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| **APPLICATION COVERSHEET****MCRI SPONSORSHIP COMMITTEE** |



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| **Have you read the** [**Sponsorship SOP**](https://webedit.rch.org.au/uploadedFiles/Main/Content/ethics/Sponsorship%20SOP%2031Oct19.pdf) **prior to completing this Application Form?** | Yes/No |
| **Project Reference Number:** Please also refer to the guidance material on **"**[**How to get a project reference number**](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/How%20to%20get%20your%20Project%20Reference%20Number.pdf)**."** |  |
| **Project Title:** |  |
| **Co-ordinating Principal Researcher** | **Name** |
| **Dept or Group** | **Institution** |
| **Phone** | **email** |
| **Contact Person (if different from above)** | **Name** |
| **Dept or Group** | **Institution** |
| **Phone** | **email** |
| **Do you wish MCRI to be the Sponsor of this trial?** | [ ]  Yes [ ]  No |
| **Is the protocol attached?** | [ ]  Yes [ ]  No |
| **Steps for researchers to complete:**1. Read “Standard Operating Procedure (SOP) for Institutional Sponsorship Application and Approval for Sponsor- Investigator Initiated Trials (IITs)” via this research link: https://www.rch.org.au/research/researchers
2. Complete “Table B: The Risk Management Table” for your project.
3. Contact the MCTC Medical Director (email crdo.info@mcri.edu.au) to arrange a review of the documents listed below:
	1. *This application coversheet*
	2. *Draft or Final Protocol*
	3. *Any relevant supporting documents for your protocol (i.e. Investigator Brochure (if you have one)*
	4. ***Completed*** *Table B: Risk Management Table*
4. Attend review meeting with MCTC Medical Director to discuss project prior to sponsorship committee review
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| **Please list below all the institutions planning to conduct this research if different from above.** Please provide names of all participating sites, if there are more than 3, add an additional page to this application if needed |

|  |  |
| --- | --- |
| **Name of Institution** |  |
| **Name of Contact Person** |  |
| **International**  | **[ ]  YES** | **[ ]  NO** |
| **Name of Institution** |  |
| **Name of Contact Person** |  |
| **International**  | **[ ]  YES** | **[ ]  NO** |
| **Name of Institution** |  |
| **Name of Contact Person** |  |
| **International** | **[ ]  YES** | **[ ]  NO** |

**For MCRI Sponsorship Committee to Complete:**

|  |  |
| --- | --- |
| Original Submission  | Date |
| Review by MCTC Director | Date |
| Review at Sponsorship Committee Meeting  | Date |

* 1. Risk Management Table A and B

The table below, “Table A: RISK IMPACT”, helps the SC to make an Impact Level Assessment for each risk detailed for the trial. It is used to complete the last column of Table B. For example, a risk that has a **possible** likelihood of occurring, and would have **major** consequences for the study outcome and/or for the organisation if it was to occur, has a (see dashed circle on the table below). This level of HIGH (Red) RISK IMPACT is used in Table B.

The Table B is prepopulated with 10 risk categories. Most would be applicable to all trials. Each category may have a number of distinct risks. The table has in italics some examples of risks in each category. These are examples which would be applicable to most trials. Sponsor- Investigators may delete those risks that are clearly not applicable and add other risks that are relevant to their trial. It would be expected that Sponsor- Investigators identify individual risks, beyond those given as examples. The table also includes examples in italics of possible impacts and mitigation strategies. Sponsor- Investigators should not just cut and paste these. Each should be considered carefully in the context of the trial and amended or added to as appropriate.

**Table A:** **RISK IMPACT**

| **Likelihood** | **Insignificant Consequences** | **Minor Consequences** | **Moderate Consequences** | **Major Consequences** | **Catastrophic Consequences** |
| --- | --- | --- | --- | --- | --- |
| **Almost Certain** | Low | Medium | High | High | High |
| **Likely** | Low | Medium | High | High | High |
| **Possible** | Low | Medium | Medium | High | High |
| **Unlikely** | Low | Low | Medium | Medium | High |
| **Rare** | Low | Low | Medium | Medium | Medium |

