SWSLHD
Research Directorate

Ethics and Research Workshop Series 2023

Workshop 4:
Research Contracts and Agreements
22 May 2023

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NSW GOVERNMENT Health
South Western Sydney Local Health District

Ethics and Governance Workshop series 2023

Workshop 1:
Overview of Requirements for Submitting Applications

Workshop 2:
Requirements for Post-Approval Submissions

Workshop 3: Safety Submissions

https://www.swslhd.health.nsw.gov.au/ethics/workshops.html

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Overview

- What are agreements?
- Why do you need agreements?
- What are the common types of agreements we see in Research Office
    1. *Non-disclosure agreements: Confidential Disclosure Agreement (NDA / CDA)*
    2. *Research Agreements – Clinical Trials*
    3. *Research Agreements – Non Clinical Trials*
    4. *Research Collaboration Agreement (RCA)*
    5. *Data Sharing Agreement*
    6. *Material Transfer Agreement (MTA)*

- Who to contact if you are not sure?

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What are Agreements?

- An agreement is an **understanding or arrangement** reached between two or more parties.
- Written Agreement are **usually enforceable** unless there are factors which nullify or invalidate them.
- A **contract** is an agreement which creates **legally enforceable obligations** between parties.

Reference: LawPath

Why do we need Agreements?

- ✓ Offer clarity
- ✓ Provide proof of details
- ✓ Enforceability
- ✓ Offer protection
- ✓ Make disputes easier to navigate
- ✓ Confidentiality

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1. Non-Disclosure Agreements Confidential Disclosure Agreement (NDA / CDA)

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NDA/CDA

- These are **two titles for the same agreement type.**
- The purpose of these agreements are to ensure SWSLHD or both parties keep information confidential during discussions of working together for a potential project **to be conducted within SWSLHD.**
- NDA / CDA should **ideally be project specific**. If a company would like to establish a Master NDA / CDA please ask them to contact our office to progress this.
- **There should be no reference made to the investigator. They cannot be a third signatory in the agreement.**
  - **Signatory should be** SWSLHD Delegate (refer to SWSLHD Delegations manual)
  - ***Only SWSLHD Research Directorate can facilitate sign off from the Director of Research for all NDAs/CDAs***

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NDA/CDA

Points to remember

1. NDA/CDA should have a term – **1 or 2 years**

2. **Governing laws should be in Australia or New South Wales**. We cannot accept Foreign laws. We can choose to remain silent on Governing laws, however, this needs to be noted on the NDA/CDA

3. Details for Sponsor is correct (Name of organisation, address, ABN). SWSLHD entity details in agreement must be as follows, word for word:

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

4. SWSLHD is happy to exchange electronically – this is preferred and will result in a faster turnaround.

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2. Clinical Trials

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Clinical Trials

- The **Southern and Eastern Border States (forming the SEBS Panel)** (comprising the NSW, QLD, VIC, SA and TAS jurisdictions with ACT and NT as observers) together with Medicines Australia have developed **five Clinical Trial Research Agreements (CTRAs)**

- Appropriate CTRA can be used by any sponsor and/or institution for specific clinical trial scenarios.

Website: https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/

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Clinical Trials

Clinical Trial Research Agreement (CTRA)

- CTRA - Medicines Australia Standard Form
- CTRA - Contract Research Organisation (CRO) acting as the Local Sponsor
- CTRA - Collaborative or Cooperative Research Group (CRG) Studies
- CTRA - Phase 4 Clinical Trial (Medicines)
- CTRA - Phase 4 Clinical Trial (Medicines) Contract Research Organisation (CRO) acting as the Local Sponsor

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CTRA – Medicines Australia Standard Form

- Used when an **Australian pharmaceutical company is the sponsor** of the study (commercial sponsor).
- **Principal investigator is responsible to update**: Institution details, Sponsor details, and information in the Schedules as appropriate.
- **Schedule 7** is for special conditions only – **SEBS approval is required** and documentation is required upon SSA submission in REGIS.
- Requires submission with the **Medicines Australia Standard Indemnity**. The Standard CTRA will not be signed off without the Indemnity.

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CTRA: Contract Research Organisation acting as the Local Sponsor

- Used when the lead sponsor is an international pharmaceutical company or organisation and has an Australia Contract Research Organisation acting as the Local Sponsor within Australia.
- **Why?** Under NSW Health Policy, Public Health Organisations (PHOs) cannot sign a CTRA with an international company – it must be an Australian company for appropriate oversight of the trial within Australia.
- Requires submission with the Medicines Australia Standard Indemnity. CTRA will not be signed off without the Indemnity.

CTRA– Collaborative or Cooperative Research Group (CRG) Studies

- Used when the sponsor of the study is a collaborative research group such as a research institute, university or not for profit organisation.
- Schedule 4 is for Special Conditions – SEBS approval is required for significant changes which makes review and approval of the CTRA CRG easier. If no SEBS approval has been obtained this will require an internal legal review at SWSLHD.
- **Indemnity is not required** with a CTRA CRG as the parties are responsible for their own indemnity and insurances.

