Health
Mid North Coast
Local Health District

Checklist for Clinical Trial Regulatory documents for Site Specific Assessment (SSA)

This checklist has been developed to assist Researchers, Coordinating Principals, Clinical Trial Coordinators and Research team members to ensure clinical trial regulatory documents are correct at the time of submission to the Mid North Coast Local Health District (MNCLHD) Research Governance Officer (RGO) for Site Specific Assessment (SSA) review.

Clinical Trial regulatory documents may include:

- Medicines Australia Clinical Trial Research Agreement (CTRA)
- Certificate of Insurance or Certificate of Currency
- Medicines Australia Form of Indemnity
- Therapeutic Goods Administration Clinical Trial Notification (CTN)

This checklist should be read in conjunction with clinical trial information at:

- NSW Health & Medical Research
- Australian Clinical Trials
- Clinical Trials for Medical Devices
- ICH Guidelines for Good Clinical Practice (GCP)
- National Statement on Ethical Conduct in Human Research (National Statement)
- Therapeutic Goods Administration (TGA)

Things to remember:

- **Clinical trial documentation MUST have an Australian entity listed as the local sponsor who is responsible for the trial within Australia. Documentation listing an overseas country as the local sponsor will not be accepted.**
- **The Australian sponsor MUST be listed and the same organisation across all of the associated regulatory documents**
- **CTRA and Indemnity documents are to be signed by an authorised sponsor delegate**
- **MNCLHD accepts electronic signing of clinical trial regulatory documents. DocuSign is the preferred method, however Adobe Sign is also accepted.**

For additional information or guidance, please contact the Research Governance Officers for the MNCLHD via the below contact details:

Colleen Nosworthy – 0428 882 170
Diana Stephens – 0473 853 782

Email: MNCLHD-RGO@health.nsw.gov.au
Internet: https://mnclhd.health.nsw.gov.au/research/

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Clinical Trial Research Agreement (CTRA)

Clinical Trials to be conducted at a site under the control of a Public Health Organisation (PHO) must have a written agreement. This agreement sets out obligations, responsibilities and rights of the parties involved in accordance with Research Authorisation to commence human research in NSW PHOs. For clinical trials where the study is sponsored by an entity external to MNCLHD, one of the approved Medicines Australia CTRA templates (according to Sponsorship) must be used. There are four (4) CTRAs approved for use:

1. Standard Medicines Australia CTRA for Commercially Sponsored Trials;
2. Standard Medicines Australia CTRA for Contract Research Organisations acting as the Local Sponsor;
3. Standard Medical Technology Association of Australia CTRA; and
4. Standard Collaborative or Cooperative Research Groups CTRA.

Resources:

- Medicines Australia Clinical Trial Research Agreement (CTRA) templates
- Clinical Trial Research Agreements for use in NSW Public Health Organisations – PD2011_028

CTRA Checklist

1. Is an approved Medicines Australia template being used?	☐ Yes ☐ No
2. Is the study name correct and the same as what is listed on study protocol and other study documentation?	☐ Yes ☐ No
3. Is Mid North Coast Local Health District or Mid North Coast Local Health District trading as xxxxxx {site name} listed correctly?	☐ Yes ☐ No
4. Is MNCLHD ABN correct? i.e. 57 946 356 658	☐ Yes ☐ No
5. Is site address and contact for notice details correct?	☐ Yes ☐ No
6. Is ABN for Sponsor correct I.e. Registered in Australia (https://abr.business.gov.au/)	☐ Yes ☐ No
7. Does the budget cover all trial activity, investigations and RGO fees (for commercially Sponsored trials) in Schedule 2 - payments?	☐ Yes ☐ No
8. Are there any additional clauses added at Schedule 4 for CRG/Collaborative studies or Schedule 7 for Commercial/CRO studies? a) If yes, do you have a copy of SEBS approval letter?	☐ Yes ☐ No ☐ Yes ☐ No
9. Is there an agreement in place with Pathology for preparation of slides and/or tumour blocks?	☐ Yes ☐ No ☐ N/A

Amendments to the approved templates:

- Any clauses at Schedule 4 or 7, **should be approved** by the Southern Eastern Board States (SEBS Committee*) and **evidence of SEBS approval** must be provided with the SSA.
- Medicines Australia CTRA templates with SEBs approval schedules 4 or 7 will be accepted unchallenged by RGO upon submission with SSA provided all administrative details are correct, e.g. ABN, organisation name etc.
- Any CTRA submitted to the RGO with a variation to the CTRA or unapproved additional clauses that may require an independent legal review will be **at the cost of the sponsor.**

* The Southern Eastern Border States (SEBS) panel has representatives from the health departments of New South Wales, Queensland, South Australia and Victoria. SEBS works to standardise, as far, as possible, the terms and conditions of the Medicines Australia Clinical Trial Research Agreements (CTRAs) in an effort to streamline the administrative management of contracts for sponsors and Health Services organisations who are parties to the agreements. For further information related to the SEBS Committee – see https://www.medicalresearch.nsw.gov.au/clinical-trial-ethics-governance/

If you answered no to any of the above questions – please liaise with Sponsor to correct

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Certificate of Currency (CoC) or Certificate of Insurance (CoI)

The organisation that executes the CTRA as sponsor must provide evidence of indemnity that covers insurance arrangements as set out in the relevant CTRA and which meets the requirements of PD2011_006 Clinical Trials: Insurance and Indemnity.

