Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials

PURPOSE

This work instruction describes the process and activities required by Metro South Health (MSH) and the Metro South Sponsorship Committee to grant sponsorship, by MSH, for Clinical Trial Notification (CTN) Scheme investigator-initiated clinical trials.

OUTCOME

This work instruction aims to:

- Outline the process Principal Investigators/Coordinating Principal Investigators (PI/CPI) need to follow to request that MSH acts as the legal representative for a trial, thereby acting as the sponsor.
    - Note: MSH will not support individual employees to personally act as the sponsor of a clinical trial.
- Ensure MSH sponsored trials are conducted appropriately and efficiently and will be completed to a high quality and achieve maximum impact.
- Ensure MSH PI/CPI and/or nominated Sponsor Representative is aware of MSH sponsor responsibilities when conducting CTN investigator-initiated clinical trials and maintain consistency with the Therapeutic Goods Administration's (TGA) Good Clinical Practice (GCP) Inspection Program.
- Ensure that there is an appropriate MSH-wide process to grant sponsorship, by MSH, for CTN Scheme investigator-initiated clinical trials.
    - Note: It is preferable for the CPI/PI to request for the external collaborating party to act as sponsor in the first instance (i.e., University).
- Ensure all research conducted within MSH or in collaboration with external entities, is of the highest ethical and scientific standard and is compliant with relevant legislation, standards, and guidelines.
- Support MSH PI/CPI and/or nominated Sponsor Representative through the process by outlining available tools and resources as well as where/how to find more information and/or advice.

This work instruction outlines processes described in MSH procedure PR2023-413 Research administration and compliance and upholds principles outlined within the Research Administration and Compliance Handbook.

SCOPE

This work instruction applies to all MSH employees who are requesting MSH to act as the sponsor for a CTN scheme investigator initiated clinical trial.

WORK INSTRUCTION

1. STEP 1: CTN AND CTA SCHEMES

- All clinical trials conducted in Australia, require a specifically named Australian entity as sponsor.
- The Australian clinical trial sponsor must notify the TGA of the intent to sponsor a clinical trial involving an 'unapproved' therapeutic good. This must take place before starting to use the goods. The notification form must be submitted online via the TGA business services website.
- Should a PI/CPI wish MSH to act as sponsor, they must first seek delegate approval in writing. This will most commonly apply to MSH investigator-initiated clinical trials or international investigator-initiated trials seeking a local Australian sponsor.
- When MSH agrees to act as the sponsor of an investigator-initiated clinical trial, the ‘Metro South Hospital and Health Service’ will be the official name used on all relevant documents including contracts with third parties, CTNs to the TGA, and clinical trial registration.
- In order to request MSH, the ‘Approving Authority’, to act as the clinical trial sponsor, organisational approval must be sought from relevant MSH delegates prior to notification, ethics approval and commencement of the trial.
    - See the MSH guideline GL2021-77 Clinical Trials for more information.
    - Note: The Metro South Human Research Ethics Committee (MSHREC) will not approve any investigator-initiated CTN Scheme clinical trials without evidence of sponsor approval:
        - In the case of clinical trials that are proposed to be sponsored by MSH, approval would be required from Metro South Sponsorship Committee (MSSC) and the MSH delegate.
        - In the case of CTN Scheme trials sponsored by other organisations, this could be confirmation of an external collaborative network, company or organisation approval.

1.1 Non-CTN/Trials

- Clinical trials and other clinical research that are Metro South sponsored, but do not require a CTN to the TGA are deemed to be out of scope of this work instruction and can proceed in accordance with normal ethical and scientific review processes.
- Clinical Trials involving manufacturing of therapeutic goods and conducted via the TGA’s Clinical Trial Approval scheme are deemed to be out of scope of this work instruction.
- If unsure if the sponsorship process applies, contact Metro South Research for clarification and guidance. For example, depending on the level of risk it may be unclear if a protocol for a “pilot study” requires MSH review.

