CERTIFICATE OF SPONSORSHIP

murdoch children's research institute

This certificate has 2 functions:

1. Acknowledges that MCRI accepts of the role of sponsor for the proposed clinical trial
2. Details the delegation of specific Sponsor (Institutional) responsibilities to the Sponsor-Investigator

REFERENCE NUMBER		
PROJECT TITLE		
SPONSOR-INVESTIGATOR	**Name**	**Phone**
	Department	**Email**

In signing this document the Sponsor-Investigator acknowledges and accepts the responsibilities delegated to them and agrees to;

1. Conduct all trial related duties including the delegated duties, outlined in table 1, with diligence and integrity in compliance with:
   - This delegation,
   - The protocol and procedures,
   - The project agreement,
   - The National Statement on Ethical Conduct in Human Research (2007),
   - Australian Code for the Responsible Conduct of Research (2007),
   - NHMRC Safety Monitoring and Reporting in clinical trials involving therapeutic goods (2016),
   - Therapeutic Goods Act, 1989,
   - Therapeutic Goods Regulations 1990,
   - ICH Good Clinical Practice E6 R2,
   - Institutional policy and procedures,
   - Any other legislation, regulations, guidelines and policy (including Site responsibilities) applicable to the trial;

2. Attend project management meetings including training, monitoring and reporting meetings;

3. Submit all project reports and required information as requested;

4. Allow access to site documentation for monitoring and audit of compliance.

TRIAL SPONSORSHIP APPROVAL		
Sponsorship Committee	Signature	Date
Sponsor-Investigator	Signature	Date
PROTOCOL / AMENDMENT DETAILS		
Version		
Date		
COMMENTS		

Only amendments impacting sponsorship (i.e. change to study design or participant safety) need to be approved by the Sponsorship Committee.

SPONSOR-INVESTIGATOR/MCRI RESPONSIBILITIES

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As an employee of RCH/MCRI, and as a Principle Investigator requesting that MCRI be the sponsor of your trial, you are now responsible for the tasks listed below. If you cannot tick the boxes next to tasks, to acknowledge them as your responsibility, please name who will be responsible in your place in the space below:

_____

	DELEGATED RESPONSIBILITY	SPONSOR-INV
1	Ongoing trial related risk identification and reporting to Sponsorship committee	☐
2	Ongoing management and oversight of trial activities designed to mitigate risk	☐
3	Conduct of systematic checks and actions during the trial to ensure trial success and completion (i.e. project and budget health checks)	☐
4	Ongoing preparation and readiness for audits of the trial	☐
5	Ensure adequate source data, accuracy of recorded data, filed essential documents and adherence to GCP for all participating sites	☐
6	Representation of project management in event of an audit	☐
7	Management of 3rd parties vendors/suppliers supporting project (including contract drafting, payment and ongoing correspondence). This includes vendors providing drug/device supply sample analysis, internal service departments	☐
8	Operational management of support team working on the project, including project management of study teams located at other participating sites	☐
9	Compliance with the trial design (per protocol) and assessment and management of protocol deviations, including required updates to the protocol and management of roll-out of changes to participating sites	☐
10	Oversight of data cleaning, data analysis, data reviews, medical monitor reviews and data safety monitoring boards (DSMB)	☐
11	Ongoing Adverse Drug Reaction Reporting (if a drug trial) for this site: MCRI/RCH and all participating sites (as applicable per CRDO SOP005)	☐
12	Systematic collection of Serious Adverse Drug Reaction Reports (if a drug trial) for all participating sites for review by a DSMB (if applicable) and communication of relevant safety information to all participating investigators and HRECs, clarify the impact of each report on patient safety, trial conduct or trial documentation	☐
13	Management of trial master file essential documents and correspondence to the Lead HREC and MCRI Sponsorship Committee, including ongoing annual reporting to the lead HREC	☐
14	Management of participant data (the case report form), results and publications (maintain participant anonymity, privacy and consent) according to Australian and local jurisdiction privacy legislation.	☐
15	Provision of adequate start-up and ongoing training of the protocol and trial related tasks for each study team member at all participating sites	☐
16	If a drug or device trial, delegation of oversight of pharmacy preparation, storage and labelling for participating sites	☐
17	Make decision on Premature Termination or Suspension of the trial due to unacceptable levels of risk	☐
18	Ensure appropriate approvals are in place prior to conducting site initiation visits at all participating site	☐
19	Recruitment of appropriately trained clinical trial and therapeutic area expertise	☐
20	Ensure eCTN lodgment with TGA (with support from MCTC) – applicable to drug or device trial only	☐
21	Ensure trial is registered prior to first participant enrolled (with support from MCTC) on the applicable registries (i.e. clinical trials.gov)	☐
22	Set-up Trial Master File for each participating site and ensure it is always audit ready	☐
	Develop study specific guides and processes to ensure all data collected is consistent across participating sites	☐