Clinical Trial Research Agreements

Research Governance Factsheet

Clinical Trial templates

- Clinical Trial Research Agreements – Medicines Australia
- Statement of Purposes for the Southern Eastern Border States (SEBS) Panel

Details of parties

Name of Institution:	Metro North Hospital and Health Service
Address:	Level 7, Block 7, Butterfield St Campus Herston QLD 4029
ABN:	18 496 277 942
Contact for Notices:	Research Governance Manager
Email:	MetroNorthResearch-RGO@health.qld.gov.au
Phone Number:	07 3647 9550

Check that Date of Agreement is entered as date of last signature

Project ID/ERM Number on the front page of the Clinical Trial Agreement

- Please add the Project ID/ERM number to the front page of the contract.
- The number does not alter the body of the agreement.
- *For example*, the number can be added to the footer in brackets after the site, study name or protocol number; or in brackets after the Contact for Notices;
  - Research Governance Manager (ERM Project ID: 12345)
  - Site: RBWH (ERM Project ID: 12345)
  - Study name: A Randomised Controlled Trial of Drug A versus Drug B (ERM Project ID: 12345)

Schedule 1: Key Information

- Complete all details as per the information requirements in Schedule 1
- Where there is competitive recruitment, include the proposed target/maximum number of participants to be recruited at the site This information is used to estimate the total contract value, which is a requirement to ensure compliance with the Metro North Financial Delegation Framework. Access via QHEPS/Intranet only.
- Check that recruitment period reflects current timelines

Schedule 2 Payments/Budget

- The budget should always be endorsed by the site Business Manager and/or Research Business Manager
- Metro North does not endorse a withholding fee or retainage, any reference to this should be removed.

PAYEE Information

Payment under this Agreement shall be made payable to:

Payee (Institution):	Metro North Hospital and Health Service
Address:	Level 7, Block 7, Butterfield St Campus Herston QLD 4029
ABN/Tax Identification Number	18 496 277 942
Payee Contact Name:	*Site coordinator/administrative officer or business manager as per departmental/facility process*
Telephone Number:	*Site coordinator/administrative officer or business manager as per departmental/facility process*
Email:	*Site coordinator/administrative officer or business manager as per departmental/facility process*
VAT Registration Number (if applicable):	

Details for payment by bank transfer

Account holder:	Metro North Hospital and Health Service
Account Name:	Metro North HHS Operating Account
Bank Address:	Queensland Government Banking Centre 240 Queen Street Brisbane Qld 4001
Account No.:	1003 1010
Bank:	Commonwealth Bank of Australia
BSB	064 013
IBAN:	N/A
BIC (SWIFT) Code:	CTBAAU2S
Additional Information	<add site cost centre and name of Trial>

The email address for all remittance advices is: MetroNorthReceipting@health.qld.gov.au

Schedule 4 Special Conditions (CTRA-CRG) /Schedule 7 Special Conditions (CTRA)

- Special Conditions are used when the sponsor wishes to amendment the standard/approved clauses in the Medicines Australia clinical trial template.
- Special Conditions need to be approved by the Southern & Eastern Border States (SEBS) Panel.
- If you are unsure whether Special Conditions have been approved by SEBS, you can request a copy of the SEBS approval from the Sponsor.
- To make an application to SEBS, refer the sponsor to the Medicines Australia website
- In circumstances where Special Conditions are included solely for Metro North, clearance from Metro North Legal rather than SEBS is required.

Fees for Commercially Sponsored Trials

- Please complete the fee template, have this signed by the sponsor and submit via ERM with your site-specific assessment (SSA) application or Post-Authorisation Notification
- Submissions will not be processed until the signed fee template is received
- Research governance and site authorisation – Fee Template*
- **A major amendment constitutes an amendment to a Protocol, Investigator's Brochure, amendment to CTRA, review of new documents and/or substantial Participant Information Sheet and Consent Form (PICF) changes. Substantial PICF changes comprise those which incorporate protocol changes or updated safety information. They do not comprise administrative changes such as addition of investigators or typographical amendments.*

Review of Agreement

- In most instances the Metro North study/trial coordinator will review and confirm all details in the CTRA prior to the Sponsor and the Principal Investigator signing the agreement
- The agreement should be partially executed (signed by the Sponsor and PI) and uploaded to ERM.
- However, in circumstances where the Sponsor or Trial Coordinator wishes the Research Governance Office to review the draft agreement prior to signing, this can be uploaded to ERM with the site-specific assessment application.

Execution of Agreements

- The Metro North Research Governance Officer will arrange for agreements(s) to be executed; in accordance with the Metro North Financial Delegation Framework; Agreements are signed along with the Site Specific Assessment approval
- The Agreement may be executed in any number of counterparts. All counterparts are taken together to constitute one fully executed Agreement.
- A combination of DocuSign (for Sponsor-signature), wet-ink and digital certificate (adobe certificate) is permitted and legally binding
- The Metro North delegate does not use DocuSign.
- The Metro North Delegate will sign Adobe Digital Certificate or wet-Ink
- If wet ink signature is required, the submission cover letter should advise that a copy of the agreement for wet-ink has been delivered to the relevant research office at the site, only two copies are required. The final executed agreement will then need to be collected from the relevant research office at the site.