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CTRA – Phase 4 Clinical Trial (Medicines)

- Used for Phase 4 clinical trials with Australian pharmaceutical companies only.
- Cannot be used for anything else.
- Phase 4 Clinical Trials – post marketing phase of trial.
- This project still requires a CTN for the Phase 4 trial.
- SEBS approval required for any special conditions under Schedule 4.

CTRA– Phase 4 Clinical Trial (Medicines) Contract Research Organisation acting as the Local Sponsor

- Only used for a Phase 4 clinical trial where a CRO is acting as the local sponsor in Australia.
- These projects still need a CTN.
- SEBS approval required for any special conditions under Schedule 4.

Clinical Trials

SWSLHD's requirements for CTRAs

- We are happy to exchange agreements electronically – please advise if the sponsor is happy to exchange electronically in your cover letter upon submission via REGIS.
- SWSLHD' legal entity details are required to be included in all agreements under: Institution details: – **no deviations are allowed** *i.e. do not include (Liverpool/Campbelltown/etc Hospital)* in brackets.
- Any change from the below wording will result in an invalid CTRA and/or Indemnity:

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SWSLHD's requirements for CTRAs

- **Please do not change the content or clauses of any CTRA** – this is not permitted under Medicines Australia requirements. If any changes are desired, they must be outlined specifically in ***Schedule 7 or Schedule 4 of the CTRA under special conditions.***

- **Please provide the CTRA as signed by the sponsor and Principal Investigator**. The Director of Research will sign on behalf of SWSLHD upon authorisation of the SSA. The office coordinates this in parallel with authorisation of the SSA in REGIS.

- Please ensure all **Schedules are updated and match the content in the SSA**, with regards to the latest approved Protocol version and date, recruitment numbers, recruitment start date of study (this date should be a future date), lead HREC, site details, investigational product/equipment/device etc.

- Please provide the **SEBS approval letter in REGIS for Schedule 7 / Schedule 4 if applicable.**

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SWSLHLD's requirements for CTRAs

Schedule 2 – Budget

- Please ensure the **budget is accurate and agreed upon between the site team and the sponsor** as per negotiations with supporting departments e.g. Pharmacy, Radiology, NSW Health Pathology, Interpreter fees etc.
- Please ensure the **SWSLHD cost centre details for payment** are included and SWSLHD invoice details are included. If you are unsure of these details please contact the office directly and we can provide these.
- Please ensure the sponsor's invoice details are included.
- For commercially sponsored studies, the **Research Governance Fees** of $3,740.00 are required and **ethics review fees** of $3,300.00 if SWSLHD is the lead HREC. Further fees such as amendment, IB updates, etc. can be found on our website under the Fees tab.

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Guidance for seeking amendments to the CTRAs

No amendment required

The **CTRA templates do not require any amendments** to function as legally enforceable agreements. If no amendments are required to the subject CTRA, a SEBS review is not required.

Approaching SEBS

Changes to the existing clauses in the body of the template CTRAs should go to SEBS Panel for review. Although review by the SEBS Review Panel is not mandatory to amend the **Schedule 4/Schedule 7 Special Conditions section**, the service is recommended to assist clinical trial sponsors with timely, standardised review, where only one negotiation is required, rather than several.

Study-specific information needs to be entered in: does not require SEBS review.

- The Front Page information
- Schedule 1 – Key information
- Schedule 2 – Payments
- Schedule 6 – Study Protocol Information

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Application to SEBS

- Complete the template to request a Schedule 7 or Schedule 4 variation to a CTRA (SEBS Review Template)
- SEBS email address – MOH-SEBS@health.nsw.gov.au
- The **SEBS Panel meets monthly** to review submitted amendment requests
- Submissions and Meeting Dates – On Medicines Australia website; https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/

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3. Non Clinical Trials

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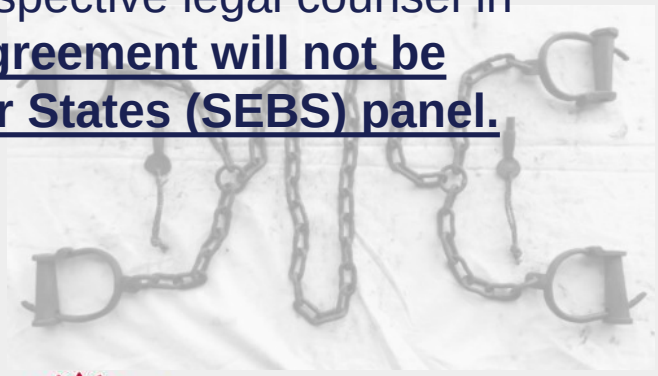
Multi-Jurisdictional Multi-Party non Clinical Trial Collaborative Research Agreement (CRA)

