MCRI SPONSORSHIP COMMITTEE (SC)
TERMS Of REFERENCE

REVISION HISTORY

Version No.	Date	Summary of Changes
1.0	04/02/2021	Initial version
2.0	20/12/2024	Updates to the scope and responsibilities of the Sponsorship Committee. Clarity provided on eligibility of trials for sponsorship as well as the SC reporting and escalation process. Communications for SC Chair and members also added.

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murdoch children's research institute

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1. STRUCTURE OF THE SPONSORSHIP COMMITTEE

1.1 Members

The Sponsorship Committee membership consists of:

Role / Affiliation
Medical Director Melbourne Children's Trial Centre (MCTC)
Business and Operations Manager Melbourne Children's Trial Centre (MCTC)
A Clinical Trial Manager (MCRI-sponsored trial) (MCTC)
Clinical Research Development Office Lead / Regulatory & Compliance Manager (CRDO)
Director of Research Operations Research and Governance (REG)
Senior Trialist (1-3 depending on expertise and availability)*
Finance Lead Research Support and Operations
General Counsel or Delegate Legal Office
Grants Manager or Delegate Grants Office
Clinical Research Development Office (CRDO) Lead
Representative from Office of Research
Invited attendees

*Senior trialists are appointed for 3-year terms, with the possibility of up to 2 further terms (9 years total).
Additional invited attendees may be:

Role / Affiliation
Sponsorship Administrator Melbourne Children's Trials Centre
Representative(s) of clinical trial team undergoing initial review
Additional expertise as required e.g. advanced therapies, qualitative research, data office etc.

1.2 Chair of the SC

The Chair of the Sponsorship Committee (SC or Committee) is the Medical Director of the MCTC or their delegate. The Chair will appoint a committee member to facilitate meetings when required.

2. SCOPE and RESPONSIBILITIES OF THE COMMITTEE

2.1 Scope of the Sponsorship Committee

The scope of the Committee's operations is clinical trials where MCRI is proposed as the Sponsor of the trial.

A clinical trial as defined by the WHO's Guidance for best practices for clinical trials is any research study that prospectively assigns human participants to one or more interventions and evaluates the effect of the intervention(s) on health-related biomedical or behavioural outcomes. A research study is a systematic investigation designed to develop or contribute to generalisable knowledge. For further clarification, and to assist in cases where it is unclear if a project is a trial or not, the project will be evaluated by the Chair as to whether or not it is a trial using MCTC187 Guidance Clinical Trial Decision Tool, and the decision referred to the Committee for discussion if needed.

2.2 Responsibilities of the Sponsorship Committee

The Committee's responsibilities are:

1. To evaluate whether a proposed Trial is eligible for sponsorship and if MCRI has capacity and capability to be the sponsor of the proposed Trial.
2. To ensure research teams have identified relevant risks and have mitigation strategies in place appropriately manage these risks.
3. To provide institutional oversight of the approved Trial, reviewing any change to the risk of the trial as reported and evaluating whether the team is adapting to changes as required.
4. To ensure the Trial aligns with the strategic goals and values of the Institute

The SC does not replicate the HREC process of considering the merit and integrity of the trial, but as the sponsoring entity shall consider the scientific quality and feasibility of the proposed trial. Where necessary, the SC may refer relevant matters to HREC.

3. SPONSORSHIP APPLICATION

3.1 Refer to the Standard Operating Procedure MCTC037b SOP | Sponsorship Application Process for IITs.

3.2 Trial requirements to be eligible for Sponsorship

Proposed Trials must meet the following conditions to be eligible:

- The Principal Investigator (PI) must be either a paid employee of MCRI or RCH, OR

- Where the PI is not employed by MCRI, must at a minimum hold an honorary position at MCRI AND
- Trial funding (and grant if applicable) is administered by MCRI

For all other situations, sponsorship may be considered by the Committee on a case-by-case basis.

4. FREQUENCY AND FORMAT OF MEETINGS

4.1 Meeting Frequency

Meetings will be held monthly (or as defined by the Committee), except in January. 50% of members are required to attend meetings, if not then a quorum is not reached.

Trial Sponsor-Investigators (or delegates) may schedule a meeting with the Chair to review and discuss their application prior to the scheduled committee meeting.