- The sponsor must provide evidence it has appropriate and sufficient insurance with respect to its responsibilities as a sponsor of the trial
- The Certificate **must have the Australian Sponsor** listed (or added under additionally insured)
- The dollar value must be stated in AUD

Further information is available within Section 2.2.2 of the NSW Health Policy Directive – Clinical Trials – Insurance and Indemnity

CoC/CoI Checklist

1. Is the name on the certificate an Australian sponsor? I.e. The insured or additionally insured?	☐ Yes ☐ No
2. Is the certificate current for the period in the trial will be conducted, i.e. for a 12 month period or for the life of the study?	☐ Yes ☐ No
3. Does the certificate contain insurance cover for a minimum amount of AUD 20 Million for any one occurrence and the annual aggregate (for commercially sponsored trials) Note: the insurance policy must not contain an excess/deductible or self-issued retention amount greater than AUD 25,000 for each and every claim or series of claims arising out of one originating cause	☐ Yes ☐ No ☐ N/A
4. Does the policy contain insurance cover (for Collaborative/CRG sponsored trials)?	☐ Yes ☐ No ☐ N/A
5. If the study name is listed, is it correct and is it the same as listed on study protocol and other documents?	☐ Yes ☐ No ☐ N/A
6. If the protocol number is listed, is this correct and is it the same as is listed on study protocol and other documents?	☐ Yes ☐ No ☐ N/A

Example of Certificate of Currency or Certificate Insurance details:

Period of Insurance:	January 30, 2020 to January 30, 2022 Both days inclusive at 16:00 hours Local Standard Time at the Australian address of the Insured
Limits of Indemnity:	AUD 20,000,000 any one event and in the annual aggregate
Deductible:	Nil

If you answered no to any of the above questions – please liaise with Sponsor to correct

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Form of Indemnity

A form of indemnity is provided by the sponsor to the NSW Public Health Organisation conducting the study at its site/s, and is used where the Indemnified Party is providing premises for the conduct of the study. One of the Medicines Australia approved templates must be used.

Where more than one legal entity is to be indemnified, separate Forms of Indemnity should be used for each legal entity to be indemnified.

Resources:

- Medicines Australia approved Form of Indemnity templates
- Guidelines for compensation for injury resulting from participation in a company-sponsored clinical trial

Indemnity Checklist

1. Does the form have the correct name and address of the legal entity where the study is being conducted? I.e. MNCLHD or MNCLHD trading as (site name)	☐ Yes ☐ No
2. Does the form have the correct name of the sponsor? I.e. Name, registered address and ABN of sponsoring company) The indemnities referred to in sections 2.2.1 (10) and 2.2.1 (11) must be an Australian corporate entity. This may be: a) An Australian company; b) An Australian company that is a subsidiary of an overseas parent company; or c) An Australian contract research organization (CRO) that has been engaged by an overseas or Australian company to conduct the trial in Australia	☐ Yes ☐ No
3. Does the form list the study protocol name and is it correct?	☐ Yes ☐ No
4. Has the Investigator's name been included in clause 1 and is it correct?	☐ Yes ☐ No

If you answered no to any of the above questions – please liaise with Sponsor to correct

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Clinical Trial Notification (CTN)

For clinical trials to be conducted under the Clinical Trial Notification (CTN) or Clinical Trial Exemption (CTX) Scheme administered by the Therapeutic Goods Administration.

Trials under this scheme may include:

- Use of any product not entered on the Australian Register of Therapeutic Goods; or
- Use of a product beyond the conditions of its marketing approval.

CTN forms are completed online. For additional information please see the TGA website. Clinical trials that do not involve **"unapproved"** therapeutic goods are not subject to requirements of the CTN or CTA schemes.

CTN Checklist

1. Is the MNCLHD site or site name and address listed correctly?	☐ Yes ☐ No
2. Is the Principal Investigator (PI) name and contact details correct?	☐ Yes ☐ No
3. Are the approving Human Research Ethics Committee (HREC) details correct?	☐ Yes ☐ No
4. Is the "Name of Approving Authority" listed as Mid North Coast Local Health District?	☐ Yes ☐ No
5. Are the following details listed under the Name of Approving Authority correct?: Approving Authority Contact Name: Research Office Approving Authority Contact Position: Research Governance Officer Approving Authority Contact Phone: 0428 882 170/0473 853 782 Approving Authority Contact Email: MNCLHD-RGO@health.nsw.gov.au **Note: If there is more than one site involved in the study for MNCLHD, each site will need to be listed separately on the CTN submission form**	☐ Yes ☐ No

If you answered no to any of the above questions – please liaise with Sponsor to correct