2. STEP 2: MSH SPONSORSHIP APPLICATION FORM

1.2 Prepare documentation

- Prior to MSH review, the CPI/PI must:
    - Complete Attachment 1: MSH Sponsorship Application Form;

- Provide a copy of the draft research proposal with a version number and date;
- Provide a copy of a completed risk assessment (see MSH work instruction WI2023-292 Assessing and managing risk in research);
- Provide a copy of Investigational Product (IP) brochure or Device specifications;
- Prepare a current trial budget including evidence of the source of trial funding (e.g., grant approval letter, email from the Head of Department etc.); and
- Provide other supporting documentation.

- Metro South Research is available to provide guidance in the preparation of the required documentation.

1.3 Sponsor Representative

- A proposed Sponsor Representative may be identified by the PI/CPI/research team, and approved by the relevant delegate, on the MSH Sponsorship Application Form.
- The Sponsor Representative takes accountability for the responsibilities of the sponsor and receives formal delegated authority to make decisions on behalf of the sponsor.
- The proposed Sponsor Representative must be suitably qualified for the role and be willing to accept the responsibilities of the role.
- The Divisional Clinical Lead or other qualified clinician may be appropriate to accept accountability for quality and safety and other sponsor responsibilities.
    - If unsure, discuss responsible officers and appropriate Sponsor Representative with Metro South Research.
    - Note: the term “Sponsor Representative” will be utilised from this point forward to describe the position responsible in MSH for the conduct of the clinical trial.
- The PI/CPI is responsible for liaising with Metro South Research to ensure a suitable MSH Sponsor Representative is identified.
    - Note: Failure to identify a suitable MSH Sponsor Representative at the time of application may delay progress of the application.

1.4 Endorsement

- The PI/CPI must seek signatures from other responsible officers as indicated on the MSH Sponsorship Application Form.
- The completed form and supporting documents are submitted signed to MSH-Research@health.qld.gov.au.
    - Note: Incomplete forms and missing documentation may cause delay in review.

3. STEP 3: REVIEW

3.1 Initial review

- The Executive Director, Metro South Research (or delegate) will review the submission to ensure all the MSH Sponsorship Application Form and documents are satisfactory and assess whether the project requires MSH sponsorship approval.
- The Executive Director, Metro South Research (or delegate) may request a meeting to discuss the details of the clinical trial and request revisions.
- Once the Executive Director, Metro South Research (or delegate) is satisfied with clinical trial documents submitted and necessity for MSH review, a MSSC will be established to review the application.

3.2 Conflict of interest

- Should the Executive Director, Metro South Research (or delegate) have a conflict of interest, the Chief, People Engagement and Research (CPER) will nominate an alternate officer to perform the initial review in the place of the Executive Director, Metro South Research (or delegate).

4. STEP 4: METRO SOUTH SPONSORSHIP COMMITTEE (MSSC)

- To assist in assessment of the trial's suitability for sponsorship, Metro South Research will stand-up an appropriate MSSC to review institutional risk, responsibilities and management processes with respect to the clinical/standard of care, financial, corporate, safety and quality of the proposed investigator-initiated clinical trial and compare against possible benefits to patients/participants.
- The MSSC does not primarily assess, nor provide approval of the scientific quality, research merit or ethical acceptability of the trial design, as this is the responsibility of the reviewing Human Research Ethics Committee (HREC).
- MSSC Membership is outlined within Attachment 2: Metro South Sponsorship Committee Terms of Reference.
- The PI/CPI and proposed Sponsor Representative may be asked to provide additional information to assist the MSSC in making an appropriate recommendation.
- The proposed Sponsor Representative will be asked to attend the meeting and provide an overview of the trial, highlight any risks that they have identified in their submission and answer any questions.

4.1 MSSC Meetings

- During the meeting, the MSSC will consider:
    - The overall risk rating of the trial.
    - The degree of MSSC (or delegate) oversight required.
    - Any further actions required for mitigating and/or monitoring the risks identified by the MSSC and Sponsor Representative (or delegates).

- Any requirement for a Data Management Plan and/or Monitoring Plan. If these documents are required, the MSSC will advise the Sponsor Representative of a due date for their submission.