4.2 Ad Hoc Meetings

Additional ad hoc meetings of the SC may be scheduled if required. Serious incidents impacting MCRI sponsored trials including serious safety issues (SSIs), urgent safety measures (USMs), serious breaches, trial suspension or substantial changes to the trial design should be brought to the Committee via an ad hoc meeting or via email notification for discussion. If the matter is deemed urgent an ad hoc meeting may be conducted with the Committee to discuss, or email circulated to notify all members. If the matter is non-urgent it may instead be added to the next available meeting agenda for discussion. Any decisions made outside of an SC meeting by any member of the SC must be noted and circulated for Committee endorsement. Where urgent and/or appropriate the Chair is to be involved in any decision making along with relevant area of expertise SC member e.g. legal representative, grants representative, integrity office etc.

4.3 Notification and Ratification of Chair Decisions

If trials are determined to be of low institutional risk the Chair may grant MCRI Sponsorship approval without the submission being reviewed by the Committee. Such decisions will then be an agenda item at the next SC meeting to notify the Committee of the decision and provide opportunity for any queries or clarifications to be made. This process will also be followed for other non-urgent Chair decisions such as the denial to sponsor a trial due to it not meeting eligibility etc.

5. CONSIDERED RISKS

The aspects of risk that the SC are concerned with are outlined in MCTC007 MCRI Sponsorship Form and Risk Matrix, and MCTC035 Trial Risk Assessment and Management Tool. However, researchers are encouraged to add to the templates as necessary.

The domains of risk identified in the matrices include, but are not limited to:

- Inadequate funding
- Inadequate insurance cover
- Recruitment fails to meet target
- Outcomes not collected
- Protocol violation
- Protection of data and samples
- Staff and skills
- Team cohesion
- Contracts with external stakeholders
- Impact
- Harm to participant
- Risk by type of investigational product
- Expected hazards related to the intervention
- Non-compliance with consent process
- Serious breach of protocol, ethical requirements, confidentiality
- Unreliable outcome assessments
- Lack of robust procedure for assignment to intervention
- Inadequate system for identification/reporting safety events
- Deficiencies in IMP manufacture/distribution
- Poor site IMP management
- Lack of clarity re personnel responsibilities
- Inadequate facilities

5.1 Reporting and Escalation Procedure

Where a Trial has been deemed to have severe risks at the outset or arise during the Trial (as defined by MCRI Risk Management Framework) associated with Trial sponsorship, the decision to sponsor must be made by MCRI Senior Leadership Team (SLT). A briefing paper drafted by the SC articulating the risks and benefits of sponsorship is to be provided to MCRI SLT for approval. The Melbourne Children's Clinical Trial Governance Committee (CTGC) will be notified of concerns and ultimate decisions following MCRI SLT review.

The MCRI Sponsorship Committee reports directly to the MCRI Executive Committee. The SC will provide quarterly reports of SC approvals and decisions to the CTGC that will be included in their own reports to the MCRI SLT.

For any urgent escalations, the Chair may take concerns or issues directly to the MCRI SLT. MCRI SLT decisions will be relayed to the Committee by the Chair.

6. COMMUNICATIONS

At any time during a Trial, regulatory authorities, the Human Research Ethics Committee, local research governance office (Melbourne Children's and external sites, as applicable), the DSMB or any other party or

individual involved with the conduct of the trial may seek the advice of the SC about any concern that they may have about the conduct, outcome, or continuation of the trial. Any such requests should be forwarded in writing to the Chair or SC Administrator at mctc@mcri.edu.au.

Matters related to sponsorship can be referred to the Sponsorship Committee at anytime by any member of the committee, or source external to the SC. The Chair will ensure that serious matters are relayed to the Committee in a timely manner via email. Other members of the SC are also required to inform the Chair if they become aware of anything relevant to sponsorship, that will then be relayed by the Chair to the Committee as appropriate, see 4.2 Ad Hoc Meetings. The Sponsorship Committee reserves the right to terminate sponsorship at any time if the risk of the trial to MCRI becomes too great.

7. REPORTS

The Sponsorship Committee reports to:

- MCRI Executive Committee
- The MCRI Senior Leadership Team

8. TERMS OF REFERENCE REVIEW

The SC Terms of Reference will be reviewed and updated at least biannually, or as required.