

Business Rules (for Tier 7 Committees)

MSH Sponsorship Committee

These business rules set out the authorisation, purpose, membership and reporting arrangements of the Metro South Health (MSH) Sponsorship Committee and apply to a meeting required or authorised by the MSH Sponsor delegate when MSH is nominated as the sponsor for Clinical Trial Notification (CTN) Scheme investigator-initiated clinical trials.

• PURPOSE

The purpose of the MSH Sponsorship Committee is to advise and make recommendations to the Sponsor delegate (as identified on the MSH CTN Checklist) and relevant Metro South Health facility/service research committee regarding risks involving:

- the clinical and standard of care participants on the clinical trial;
- the financial/corporate arrangements; and
- safety and quality.

• RISK MANAGEMENT

A proactive approach to risk management will underpin the business of MSH. When stood-up, the MSH Sponsorship Committee is to pro-actively identify and manage risks and opportunities within its scope. The role of this Committee is to:

- identify risks and opportunities within its scope including for all recommendations;
- develop and review controls and treatments where appropriate; and
- take such action as is appropriate to receive assurance that risk is being managed if relevant.

If an operational or organisational risk is identified by the Committee, the Chair of the meeting must notify the Director or Executive Director of the location most impacted by the risk. A local risk coordinator provides support for each risk register and can assist in the activity to assess facility or service risks in accordance with the Metro South Health Risk Management Framework. MSH-wide risks can be assessed with the assistance of the MSH Manager, Risk and Compliance.

• REPORTING

The MSH Sponsorship Committee provides the following reports:

Position	Report	Description	Frequency	Responsibility
Chief, People, Engagement and Research Officer, Metro South Health	Copy – Sponsorship Approval Letter for noting	A formal approval letter which is developed following review by the MSH Sponsorship Committee	As required	Executive Director, Metro South Research

The relevant Metro South Health facility/service research committee receives the following reports:

Committee	Report	Description	Frequency	Responsibility
Chair, of the relevant Metro South Health Research Committee	Copy – Sponsorship Approval Letter for noting	A formal approval letter which is developed following review by the MSH Sponsorship Committee	As required	Executive Director, Metro South Research
Executive Director of the relevant Metro South Health facility or service.	Copy – Sponsorship Approval Letter for noting	A formal approval letter which is developed following review by the MSH Sponsorship Committee	As required	Executive Director, Metro South Research

• **ATTENDEES**

The Executive Director, Metro South Research will Chair the meeting ('the Chair').

The attendees for this meeting are as follows:

Member Position	Risk Responsibility
Static members	
Chair: Executive Director, Metro South Research	Research Policy Framework
Deputy Chair: Manager, Research Integrity & Compliance, Metro South Research	Research integrity and compliance (ethics & Site-Specific Assessment)
Co-opted members as identified by the Chair based on the clinical trial	
Clinical Lead from the Division/Departmental Head - medical/nursing/allied health	Clinical and standard of care
Divisional/Departmental Director and/or Executive Director Facility/Service	Financial and corporate
Manager, Patient Safety & Quality or Executive Director Medical Services (EDMS has portfolio & responsibility for all CTN trials)	Safety and quality

Unless otherwise authorised by the Authorising Authority or by these Business Rules:

- (i) attendance at the meeting is mandatory
- (ii) an attendee is not authorised to send a proxy on the attendee's behalf.

• **ADMINISTRATIVE ARRANGEMENTS**

Meetings

Meetings are scheduled to occur when a request for MSH to act as Sponsor is received except as otherwise notified by the Authorising Authority from time to time. Cancellation and re-scheduling of meetings will be at the discretion of the Chair. Meetings will be held virtually via Microsoft Teams.

Agenda

The Agenda for the meeting will be set by the Chair.

Secretariat

The Executive Support Officer, Metro South Research ('the Secretariat') is to provide secretariat support to the meeting, including the preparation and circulation of meeting papers and administrative support.

The Secretariat will prepare and maintain a corporate file of the Committee's records.

Meeting Papers

The Secretariat will endeavour to distribute the agenda and meeting papers (if any) to the attendees at least five (5) days before the scheduled meeting date.

The Chair may allow the distribution of additional meeting papers closer to the meeting or to be tabled at the meeting.

The minimum requirement for meeting documentation is an Agenda and Action Register.

Evaluation

MSH Sponsorship Committee members will be given the opportunity to provide verbal or written feedback on the function of the Committee in its ability to meet its purpose as set out in this document.

At the end of each financial year a self-assessment of performance will be undertaken as directed by the Chair. This may take place during a scheduled meeting, or conducted via correspondence.

Review of Business rules

The Chair reserves the right to amend the Business Rules from time to time and will review the Business Rules no less than once every two years.

Business Rules Approval

These Business Rules have been endorsed by the Metro South Health Research Council and approved by the Authorising Authority:

Name: Professor John Upham

Position: Executive Director, Metro South Research

Signature: 

Date: 07/12/2023

Document History

Date	Details of Amendment
1.0	TOR attached to WI2023-303 Metro South Health sponsorship of Clinical Trial Notification (CTN) scheme trials