- This agreement is for collaborative **non-clinical trials research**
- This template agreement is non mandatory and follows the model of the Medicines Australia and Medical Technology Association of Australia suite of CTRAs
- Please note than any change to any of the clauses shall be made between the contracting parties and their respective legal counsel in Schedule 1. **Changes to clauses in this agreement will not be reviewed by the Southern Eastern Border States (SEBS) panel.**
- **Preferred Agreement type.**



https://www.australianclinicaltrials.gov.au/clinical-trials-project-reference-group-initiatives

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CRA

- **CRAs are internally reviewed at SWSLHD.** Turn around review time for RCAs are generally up to one week. However, delays can occur with the collaborative group depending on their legal review requirements.
- This agreement is used when there is a true collaboration, i.e. shared authorship, sharing of resources, sharing of skill, sharing of data, sharing of funding where SWSLHD is the sponsor of the project, registries, etc.
- The nature of the agreement is collaborative, and reflects standard good faith principles normally expected from collaborative projects.
- The CRA provides clarity on the publication process, what to do if any intellectual property is discovered (who owns it, how will it be shared, licenses), etc.

CRA

- **SWSLHD entity details** in agreement must be as follows, word for word:

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4. SWSLHD Research Collaboration Agreement (RCA)

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SWSLHD Research Collaboration Agreement (RCA)

- The **RCA is SWSLHD's agreement for projects that are not clinical trials** but are investigator-initiated and includes collaboration with other hospitals, universities, research institutes, etc. **Primarily for International collaborative studies.**
- Please contact to the Research Ethics and Governance Manager at the office if a collaborative group has requested an agreement or if you would like to establish an agreement for your project. This streamlines the process and ensures you receive correct advice in the early stages of planning.
- The review of the agreement is streamlined with the protocol that has been approved by a lead HREC, and the SSA has been reviewed by the office.
- **SWSLHD has a template that has been accepted at many sites in Australia** – this streamlines the process of an agreement review.

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5. Data Sharing Agreement

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Data Sharing Agreement

- Currently, **we not have a standard template** – in some instances, CRA/RCA can be used. Please reach out to the Office and we will advise you.

- We are happy to review if the external organization has their own template.

  Points to consider;

  1. What kind of data is being transferred? De-identified, re-identifiable
  2. Will the data storage/access at external sites be managed as at SWSLHD?
  3. Background and new intellectual Property

6. Material Transfer Agreement (MTA)

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Material Transfer Agreement (MTA)

- MTAs are not used often in SWSLHD **– the office prefers to use the Medicines Australia's CRAs or SWSLHD's Research Collaboration Agreement.**
- **MTAs are only used if there is no true collaboration of research** (this is rare). E.g. SWSLHD has only agreed to provide data / samples with no expectation of return of results, authorship of paper, etc.
- MTA provides limited collaboration and relationship.
- A MTA is suitable in some circumstances. MTAs are reviewed internally at SWSLHD on a case by case basis. It is better to contact the office to discuss before communicating that SWSLHD will agree to a MTA, as this may not be the case.

Material Transfer Agreement (MTA)

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What if a group approaches you for a project and sends you their agreement?

- This can often occur for projects that are **not clinical trials** and **SWSLHD is not the sponsor / owner of the project.**
- Examples: larger observational studies, registries.
- This can be submitted in REGIS with your SSA for a streamlined review – this is preferred.
- Alternatively if project is in earlier stages, please email the draft agreement to the office for review. Please email with the protocol, any study documents.
- Turn around time is usually within 1-2 weeks depending on above process. However, any agreements that require legal review may need to be sent externally to the office which could incur delays. As such, please contact the office as soon as an agreement is received so the office can avoid further delays.

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What if a group approaches you for a project and sends you their agreement?

- **Why is there a longer turnaround?** These agreements require more in-depth review as they are not using a SWSLHD approved template.
- These agreements are reviewed internally however, in some instances may be sent externally for legal review depending on the nature of the agreement.
- **There may be amendments made in accordance with SWSLHD requirements.** The office will complete this in tracked changes and collaborate directly with the research team that has provided the agreement for a streamlined approach.
- The reason for any amendments is to protect the investigators, the participants and the institution.

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Who do I contact?

Research Directorate

Location: Research Directorate, Locked Bag 7279, Eastern Campus, Liverpool BC NSW 1871
E-mail: SWSLHD-Ethics@health.nsw.gov.au

Website: http://www.swslhd.nsw.gov.au/ethics/
Phone: 02 8738 8304

REGIS
For: technical queries such as system issues or faults, and account access issues. The Help desk is available 7am-7pm Monday-Friday, excluding ACT Public Holidays.
Email: support@f1solutions.com.au
Website: https://regis.health.nsw.gov.au/
Phone: 1300 073 447

- Assistance with registration, applications, and post-approval/authorisation
- Missing or incorrect Department information (site-governance applications)
- How to use REGIS (non-technical)

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Questions?

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