

To be used in conjunction with SWSLHD Research Agreement Checklist, version 1.0, 19 June 2026

Purpose:

This document provides guidance to researchers and study teams for the preparation and submission of **Research Agreements**. It intends to support complete, accurate and consistent submission to enable efficient and streamlined review by the SWSLHD Research Ethics, Governance, and Integrity Unit (REGIU). This guidance should be read in conjunction with relevant ethics and governance policies and requirements.

This guidance document is subject to periodic review and may be updated as institutional or regulatory requirements change. Researchers are encouraged to access the latest version available from the [Research and Partnerships](#) website.

If you have any feedback relating to this process, please complete this [feedback form](#) during the trial period (1 July 2026 – 1 October 2026).

Why is a research agreement required?

A research agreement is required when two parties enter into an agreement to conduct research.

An agreement aims to:

- Clarify roles, responsibilities, expectations and agreed deadlines for delivery of work.
- Protect for Intellectual Property (IP), including licensing rights, ownership and rules for sharing and publishing findings.
- Ensure compliance with ethical standard and regulations.
- Address privacy, confidentiality and data protection.
- Manage financial arrangements, including funding amounts, payment schedules, purpose and rules for auditing and reporting.
- Address risk and liability, including indemnity and insurance arrangements.
- Satisfy grant requirements.

Pre-submission Requirements:

Before submitting a research agreement, researchers must ensure that all applicable approvals are in place or have been submitted concurrently, including amendments to both the Human Research Ethics Committee (HREC) and, where applicable, the SWSLHD Research Governance Officer (RGO) for authorisation.

Submissions relating to ethics and governance submissions must be made via the Research Ethics and Governance Information System (REGIS) platform, available via:

<https://regis.health.nsw.gov.au/>. Submissions received via email will only be accepted where the agreement relates to a program of work or grant submission that does not directly relate to a project registered in REGIS. A copy of the **Researcher Checklist for Research Agreements** must be submitted with the draft contract.

A checklist is not required for standard Clinical Trial Research Agreements available from <https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/>, unless extensive modifications are proposed.

Completion of the Researcher Checklist:

Section 1: Project details

- Ensure that the study title matches the approved title exactly as recorded in REGIS, if appropriate.
- Ensure that HREC/SSA references and details are included on the checklist and that these details match the draft Research Agreement.

Section 2: SWSLHD involvement

- Include the clinical and/or service departments that will be involved in the project.
- Ensure that relevant clinical/service departments and Heads of Departments have been appropriately consulted. Please indicate who has provided support in the checklist. Please note, completion of this checklist constitutes agreement that they have been appropriately consulted.

Section 3: Agreement details

- Indicate in this section the type of agreement and whether this is a standard agreement, or whether there have been modifications. If a standard template is available and is not being used, justification is required to support the request. For a list of approved templates, please see Appendix A.

Section 4: Budget considerations

- Indicate whether the project will receive external funding (4.1).
 - **No funding to SWSLHD:**
 - Provide details on how the project will be conducted with no funding (section 4.5).
 - **Funding to SWSLHD:**
 - Ensure that the amount and source is detailed both in the draft agreement and in the checklist (4.2).
 - Indicate in the checklist what the funds will be used for (e.g. staff time, infrastructure, access etc) (4.4).
- If there is an overarching funding agreement in place, provide a copy of this agreement (4.3).
- Include details on what SWSLHD will be contributing, including cash, resources and/or in-kind contributions (4.6).
- Ensure that Head of Department/General Manager support is sought for any cash, resources and/or in-kind contributions (4.6).
- Provide a copy of any Letter/s of Support from SWSLHD (if grant funded) or a justification of why SWSLHD support was not sought at the time of grant submission.

Investigator declaration:

- The Principal Investigator is to confirm the details provided in the checklist by completing the declaration.

Information Required in the Research Agreement:

1. SWSLHD Institution details:

Ensure the following **institutional details** are accurately reflected in the amendment:

South Western Sydney Local Health District Administration Building, Eastern Campus, Liverpool Hospital, Locked Bag 7279, Liverpool BC NSW 1871 ABN: 46 738 965 845

Ensure the **SWSLHD delegated signatory** is as follows:

Name: Dr Sayali Pendharkar Position: District Director, Strategy Planning and Research

2. Project information:

- Ensure that the study title matches exactly as registered in REGIS.
- Ensure that all relevant details in the agreement align with the Researcher Checklist, the approved protocol and Human Research Ethics Application (HREA) and SSA forms, this includes financial/budget information, details surrounding sharing of data and/or materials.