4.2 Response to MSSC feedback

- If any revisions/concerns are recommended by the MSSC, the Sponsor Representative must address these and re-submit the revised documents to the Executive Director, Metro South Research (or delegate) for approval.
- The Sponsor Representative is required to address the concerns from the MSSC in writing and provide a management plan/solution to a level that satisfies the feedback received.
- The MSSC will be reconvened to review revised documents/additional information.

4.3 Decisions not to sponsor a clinical trial

- Should the MSSC determine that risks to MSH are inadequately addressed by the PI/CPI or Sponsor Representative, the MSSC may refer to the delegate for review who may recommend against MSH sponsorship.
- The reason for rejecting an application will be provided to the CPI/PI and Sponsor Representative in correspondence (e.g., an email) from the Executive Director, Metro South Research (or delegate).
- As HREC and Site Specific Assessment (SSA) processes require evidence of sponsorship prior to approving clinical trials, this may also prevent the trial from receiving HREC approval.
- Where appropriate, the Sponsor Representative may discuss the decision with the Executive Director, Metro South Research (or delegate).

5. STEP 5: SPONSOR REPRESENTATIVE AUTHORITY LETTER

- The Sponsor Representative will receive a ‘Sponsor Representative Authority Letter’ signed by the relevant delegate in accordance with the MSH Financial Delegations Framework – restricted delegation:
    - Executive Director, Metro South Research or Executive Director, Medical Services (EDMS) if the total financial commitment of the clinical trial is <$500,000.
    - Chief, People Engagement and Research Officer or Health Service Chief Executive if the total financial commitment of the clinical trial is >$500,000.
- The MSH relevant facility/service research committee will receive a copy of the Sponsor Representative Authority Letter’ for noting.
- The Sponsor Representative Authority Letter is not the confirmation to commence recruitment. It is an approval document certifying MSH is willing to act as the sponsor for the trial in accordance with regulatory requirements.

5.1 Submit to Metro South Human Research Ethics Committee

- The Sponsor Representative Authority Letter must be provided when submitting a Human Research Ethics Application (HREA) to the MSHREC.

- See MSH work instruction WI2023-299 Ethical and scientific review of research for more information regarding the ethical review process in MSH.
- The MSHREC will not approve an ethics application for MSH sponsored trials until the MSH delegate has issued a Sponsor Representative Authority Letter.

6. STEP 6: PROTOCOL AMENDMENTS POST MSSC APPROVAL

6.1 Assess impact of amendments

- If changes are made to the protocol or trial that substantially impact the ability for MSH to continue to act as the sponsor at any time after approval by the MSSC, then the Executive Director, Metro South Research (or delegate) should be notified prior to notification to the MSHREC and Metro South Research Governance Office (MSRGO).
- The MSSC may be reconvened to reassess, and all documentation outlined in Step 2 must be updated and resubmitted to MSH-Research@health.qld.gov.au

6.2 Change of Sponsor Representative

- A change in nomination of a Sponsor Representative is considered a major amendment and must be resubmitted to the Executive Director, Metro South Research.
- The previous Sponsor Representative may suggest another suitable nomination however final determination of a new Sponsor Representative is at the discretion of the relevant delegate.
- If an appropriate Sponsor Representative is unable to be identified, MSH may withdraw its sponsorship of the clinical trial.

6.3 Re-issue of Sponsor Representative Authority Letter

- If deemed necessary by the MSH delegate, the Sponsor Representative Approval Letter may be updated and re-signed by the Executive Director, Metro South Research (or delegate) each time a significant change is made to the protocol/trial design (including protocol amendments); particularly if the changes will significantly impact MSH's decision to sponsor the trial.

7. STEP 7: OVERSIGHT OF MSH SPONSORED TRIALS

7.1 Expedited Safety and non-compliance event reporting

- Apart from protocol amendments as outlined above, the MSRGO must be notified as soon as possible of any other events (internal or external) which may impact the risk assessment of the trial.
- The Sponsor Representative must report to the MSRGO and MSHREC safety and non-compliance events in real time. This includes:
    - Serious Breach reports (Sponsor-level and MSH's site), within 7 calendar days of confirmation;
    - Significant Safety Issues (SSIs), within 72 hours of becoming aware of the event;
    - Urgent Safety Measures (USMs), within 72 hours of becoming aware of the event; and/or

- Suspected Unexpected Serious Adverse Reactions (SUSARs), within 72 hours of becoming aware of the event.

