Governance Framework Accreditation Preparedness Activities - Principal Investigators and Trial Teams

	#	Team Review Status comments	Action	What you need to do	More information and CHECKLIST
Critical	1	Identifying Active Trials	**All principal investigators and study coordinators need to know all the trials active in their Departments.**	The NCGTF will assess CTN-registered clinical trials. Contact the Discovery & Innovation Unit if you do not know the status of your trials.	*All Principal Investigators and study co-ordinators should know what studies are active.* **Evidence** • Research teams must maintain evidence of project submission and Ethics and Governance approval in individual project folders (online and/or physical folders). • Maintain up-to-date individual electronic and physical folders for: a. Research projects (Master Site File) b. Participants (Participant sub-file) c. Research Architect – Austin Health clinical research management platform
			Review trial status and close trials that are completed. Consider how open trials have performed against recruitment targets.	Check the Cerner & ERM status of trials that have been closed. Review if active trials are performing well or underperforming; consider reasons for discussion with the Accreditors. Contact Discovery & Innovation Unit to close trials that are not active.	*Details of ALL active clinical trials will be sent to the assessors to select 30 trials for review at accreditation. Trials remaining open in ERM will be included in the list sent to the Assessors for sampling during accreditation.* *Refer to the Commissions Fact Sheet - Sampling for Clinical trials accreditation assessment at* https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework/resources-national-clinical-trials-governance-framework **Evidence** • Check status of all projects and maintain a list of currently active projects with target vs actual recruitment numbers. • Close projects that are not current by submitting a Final Report.
	2	Trial Documentation	**Know where trial documentation is stored and how to access it (appropriate to role).**	Trial Investigator Site File (you may also call this the Research Folders) - may be in SiteDocs, SharePoint or paper-based. This requirement also refers to other source documentation such as CERNER, clinical databases, consent forms, other documents etc. in electronic, paper formats or other formats	*Study co-ordinators and investigators should know where to find the Site Files and ensure they are up to date and CGP compliant.* **Evidence** Principal Investigator demonstrates oversight by: a. Managing/ assigning delegate to maintain and manage delegation logs for individual projects. b. Signing against delegation log to assign responsibilities to suitably experienced and qualified staff in accordance with Austin Health mandatory trainings, obligations and policies. Being informed of the location of project identifiable information, e.g. within secure research department computers, online and physical electronic medical records, registries, databases, participant folders and case report forms.
			Check that the trial Investigator Site File (ISF) is up-to-date and can be located by trial staff.	For all your active clinical trials, ensure the ISF (you may also call this the Research Folders) is up-to-date and is being maintained contemporaneously in accordance with GCP.	*Ensure that you have copies of all approvals, fully executed agreements, CTN information, current protocol, participant facing documents, statements of approvals for service department, screening logs etc.* **Evidence** • Research teams to maintain individual projects folders with current delegation log, evidence of project related training and core study documents (e.g., protocol, IB, master documents, executed agreements etc.
			Confirm Clinical Trial Notification (CTN) documentation is complete and stored in the study file	For CTN studies, ensure that the final CTN documentation (not just the draft) is stored in the study file.	**Evidence** CTN documentation to be stored in project files.