3. Budget Information:

- Ensure that the agreement clearly outlines:
 - Whether SWSLHD will receive funds.
 - The amount (\$AUD) and schedule for funds (including any milestone payments or conditions that must be met prior to funds being distributed).
 - Clear invoicing details are provided for the Sponsor, including an Australian address.
 - If SWSLHD is receiving funds, complete the **SARA Form: Payment Information for Non-Patient and Sundry Billing**:
 - Study team to complete the SARA form: Payment Information for Non-Patient and Sundry Billing Form, Additionally:
 - Sponsor and institutional details must be accurately completed.
 - PayNSW will provide banking details for this transaction. These details need to be included in the CTRA amendment.
 - Include the following contacts for finance and remittance: paynswhealth@health.nsw.gov.au (*remittance advice*) SWSLHD-ClinicalTrialsSupportUnitFinance@health.nsw.gov.au (*primary finance contact*).
 - If commercially sponsored, ensure that:
 - Minimum **20% overheads** are applied for commercially-sponsored trials.
 - Applicable **HREC/RGO fees** are included, stating that the RGO fees are to be paid based on the rates listed on the [SWSLHD Research and Partnerships website](#). Alternatively, state that HREC/RGO fees will be reimbursed on a pass-through basis upon receipt of a formal invoice issued by the site team.
- If grant funded, provide evidence of SWSLHD support (Letter of Support). If no Letter of Support was provided, ensure that a reason is provided in the Researcher Checklist.

4. Data transfer:

- Ensure that the agreement clearly outlines:
 - Where SWSLHD data will be transferred (e.g. organisation and person/s responsible).
 - Whether data is de-identifiable, re-identifiable or identifiable.
 - Whether data linkage is planned*.
 - Appropriate safeguards in place to protect data (e.g. secure storage, controlled access, encryption etc).
 - That participants have been informed that their data would be shared and that this aligns with the approved consent process (e.g. information is included in the Participant Information Sheet and Consent Form).
 - That the transfer will comply with NSW Health privacy legislation.

4. Material transfer:

- Ensure that the agreement clearly outlines:
 - Where SWSLHD materials will be transferred (e.g. organisation and person/s responsible).
 - Whether samples are de-identified, re-identifiable or identifiable.
 - Whether data linkage is planned*.
 - Appropriate safeguards in place (e.g. handling, storage and use of materials etc).
 - That participants have been informed that their materials and/or data would be shared and that this aligns with the approved consent process (e.g. information is included in the Participant Information Sheet and Consent Form).
 - Any restrictions on use.
 - Storage, destruction and/or return of materials.
 - That the transfer will comply with NSW Health privacy legislation.

* Please note, this Guidance Document does not replace information available from the [NSW Population and Health Services Research Ethics Committee](#). Please ensure appropriate HREC approval is sought for data linkage projects that seek to access data held by the NSW Ministry of Health or Cancer Institute NSW.

5. Intellectual Property (IP):

- If not a standard agreement template, ensure that the agreement clearly outlines:
 - Ownership of Background IP.
 - Ownership of Project IP.
 - Publication rights and restrictions.

6. Legal considerations:

- Governing law should be New South Wales, Australia.
- The agreement term should align with HREC approval. If the agreement extends beyond HREC approval, justification must be provided.
- If not a standard agreement template, ensure that the agreement clearly outlines:
 - Confidentiality arrangements.

- Indemnity details.
- Insurance requirements.
- Termination clause/terms.
- SWSLHD and other party obligations must be clearly outlined and must align with the HREA, approved protocol and SSA.
- Deliverables, milestones and timelines must be clearly specified.
- Ensure that operational feasibility is confirmed with the relevant department/service and included in the Researcher Checklist.

General advice:

- Ensure that the project has been submitted for Human Research Ethics Committee (HREC) approval and/or Site Specific Assessment (SSA) authorisation.
- Ensure that the details within the agreement align with the Researcher Checklist, the approved protocol and Human Research Ethics Application (HREA) and SSA forms.
- If the agreement is non-standard (not an agreement listed in **Appendix A**) or a modified version of a standard agreement, it may require legal review. Where possible, standardised templates (approved for use in SWSLHD) should be used. For details on how the Research and Partnerships team determine review pathway, see **Appendix B**.