- For all serious breaches both at the sponsor and trial site level, the PI/CPI must provide a Corrective and Preventive Action plan (CAPA) to both the MSHREC and the MSRGO as soon as possible.
- Any trials that have an increased risk rating as a result of a safety event must be re-assessed by the MSSC to determine the ongoing appropriateness of MSH to act as the sponsor for the clinical trial.

7.2 Research Monitoring

- The Sponsor Representative will be responsible for establishing appropriate monitoring of the sponsored clinical trial including source data verification (SDV), based on the risk and recruitment status of the trial.
- MSH sponsored clinical trials may also be reviewed by the Metro South Research Monitor as determined by the Executive Director, Metro South Research, and based on the risk and recruitment status of the trial.
- The aim of the periodic review is to ensure the trial is being conducted in a manner consistent with relevant protocols, approvals and authorisations, and in the context of the most recently submitted Risk Assessment.
- The PI and Sponsor Representative are responsible for meeting any costs associated with monitoring.

7.2.1 Monitoring Plan

- In accordance with the GCP Guideline Section 5.18.7, the Sponsor Representative must develop a monitoring plan that is tailored to the specific human subject protection and data integrity risks of the trial. This plan must describe the monitoring strategy, the monitoring responsibilities of all the parties involved, the various monitoring methods to be used, and the rationale for their use.
- The depth and breadth of the monitoring will be determined by the risk profile and must be outlined within the Monitoring Plan. It will typically involve between one to three hours of review, including meetings between the Sponsor Representative and Monitor as appropriate.
- Please see MSH work instructions WI2023-292 Assessing and managing risk in research and WI2023-305 Research monitoring for more information.

8. STEP 8: ESTABLISHING A DATA SAFETY MONITORING BOARD

- The Sponsor Representative and PI/CPI are responsible for establishing a Data Safety Monitoring Board (DMSB) for clinical trials where there is a significant risk of harm or where unblinded interim data analysis is necessary to ensure the safety of research participants. The MSSC will determine the requirement for establishing the DSMB based on the risk assessment of the clinical trial when application for sponsorship is made.
- A DSMB is an independent multidisciplinary group established by the Sponsor representative whose responsibility is to review, at regular intervals, accumulating trial data, in order to monitor the progress of a clinical trial. The primary role of the DSMB is to provide advice on safety and/or trial conduct

issues by making recommendations to the sponsor on whether to continue, modify or stop a trial for safety or ethical reasons.

- Members of the DSMB should have no involvement in the design and conduct of the trial, except through their role on the DSMB and have no financial or other connections to the sponsor that could influence or be perceived to influence their objectivity in evaluating trial data.
- Membership to the DSMB should include a statistician and individuals with relative experience in the clinical aspects of the disease/patient population being studied as well as members with practical experience and expertise in current clinical trial conduct and methodology.
- The role and function of the DSMB is described in a Charter which generally includes operational procedures including membership, role and remit of the DSMB, what recommendations are permissible, minimum number of attendees for quorum, frequency of meetings, to whom they report and how decisions are made. A Charter template can be found (will need to create a DMSB Charter template – similar to the Terms of Reference for the HREC).

9. STEP 9: QUALITY MANAGEMENT SYSTEM

- The Sponsor Representative and PI/CPI is responsible for implementing an appropriate quality management system which includes a Trial Master File, Study Procedure Manual, Delegation Log, Investigational Product/Device Accountability Log and other relevant documents. Refer to MSH work instruction WI2023-288 Research quality management systems for more information.