			Review and discuss screening, recruitment, consent and trial processes with the trial team and ensure they are cognisant with the processes and their role in them.	Be prepared to discuss: Who on the trial team can consent (according to HREC approval, Delegation and Signature log), inclusion and exclusion criteria, process for screening, fair and equitable approach to potential participants, consent discussion, translators/support for First Nations or CALD peoples, forms, recording in CERNER etc.	*In the mock accreditation there were a lot of questions about how participants were selected for approach (fair and equitable access to trials) as well as the consent process and documentation.* **Evidence** • Clinical review notes e.g. on Austin Health systems Medical Records, CERNER, TrakCare. • Research Architect – Austin Health clinical research management platform
			Check Consent documentation is complete	Consent is via the HREC (Human Research Ethics Committee) approved process. Documentation = consent forms (current version used when person was consented/reconsented) and medical records entries for the consent discussion/process. Documentation is available for each participant.	*Documentation is complete i.e. signatures, dates, description of consent process in medical records including use of interpreters if used, witness if present, time given to consider decision, note that the person voluntarily chose to participate i.e. consent according to National Statement and GCP requirements* **Evidence** • PICF versions are current and approved by HREC; with evidence of HREC and Governance approval. • PICF has been countersigned by treating clinician or appropriately delegated personnel. • Consent is sought **prior** to screening and treatment. • Maintain physical fully executed consent form in participant file; copy of PICF is given to participant and copy of executed PICF is stored in Medical Records. *PICF: Participant Information Sheet and Consent Form
			Review processes for ensuring fair and equitable access to the clinical trial for all populations	Be able to talk about fair and equitable access to the trial - especially for CALD and Indigenous communities.	*Check if screening logs can identify if First Nations or CALD peoples were approached to consider participation/ were included in the trial - add columns to your screening log to capture in future trials.* **Evidence** • Clinical notes indicating recruitment of participants is conducted ethically, considering circumstances, eligibility criteria and efforts made to include CALD and Indigenous communities. • Notes indicating consumer engagement in designing research (e.g., in Protocol, HREC submission documents – Human Research Ethics Application (HREA), PICF etc.). *CALD: Culturally and Linguistically Diverse *HREC: Human Research Ethics Committee *PICF: Participant Information Sheet and Consent Form *HREA: Human Research Ethics Application
			Study team training and GCP certificates	Ensure all your research staff have completed study training and have available their GCP certificates documented in the study site files. Ensure that Principal Investigators and Associate Investigators have completed Open Disclosure and Statutory Duty of Candour training	*This issue was raised in the mock accreditation process.* **Evidence** • PI and research team have completed required training:

					a. GCP b. Research specific training (e.g. Protocol, eCRF, device or process training if applicable etc.). c. Austin Health organisation mandated training (ATLAS) d. Evidence of training is stored in Research Department folders and personal team member folders (online or physical) and Research Architect – Austin Health clinical research management platform *GCP: Good Clinical Practice *eCRF: electronic Case Report Form
Important	3		**Policy and procedures**	Ensure you are using the most current version of Austin Health policies (available from OPPIC).	**Evidence** *All Research related policies and procedures can be found on the Austin Health intranet page OPPIC at:* https://austinhealth.sharepoint.com/sites/OPPIC
	4		**Check ALL staff know how to report RESEARCH incidents in Riskman**	Ensure everyone in your team understands how to report incidents in trials through Riskman and is familiar with theClinical Trial Adverse Events and Complaints policies	**Evidence** • All significant clinical trial/ clinical research incidents should be reported through: a. Austin Health Research page b. RiskMan • Adverse Events are reported/noted in: a. Clinical notes stored on Austin Health applications (e.g. CERNER, Trakcare, Medical Records) b. Sponsor proprietary platforms (e.g. eCRF) c. RiskMan