After Submission:

Once submitted, the research agreement will be reviewed by the REGIU. Researchers may be contacted if additional information or clarification is required prior to finalisation and execution. This may occur via the REGIS platform or via email, depending on the submission source.

Consultation and Support

Where there is any uncertainty, researchers are strongly encouraged to seek guidance from the REGIU prior to submission.

Researchers and study teams can book in a 15-minute consultation with the REGIU team by [making a booking](#).

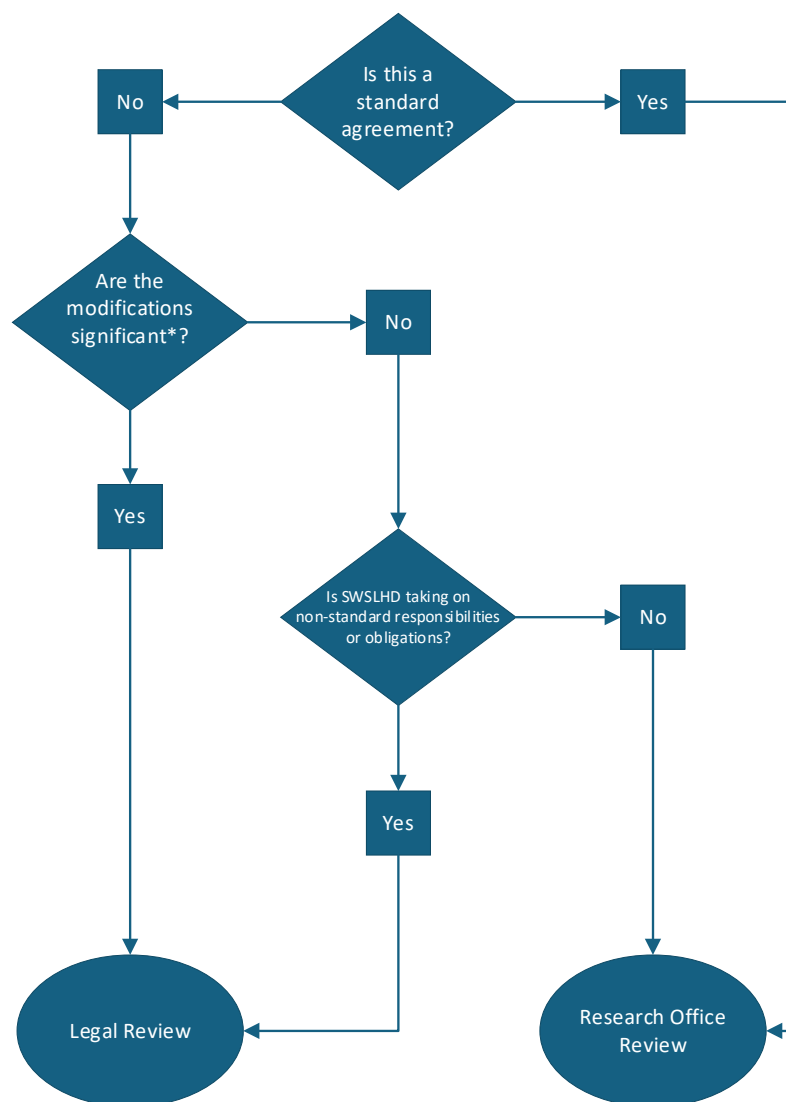
Appendix A: List of approved templates as of 19 June 2026:

- **Clinical Trial Research Agreements** available from <https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/> (please note, submission of the Researcher Checklist is not required for standard CTRA templates available from Medicines Australia).
- **SWSLHD Material Transfer Agreement**, available on request from SWSLHD-Ethics@health.nsw.gov.au.
- **Collaborative Research Agreement template – for projects not involving Clinical Trials** available from <https://www.australianclinicaltrials.gov.au/resources/collaborative-research-agreement-template-projects-not-involving-clinical-trials>.

Appendix B: Review Pathway determination

Significant modifications include:

- Intellectual property ownership changes
- Commercialisation rights
- Revenue sharing
- Liability or indemnity clause
- Insurance requirements
- Non-NSW governing law
- Large financial value (> district threshold)
- Data transfer outside Australia
- International partner



Non-standard obligations:

- Providing staff time without funding
- Providing patient data
- Providing biological samples
- Hosting external researchers