National Clinical Trial Governance Framework

How to prepare for accreditation

What is the NCTGF?

The NCTGF is a subset of the first two National Standards:

Standard 1 – Governance, and

Standard 2 - Partnering with Consumers.

The actions required to meet the NCTGF are designed to integrate clinical trials with routine clinical care in a health service.

Will all clinical trials be assessed?

No, the lead assessor will request a list of ALL open clinical trials across the campus.

Note: If you have finalised trials that have not been closed in DERP – please considered / when these need to be closed. If in doubt, check with the REG Office

The assessors will select approximately 30 trials to review and will expect to speak with the clinical trials team, including PIs, research support staff and participants.

What do I need to do?

To be ready for the assessors when they visit, we have included a list of evidence that you will need to have 'at hand' and be ready to show assessors if your trial is identified as one being assessed.

Follow the steps in the table below to ensure you are ready for the RCH Organisational Wide Accreditation – short notice assessment (also known as SNAP).

Action		Details	Evidence required
1..	Verify trial documentation	• Ensure your **Investigator Site File (ISF)** is up to date and stored securely (e.g. SiteDocs, Florence, SharePoint). • Maintain complete records for Clinical Trial Notifications (CTN), ethics approvals, and current protocols.	Some examples include (but not limited to) Current delegation logs, consent forms, participant information and agreements.
3.	Confirm consent process compliance	• Verify that all consent processes align with Good Clinical Practice (GCP) and HREC-approved protocols. • Ensure documentation of the consent process, including use of interpreters and participant engagement	Complete, accurate and up-to-date records as required by ICH E6 (R2) GCP Examples include (but not limited to). Signed Participant Information and Consent Forms (PICFs) and medical record entries for consent discussion

4.	Ensure study team training	• Ensure all team members have completed required training (GCP, Open Disclosure, Statutory Duty of Candour) • Store certificates in both personal files (e.g. Florence) and Site Files	Training logs with documented completion of mandatory and site-specific training Training certificates MCTC194a SOP Trial Specific Qualification, Education and Training - Clinical Trials Team Members
5.	Clinical Trial Governance	• Familiarise your team with the Governance structure for clinical trials at the Melbourne Children's	Be able to refer to the Melb Children's Clinical Research Governance and Support handbook on the MCC Research Hub (soon to be published)
6.	Roles and Responsibilities of Clinical Trials staff	• Ensure members of the trial team are aware of and know their Roles and Responsibilities.	Be able to refer to the Melb Children's Clinical Research Governance and Support handbook on the MCC Research Hub. (soon to be published **SOPs** MCTC182 SOP | Sponsor-Investigator Responsibilities in MCRI-Sponsored IITs
7.	Update Policy and SOP awareness, including incident / adverse event reporting	• Familiarise your team with current MCTC, RCH and MCRI policies and procedures and ensure everyone knows how to report adverse events/ incidents etc	Documented adverse event / incident reports and adherence to clinical trial safety reporting SOPs
8.	Open Disclosure	• Familiarise your team with the RCH Open Disclosure e-Learn and SIM training	Evidence of training for Open Disclosure
9.	Consumer / Participant Feedback	• Familiarise your team with the MCTC, RCH, MCRI policies and procedures for consumer (participant) feedback management	Documented examples of consumer feedback related to your clinical trial.
10.	Charter of Healthcare Rights	• Ensure you are aware of the Charter of Healthcare Rights and how you can direct participants to the Charter	Evidence of information relating to the Charter of Healthcare rights in participant information packs, and on poster boards in clinical trial spaces.

11.	Demonstrate Consumer Involvement	• Document consumer engagement in trial design, ensuring fair and equitable access for all populations, including CALD and Indigenous communities.	Notes on consumer engagement and efforts to ensure equitable trial participation.
12.	Access facilities and equipment	• Ensure that trial equipment is operational, tagged and that unused equipment is removed. • How do you (your team) know that equipment is checked and calibrated/ serviced as required?	Documentation of equipment maintenance and facility readiness
		•	