10. STEP 10: TERMINATION OF SPONSORSHIP

- MSH may decide to withdraw sponsorship, if needed, and will notify the reviewing HREC of this decision. This may then trigger the reviewing HREC to withdraw ethical approval and/or MSHRGO to withdraw SSA authorisation. The TGA may also need to be notified.
- The Sponsor Representative will be given clear notice, in writing, to cease all trial activities other than those deemed necessary for participant safety.
- The Executive Director, Metro South Research (as the Chair of the MSSC), will advise the Sponsor Representative if there is a need to cease administration of treatment for all trial participants and will discuss the requirements for advising participants about the closure of the study and the follow-up steps which need to be completed.

10.1 Appeals to reconsider sponsorship

- Any MSH employee may write to the Executive Director, Metro South Research:
    - Where they believe they have grounds to request that a trial not be sponsored by MSH or have an existing sponsorship revoked.
    - Where they would like the MSSC to reconsider sponsorship after it was initially declined.
- Each appeal will be considered by the MSSC, who may seek clarification from relevant sources. If the MSSC decides that there are legitimate grounds for revoking or withholding sponsorship, then the committee will prepare a recommendation for the Executive Director, Metro South Research for approval and/or comment.

RESPONSIBILITIES

Position	Responsibility	Audit criteria

MSH (institution/organisation)	• Implement a system to manage quality throughout all stages of a MSH sponsored clinical trial process using a risk-based approach including:
	  ○ provision of the necessary financial and logistical support,
	  ○ ensuring adherence to ethical principles and obtaining regulatory approvals,
	  ○ providing investigational product and trial-related materials,
	  ○ overseeing data management and analysis and maintaining documentation,
	  ○ monitoring the clinical trial's progress,
	  ○ ensuring safety reporting and adverse event management, and
	  ○ ensuring compliance with applicable regulations and guidelines.
	• MSH must have oversight of any clinical trial related duties and functions carried out on its behalf, including clinical trial-related duties and functions that are subcontracted to another party.
	• Systematic, prioritised and risk-based approaches to monitoring clinical trials that are sponsored by MSH must be developed, including but not limited to, the development of a study procedure manual, Standard Operation Procedures (SOPs) and a research monitoring plan.
	• All site-related materials must be made available for review, by auditors or regulatory authority(ies) and sponsor's representatives for all clinical trials regardless of the sponsoring entity.
		N/A

Metro South Sponsorship Committee	• Review all documentation as outlined on the MSH Sponsorship Application Form provided by the Sponsor Representative and approved by the relevant Head of Department and consider endorsing the request for MSH to act as Sponsor for a clinical trial. • Endorse a request for MSH to act as a sponsor for a clinical trial if all requirements are met. • Where MSH is identified and endorsed as the sponsor of a clinical trial, delegate sponsor responsibilities as outlined in Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) (2016) Section 5 - Sponsor to the Sponsor Representative through a 'Sponsor Representative Authority Letter'.	N/A
Metro South Delegate	• The Research, Ethics and Governance Directive (QH-HSD-035) details requirements for research conducted at a Queensland Health or Hospital and Health Service facility. The Health Service Directive is primarily focussed on ethical review and site-specific assessment, and includes the following: • "The relevant health service chief executive (HSCE) (or their delegate) will review the application and make a decision whether to authorise the carrying out of the research activity proposed in the research application within 25 clock days from the date of acknowledgement by the RGO of a valid SSA (i.e., referral for a decision)".	N/A
Sponsor Representative	• Responsible for the conduct of the entire trial at the site/s including ensuring that appropriate monitoring of site is in accordance with this work instruction and any other applicable requirement. • The Sponsor Representative is nominated via the MSH Sponsorship Application	N/A

	Form and endorsed by the Metro South Sponsorship Committee.	
Principal Investigator (PI)/ Coordinating Principal Investigator (CPI) and study team	• For single site trials, the Principal Investigator is responsible for overseeing the conduct of the trial at the stie ensuring that appropriate monitoring of trial activities is in accordance with this work instruction and other applicable requirement. • For multi-site trials, the Coordinating Principal Investigator is responsible for overseeing the conduct of the trial at each site participating in the trial including ensuring that appropriate monitoring of trial activities is in accordance with this work instruction and any other applicable requirement. • Other trial personnel are responsible for conducting monitoring activities under the direction of the CPI/PI in accordance with the trial delegation log. • The PI/CPI is responsible for preparation of the MSH Sponsorship Application Form and associated documents	N/A

