

Frequently Asked Questions (FAQ)

Who needs to apply for Sponsorship Approval?

All Clinical Trials require a Sponsor. The Research, Ethics and Governance office will not approve new studies that do not have a clear sponsor. If a Clinical Trial is being led by MCRI and does not have a commercial organisation or external collaborative group acting as the Sponsor then it will need to be submitted to the Sponsorship Committee to get the MCRI's Sponsorship approval. This will mostly effect Investigator Initiated Trials (IITs). The MCTC Director can review your study at any stage and provide feedback on if your study requires Sponsorship.

Why do I need Sponsorship Approval?

MCRI needs to ensure that the organisation has oversight over any trials we are sponsoring, and all risks to the MCRI as the Sponsor and institution conducting the study are identified and managed or mitigated. We want to make sure that all trials have resources for their entire duration, can reach their objectives, are audit-proof, and are publishable. NHMRC requires all trials to have a clear sponsor.

At what stage should I apply for Sponsorship Approval?

You should submit when you are close to submitting your ethics application. The sponsorship committee require a protocol that is complete, or close to completion.

Will this hold up my research?

No. Sponsorship Approval runs in parallel to Ethics Review, so this should not slow down a trial that is otherwise ready for Research, Ethics and Governance Approval. In addition, the Risk Management Plan will ensure that your trial is less likely to be held up should you encounter any bumps down the track.

The Committee meets on a [monthly basis](#), and submissions close two weeks before this to make sure any questions the Committee members have can be addressed. Please submit your trial early if you have any concerns about your preparedness for approval.

How does this interact with Peer Review, Ethics, and other reviewing bodies?

We recommend that you submit your application to the Sponsorship Committee close to ethics submission to ensure that you do not need to resubmit your Protocol if/when you need to make substantial changes.

What do I need to do to apply?

Please read the [Standard Operating Procedure \(SOP\) for Institutional Sponsorship Application and Approval](#), complete the [Sponsorship Application form and Risk Matrix](#), and submit this with a draft of your Protocol, Evidence of Funding, and your budget to mctc@mcri.edu.au. This will be reviewed

by the MCTC Director, who will let you know if you need to make any alterations or additions. After the appropriate changes have been reviewed and signed off by the MCTC Director your submission will be reviewed at the next Sponsorship Committee Meeting.

Can I just outsource this whole thing to my PhD student?

No! The Principal Investigator will be delegated a range of institutional (Sponsor) responsibilities as the Sponsor-Investigator, including (but not limited to) identifying, reporting and mitigating trial related risks – not the PhD student.

What happens after I have been approved?

You will be sent a Certificate of Sponsorship which you can include in your application to REG. The Sponsorship Committee will review the trial to ensure there are no changes in risk on an annual basis. Trials found to be of higher risk may be reviewed more regularly.

What if my Protocol is amended?

You will need to notify the committee if changes are made to the protocol any time after the initial approval that substantially impacts the risk of the trial. You will also need to update and resubmit the Risk Management Table for review at the next Sponsorship Committee Meeting.

While the Sponsor-Investigator holds the primary responsibility for determining whether a protocol amendment substantially changes the risk of a trial, REG staff reserve the right to reject an amendment that has not been reviewed by the Sponsorship Committee should they consider the proposed amendment to substantially change the trial's risk.

Do all applications have to go to the Committee?

No. The MCTC director can provide a Certificate of Sponsorship for trials which are deemed of negligible risk without you needing to submit a risk matrix. The MCTC director would of course need to see the protocol and budget to make this decision and is likely to want to discuss the project with you directly.