	5		**Confirm if there has been Consumer Involvement in trial design.**	All trials under the Framework are required to show evidence of consumer engagement in study planning. Document evidence of consumer involvement in the trial planning in the Investigator Site File. Most current commercial trials have involved consumers in trial design (ask monitor/sponsor)	*The Commission recognises the important role consumers play in the conduct of clinical trial services. The NCTGF requires involvement of consumers at many levels, not just as potential participants. All trials submitted to Austin Health for Ethics and/or Governance Approvals require a statement about consumer involvement in the protocol or as a cover letter.* **Evidence** • Document clinical notes indicating recruitment of participants is conducted ethically, considering circumstances, eligibility criteria and efforts made to include participants from CALD and Indigenous communities. • Notes indicating consumer engagement in designing research (e.g. in Protocol, HREC submission documents – Human Research Ethics Application (HREA), PICF etc.) *CALD: Culturally And Linguistically Diverse *HREC: Human Research Ethics Committee *PICF: Participant Information Sheet and Consent Form *HREA: Human Research Ethics Application
	6		**Be familiar with Austin Health reporting lines with respect to your study trials - i.e. from PI through your service department, division etc. up to the Board** *and* **from PI to Discovery & Innovation Unit up to CEO.**	Understand the reporting structure in your department i.e. via your departmental reporting lines to the PI, thence to the Department Head according to the Organisational Structure. For trials progress reports through the Discovery & Innovation Unit, which reports to the CEO and provides quarterly reports to the Board.	*Clinical Trials are accredited to Quality & Safety Committees: Standard 1- Governance Committee and Standard 2- Partnering with Consumers https://austinhealth.sharepoint.com/sites/NationalStandardsAccreditation/SitePages/National-Standards-Committees.aspx* **Evidence:** Researcher awareness of reporting structure from: a. Individual position to Austin Health Board b. PI to Discovery & Innovation Unit c. PI to lead site/ HREC d. PI to Sponsor and TGA
Good to do	7		**Feasibility reviews**	All feasibility questionnaires are managed locally and with the Discovery & Innovation Unit via Research Architect. The SMART Governance process will help you decide if a project is feasible. Capture the number of commercially sponsored trial feasibilities your Department conducts and how many trials are awarded.	**Evidence** a. Feasibility questionnaires complete b. Meeting minutes of feasibility deliberations c. SMART Governance Committee meeting and minutes d. Research Architect – Austin Health clinical research management platform
	8		**Ensure the trial team members know their role on the trial**	In accordance with the NCTGF the Clinical Trials Workforce includes: a. Principal and coordinating investigators b. Clinical Trial Liaison Officers (if you have them) c. Study Coordinators d. Trial Manager e. Trial Pharmacist on your study f. Research Nurse (Trials) g. Any Austin Health Service Departments involved in your study	*Ensure the delegations log is able to be located, is current and all trial staff listed know their roles.* *Refer to the Commissions Fact Sheet - Roles and Functions for the Clinical Trial Workforce at* https://www.safetyandquality.gov.au/standards/national-clinical-trials-governance-framework/resources-national-clinical-trials-governance- framework.
	9		**Familiarise yourself with what the Austin Health provides to you in terms of clinical trial support**	Includes the Discovery & Innovation Unit, Clinical Trials Pharmacy, Pathology, Radiology and other trial-related partnering departments.	Secure storage, offices, cupboards, secure electronic environment for study records and CERNER, TrakCare, Medical Records, Sponsor proprietary platforms for patient records with designated study builds.
	10		**Check appropriateness of the facilities to conduct clinical trials activities**	Ensure that trial equipment is tested and tagged. Ensure old, unused or broken equipment is removed from the areas where you conduct clinical trials.	*Assessors will look at the general presentation and order of the area.* **Evidence:** • Assessors will visit Research offices, wards, clinics and partnering departments for appropriateness in conducting clinical trials.
	11		**Sponsor provided equipment returned at end of closed clinical trials**	Check that all equipment to be returned to sponsors at the closure of a clinical trial has been sent back. Notify Clinical Engineering that the equipment has been returned so they can update the equipment registries.	*If due to be returned and not yet done, just put a flag on the equipment to indicate you know it is due to be returned*
	12		**Maintain a study Risk Register**	The NCTGF requires risks to be identified and captured in a risk register. A model template for Level 1 risk capture is available from your Divisional Manager/Director. If you have any questions on completing Level 1 risks for your Department, please contact your Divisional Manager/Director or your Quality and Safety Officer.	*Be aware that Level 1 departmental risks are captured at the department level by the HOD. Level 2 risks are those that affect broader operations. Ensure your leadership team is able to enter Level 2 risks per your Division's processes. The Risk policy outlining this process is available on the Pulse. https://austinhealth.sharepoint.com/sites/CorporateServices/SitePages/Enterprise-Risk.aspx .*