DEFINITIONS

Term	Definition
Budget	A detailed budget which outlines the adequacy of available resources to support the ongoing management of trial sponsor responsibilities (quality assurance, monitoring, audit).
Clinical Trial *(National Clinical Trials Governance Framework)*	A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials include but are not limited to: • Surgical and medical treatments and procedures • Experimental drugs • Biological products • Medical devices • Health-related service changes

	• Health-related preventative strategies • Health-related educational interventions.
CTN and CTA Scheme	The Clinical Trial Notification (CTN) scheme is a process for the clinical trial sponsor to notify the TGA of the intent to sponsor a clinical trial involving an 'unapproved' therapeutic good. The Clinical Trial Approval (CTA) scheme is an approval process for the TGA to supply 'unapproved' therapeutic goods in a clinical trial.
Data Safety Monitoring Board (DSMB)	A multidisciplinary group established by the trial sponsor to review, at regular intervals, accumulating trial data, in order to monitor the progress of a clinical trial. Their role is to provide advice on safety and/or trial conduct issues by making recommendations to the sponsor on whether to continue, modify or stop a trial for safety or ethical reasons.
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.
Investigator-initiated clinical trial	A clinical trial that has the following characteristics: • A pharmaceutical/device company is not acting as the sponsor for the purposes of the CTN application. • A pharmaceutical/device company is not fully funding the conduct of the study, that is, making payment to the relevant hospital or investigator. • The clinical trial addresses relevant clinical questions and not industry needs. The CPI/PI or the hospital/institution is the primary author and custodian of the clinical trial protocol.
Monitor	A person appointed by the sponsor to undertake the role of monitoring for the trial. Monitors should be appropriately trained and should have the scientific and/or clinical knowledge needed to monitor the trial adequately.
Principal Investigator (PI)/Coordinating Principal Investigator (CPI)	An individual responsible for the conduct of a clinical trial at a trial site ensuring that it complies with GCP guidelines. If a trial is conducted by a team of individuals at a trial site, the Investigator is the responsible leader of the team and may be called the PI/CPI in this instance they may delegate tasks to other team members.
Research proposal	A research proposal is a document prepared by researchers to outline the planned research project. It is usually submitted to funding agencies, research institutions, or academic committees to seek approval and secure resources, such as grants or permissions, necessary to conduct the research.

Research protocol	A research protocol, also known as a research plan or study protocol, is a detailed document that provides a roadmap for carrying out a specific research project. It is typically developed after the research proposal has been approved and serves as a guide for the research team during the implementation phase of the project. Preparation of a research protocol is mandatory. Researchers may utilise MSH research protocol guides and templates however, it is important to note that not all fields are required.
Sponsor	The sponsor is responsible for ensuring that the clinical trial is conducted in accordance with the protocol, GCP and applicable regulatory requirements. Specifically, MSH is the sponsor for investigator-initiated clinical trials where MSH personnel has written the protocol, data is owned by MSH and/or is named on the CTN (as applicable).
Sponsor representative	An appropriate accountable officer who has the required knowledge, skills and attributes to effectively manage and monitor activities required to meet Metro South Health's responsibilities in accordance with relevant regulatory frameworks and guidelines. The Sponsor Representative has delegated authority to: assess risk associated with the trial; identify which risks are acceptable and which must be addressed; implement an appropriate monitoring program that is proportional to the risk; and determine whether an independent data and safety monitoring committee needs to be established, based on the requirements of the study. Options may include: • Principal Investigator of the Clinical Trial • An experienced Clinical Trial Coordinator or Trial Unit Head • Head of Department/Division • Executive Director, Facility/Service • Executive Director, Research