**Table B: Risk Management Table**

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| **Risk Identification*****What event(s) can happen and how it can happen*** | **Consequence*****What are the effects if the risk does occur*** | **Likelihood*****What are the chances that the risk will actually happen*** | **Mitigation Strategy*****What are you doing to prevent the risk from happening or manage the risk if it does happen*** | **Risk Monitoring Plan*****How will you monitor this risk?*** | **Impact Level*****Assigned by Committee from Table 16.1 asssessed on likelihood and consequence*****LOW (Green)** **MED (Orange)****HIGH (Red)** |
| --- | --- | --- | --- | --- | --- |
| 1. **Inadequate funding**
 |  |
| *1.1 funding will run out part-way through the trial*  | *Resources for managing and conducting trial will not be available, trial may not run to completion*  | Choose an item. | *We have funding from the following sources and we plan to seek further funding form the following source*  | *PI will review budget 6 monthly*  |  |
| 1. **Recruitment FAILS TO MEET TARGET**
 |  |
| *2.1 INNACURATE ESTIMATE OF Participant AVAILABILITY*  | *Insuffiicent participant recruitment will mean the study will not have sufficient data to make a satisfactory conclusion regarding the end-point of the study* | *Choose an item.* | *Pilot data on availability of eligible participants has been collected* *Consent likely to be high due to low burden/low risk for participants*  | *NA* |  |
| *2.2 SLOWER Recruitment THAN EXPECTED* | *Insuffiicent participant recruitment will mean the study will not have sufficient data to make a satisfactory conclusion regarding the end-point of the study. Costs may increase* | Choose an item. | *Extend study duration if needed* *Open new sites if needed**Identify and increase recruitment efficiency at each site* *Alter inclusion criteria if needed* *Mass media strategy to increase public awareness*  | *Recruitment rates will be reviewed quarterly by the trial steering committee or DSMB* |  |
| 1. **OUTCOMES NOT COLLECTED**
 |  |
| *3.1 OUTCOME MEASURES NOT FEASIBLE*  | *Loss of primary outcome data* | Choose an item. | *Outcome is a widely recognised tool* *Outcomes have been assessed to be feasible in pilot studies* *Sponsor- Investigators and trial staff trained appropriately in outcome collection* | *DSMB will monitor primary outcome data* |  |
| *3.2 PARTICIPANT DROP OUT*  | *Loss of priary outcome*  | *Choose an item.* | *Careful selection of participants based on…**Retention of participant enthusiasm through…* | *DSMB will monitor primary outcome data*  |  |
| 1. **PROTCOL VIOLATION**
 |  |
| *4.1 Protocol difficult for participants to comply with*  | *Loss of outcome data*  | Choose an item. | *Protocol tested in feasibility studies* *Amendments will be made as required*  | *Outcome data monitored by DSMB and Trial Steering Committee (TSC)* |  |
| *4.2 Protocol difficult for Fellow INVESTIGATORS/clinicians to follow*  | *Loss of outcome data*  | Choose an item. | *Protocol is simple and does not vary substantially from standard of care**Protocol tested in feasibility studies*  | *Trial management team will review sites regularly to ensure protocol is being followed*  |  |
| 1. **DATA and SAMPLES**
 |  |
| *5.1 ERRORS in DAta COLLECTION*  | *Loss of outcome data*  | Choose an item. | *CRFs piloted and found to be easy to complete* | *Data cleaning will be performed in real time and errors reported to trial TSC* |  |
| *5.2 ERRORS IN DATA ENTRY*  | *Loss of outcome data*  | Choose an item. | *Source data regularly checked as follows…**Data will be double entered**Checks placed in data base* |  |  |
| *5.3 LOSS OF DATA through theft, malware etc*  | *Loss of data*  | Choose an item. | *Follow MCRI data husbandry policies**Use recognised secure database maintained on and institute platform*  |  |  |
| *5.4 LOSS OR DeGRADATION Of SAMPLES OR Specimens* | *Loss of data*  | Choose an item. | *Follow MCRI policies* *Use of core lab to store specimens**Use of appropriate refrigerators with appropriate alarms and backup power*  |  |  |
| 1. **STAFF and skills**
 |  |
| *6.1 Lack of experience in trial Central management* | *Failure of trial goals*  | Choose an item. | *Senior staff on trial team**Mentorship from senior staff on team**Experienced coordinator employed**Mentorship from experienced coordinator* |  |  |
| *6.2 Lack of trial statistics skills*  | *Inapprorpiate analyses* | Choose an item. | *Trial statistician on study team**Mentorship and supervision from experienced trial statistician*  |  |  |
| *6.3 Site coordinator or RA under skilled*  | *Poor data collection and protocol adherence*  | Choose an item. | *Site staff trained**CVs maintained for all site staff* *Initiation visits to ensure site staff trained*  | *Central coordinator will ensure site staff qualifications recorded and reviewed*  |  |
| 1. **team cohesion**
 |  |
| *7.1 overall team cohesion fails during the trial*  | *Poor recruitment and data collection*  | Choose an item. | *Regular meetings across sites**Regular trial meetings and updates at conferences**Regular newsletters to all involved Sponsor-Investigator and central study coordinator regularly visits all sites*  | *PI visits sites*  |  |
| 1. **contracts and indemnity**
 |  |
| *8.1 contracts not in place*  | *Disputes lead to poor cohesion or failre to publish**Delay in recruitment if not in place*  | Choose an item. | *Ensure all appropriate contracts between sites are in place* | *PI ensures contracts in place before recruitment at each site*  |  |
| *8.2 indemnity not in place* | *Sponsor-Investigators and institutions liable* *Delay in recruitment if not in place*  | Choose an item. | *Ensure appropriate indemnity in place prior to recruitment at each site*  |  |  |
| 1. **impact**
 |  |
| *9.1 question is irrelevant to practice*  | *Trial has limited impact*  | Choose an item. | *Stakeholders are engaged before design finalised* |  |  |
| *9.2 Question becomes irrelevant due to other advances in understanding of the problem or another similar trail is published*  | *Trial has limited impact* *Trial may be stopped as it is futile*  | Choose an item. | *NA* | *Literature monitored by Sponsor- Investigator or DSMB* |  |
| 1. **harm to participant**
 |  |
| *10.1 intervention is unsafe*  | *Patient harmed* *Trial suspended**Sponsor-Investigators liable* | Choose an item. | *Protocol reviewed by HREC, CTX filed with TGA**Intervention is similar to standard of care* | *DSMB monitors events*  |  |
| *10.2 protocol is inherently unsafe* | *Patient harmed* *Trial suspended**Sponsor-Investigators liable*  | Choose an item. | *Protocol reviewed by TGA, via CTX and/or HREC* | *DSMB monitors events* |  |
| *10.3 error in following protocol*  | *Patient harmed**Trail suspended*  | Choose an item. | *Site staff trained**Delegation log kept to ensure only trained staff are involved in the trial*  | *Chief coordinator reviews delegation log**Sites are audited**DSMB monitors events*  |  |