Aim of the Melbourne Children’s Trials Centre (MCTC) endorsement process

The ultimate aim of MCTC is to aid the efficient delivery of high quality clinical trials. A number of strategies have been developed to enable this. One strategy is endorsement.

The specific aims of endorsement are to:

a) Increase the quality of trials by providing an incentive for trials to be designed and run at a uniformly high standard
b) Increase the quality of trials by encouraging researchers to fully engage with the enabling services of MCTC
c) Increase the chance of external funding by establishing a recognised high quality brand
d) Increase efficiently in MCTC by focusing the finite resources within the MCTC to support high quality trials
e) Set the framework for a future accelerated or prioritised ethics approval process
f) Set a framework for future prioritisation of trial funding at a campus level

What projects can be submitted for endorsement by MCTC?

MCTC will consider any investigator-driven trial where Melbourne Children’s Campus plays a leading role in the design and conduct of the trial for endorsement.

Endorsement process

Endorsement by the MCTC will be determined by the Medical Director of MCTC and the Associate Director of Biostatistics of the MCTC. If any issues are identified during the endorsement process, these must be resolved in a manner that is satisfactory to the MCTC prior to endorsement being granted.

Endorsement is an ongoing process. The standards required for endorsement will change as the trial goes from planning to completion. Trials may be endorsed at any stage.

There are key stages where endorsement will be granted or renewed:

• Concept stage
• Prior to submission to ethics
• Prior to submission to funding bodies
• During recruitment
Ideally researchers would take advantage of the endorsement process and seek endorsement in the concept stage.

Endorsement in the concept stage is given once the MCTC is satisfied that the trial concept and broad plans are satisfactory (see endorsement criteria). To be considered for endorsement the PI must attend a meeting with the MCTC Medical Director and Associate Director of Biostatistics to discuss the research question and study plan. To do this email mctc@mcri.edu.au

After this initial meeting, the PI will be asked to complete a Concept Statement providing a summary of the details of the trial. This will begin the endorsement process.

Once the Director of the MCTC and the Associate Director of Biostatistics are satisfied that the criteria are met then a written letter will be issued indicating that the planned trial has received endorsement.

Endorsement should be renewed prior to ethics submission and grant submission. Endorsement will not be ongoing if the protocol is not reviewed by the MCTC or if it is not of sufficient quality. Another letter indicating ongoing endorsement will be issued at each of these stages.

Lastly endorsement will only be continued if the trial is conducted according to the protocol and the basic principles of Good Clinical Practice. This will be assessed regularly by MCTC throughout the study. The MCTC reserves the right to withdraw endorsement at any stage should the study not be progressing appropriately and/or if the above conditions are not met.

Investigators must not indicate in the protocol, or anywhere else, that a study is endorsed by the MCTC unless an appropriate endorsement letter has been received.

**Endorsement criteria**

In order to qualify for initial endorsement, a trial must have the following:

- a relevant and answerable research question; including some evidence that there has been sufficient engagement with all stakeholders
- an appropriate trial design, including an appropriate plan for randomisation and blinding of participants
- a feasible sample size
- a detailed research plan, including:
  - clear objectives
  - details on recruitment and randomisation
  - a valid process of informed consent
  - details on follow-up of participants
  - an appropriate sample size calculation
  - a reasonable statistical analysis plan
- a suitable team to carry out the research, including relevant clinical and trials experience, mentorship (if required), and statistical support
- a budget plan
Along with an appropriate protocol the trial will receive ongoing endorsement providing that:

- ethics approval has been granted
- the trial is registered on either ANZCTR or clinicaltrials.gov
- the MCTC are satisfied that the trial is being conducted to a high standard in line with Good Clinical Practice and that the trial is conducted in compliance with the protocol.

**Endorsement and MCTC Support**

Endorsement is not a requirement for support from MCTC, although support will be prioritised to endorsed trials.

Benefits of MCTC endorsement:

- Endorsed trials will benefit from close collaboration between the MCTC and members of the trial team.
- Endorsement will be a mark of quality that will be appreciated by external funding agencies.
- Resources within the MCTC (including assistance with protocol development and grant applications, statistical and data management support, and mentorship for trial co-ordinators and PIs) will be prioritised to trials that are endorsed by the MCTC.
- Endorsement by the MCTC will also be seen favourably by both the Ethics Committee and the hospital foundation, and we envisage a smoother run through both ethics and NHMRC for endorsed studies.

**Endorsement for studies other than trials**

In some circumstances observational, pilot and feasibility studies may receive letters of support if they are of suitable quality and there is a commitment by the researchers to seek endorsement for the subsequent trial (if appropriate). Note, letter of support of a pilot or feasibility study does not mean automatic endorsement for a subsequent trial.