RELATED AND SUPPORTING DOCUMENTS

Legislation and other Authority	**Legislation (as updated and replaced from time to time)** • *Hospital and Health Boards Act 2011* (Qld) • *Information Privacy Act 2009* (Qld) • *Privacy Act 1988* (Cth) • *Public Health Act 2005* (Qld) • *Statutory Bodies Financial Arrangements Act 1982* (Qld) • *Therapeutic Goods Act 1989* (Cth) **Regulations** • *Hospital and Health Boards Regulation 2012* (Qld) • *Information Privacy Regulation 2009* (Qld)

	• *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) **Other authority** • National Statement on Ethical Conduct in Human Research (2023) • Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) • ICH Quality Guidelines • ISO 9001:2015 Quality management systems – Requirements • Safety monitoring and reporting in clinical trials involving therapeutic goods • Risk-based management and monitoring of Clinical Trials involving therapeutic Goods 2018 • Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving therapeutic Goods • Data Safety Monitoring Boards • Guide to Managing and Investigating Potential Breaches of the Code (2018) **Therapeutic Goods Administration** • Australian Clinical Trial Handbook: Guidance on conducting clinical trials in Australian using "unapproved" therapeutic goods (2020) • Clinical Trials Good Clinical Practice (GCP) Inspections Program • Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) (2016) • Note for Guidance on Clinical Safety Data Management: Definitions and Standards for Expedited Reporting (CPMP/ICH/377/95) 2000 **Department of Health** • Health Service Directive: Research Ethics and Governance Directive QH-HSD-035:2023 • Research Management Policy QH-POL-013:2022 • Research Management Standard QH-IMP-013:1:2022 **Metro South Health** • Metro South Health Research Strategy • Finance Management Practice Manual (FMPM) • Human Resources (HR) Delegations Matrix and Schedule • Metro South Financial Delegation Schedule and Framework • MSH Risk Management Framework • Risk Register - CAMMS • CAMMS Data Definitions
Standards	• National Clinical Trials Governance Framework • National Safety and Quality Health Service (NSQHS) Standards 2nd Ed.

	○ Standard 1 – Clinical Governance ○ Standard 2 – Partnering with Consumers
Supporting documents	**Procedures** • PR2023-411 Research excellence • PR2023-412 Research support and management • PR2023-413 Research administration and compliance **Work instructions** • WI2023-299 Ethical and scientific review of research • WI2023-300 Exemptions from research review • WI2023-301 Site specific assessment in research • WI2023-302 Research contracts and study execution • WI2023-304 PowerTrials - ieMR research support module • WI2023-305 Research monitoring • WI2023-306 Post approval – research amendments, reporting and closure **Guidelines** • GL2023-99 Planning a research project • GL2023-100 Research Participant Information and Consent Form (PICF) • GL2023-101 Research contract clauses • GL2023-102 Use of electronic signatures in research contracts • GL2021-77 Clinical trials • GL2023-103 TeleTrials **Attachments** • Attachment 1: MSH Sponsorship Application Form • Attachment 2: Metro South Sponsorship Committee Terms of Reference

HUMAN RIGHTS ACT 2019

Metro South Hospital and Health Service is committed to respecting, protecting and promoting human rights. Under the *Human Rights Act 2019*, Metro South Health has an obligation to act and make decisions in a way that is compatible with human rights and, when making a decision, to give proper consideration to human rights. When making a decision about research, decision-makers must comply with that obligation. Further information about the *Human Rights Act 2019* is available at: https://www.forgov.qld.gov.au/humanrights.

WORK INSTRUCTION DETAILS

Work Instruction Name	Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials
Work Instruction Number	WI2023-303

Current Version	V1.0
Keywords	Sponsor, responsibilities, investigator-initiated clinical trials, monitoring, research, CTN, CTA, TGA
Primary MSH or Directorate Procedure Reference	PR2023-413 Research administration and compliance
Executive Sponsor	Chief People, Engagement and Review Officer
Document Author	Manager, Research Development, Metro South Research
Next Review Date	December 2026

REVIEW HISTORY

Version	Approval date	Effective from	Authority	Comment
V1.0	7/12/2023	13/12/2023	Chief People, Engagement and Review Officer	• New document