

National Clinical Trials Governance Framework

Short Notice Assessment Checklist for Each Clinical Trial

✓	Checklist items:	Which NCTGF standard does this item address?
	HREC and governance approval letters on Study Master File (SMF)	1 – Clinical Governance
	Signed & dated Participant Informed Consent Form for each participant is on the participant's Scanned Medical Record and on the Study Master File (SMF)	1 – Clinical Governance, 2 – Partnering with Consumers
	EMR Alert created for each participant enrolled on the clinical trial	1 – Clinical Governance
	Recording of participants who identify as Aboriginal or Torres Strait Islander on EMR	1 – Clinical Governance, 2 – Partnering with Consumers
	Total number of actual and planned participants recruited overall in the study is easily accessible at short notice.	1 – Clinical Governance
	Total number of actual and planned participants recruited at this site in the study is easily accessible at short notice.	1 – Clinical Governance
	GCP for all study personnel up to date and a copy on the Study Master File	1 – Clinical Governance
	Authority delegation log for the study up to date and on the Study Master File	1 – Clinical Governance
	All of the study team understand the complaints management process in the event of a participant complaint	1 – Clinical Governance
	Safety reporting is up to date and copies on the Study Master File, along with HREC and Governance acknowledgements <i>*please note that safety reporting will be monitored at an organisational review level</i>	1 – Clinical Governance
	Progress reporting is up to date and copies on the Study Master File, along with HREC and Governance acknowledgements	1 – Clinical Governance
	The Charter of Healthcare Rights is provided to all participants & posters are visible in clinical area	1 – Clinical Governance 2 – Partnering with Consumers
	Record of Device calibration/credentialing documents for all device studies on Study Master File	1 – Clinical Governance
	Mandatory Training up to date for all study personnel, including Open Disclosure Training for the Principal Investigator	1 – Clinical Governance
	Ensure participants are aware of study emergency contact (i.e. does the participant know who to contact in an emergency?)	1 – Clinical Governance
	Ensure team is aware of Aboriginal Health contact and interpreter services contact to link participants who require it.	1 – Clinical Governance 2 – Partnering with Consumers
	Ensure all staff is aware of how to lodge a feedback on RiskMan (including complaints and compliments)	1 – Clinical Governance
	Awareness of the Consenting procedure/process	1 – Clinical Governance
	Awareness of the Safety Reporting procedure	1 – Clinical Governance
	Awareness of departmental strategic plan and position descriptions	1 – Clinical Governance
	Awareness of consumer feedback reporting procedure (i.e. where do consumer complaints & compliments get reported and how)	1 – Clinical Governance 2 – Partnering with Consumers

ALL staff supporting the study should be aware of these resources:

- [Research Complaint Resolution Procedure Training](#) and [Research Related Complaints FAQs](#) on Latte.
- [EMR Alerts Training](#) video on Latte.
- Many of Monash Health's research related procedures have been updated to match the standards of the [National Clinical Trials Governance Framework](#), and can be accessed on [Prompt](#).
A summary table is available on the Research Support Services [Forms Library](#) webpage that provides information on the updated/retired procedures.
- There is a [Monash Health Accreditation](#) webpage open to all Monash Health employees, that has [Employee Resources](#) and [Patient Information Resources](#), and handy information on all the [National Standards](#).
- See Monash Health '[Research Progress Reports](#)' on Prompt and [Progress Reports](#) webpage.
- See '[Research Ethics and Governance - Safety Reporting](#)' on Prompt.