CLINICAL TRIAL WORKFORCE

	Responsibility	Checklist
1	Working familiarity of your Organisational Clinical Governance framework policies, procedures, and the related processes and systems	☐
2	Understand the complexity of service user interactions with the clinical trial service, the complexity of the context in which they reside, and their needs as a clinical trial participant Learn to tailor your approaches to meet the differing needs of service users.	☐
3	Undertake regular education and training to maintain credentialling and keep skills and competencies up to date, and expand your scope of practise, as per your organisation's standard schedule	☐
4	Work within your defined scope of practise and in line with your skills and experiences. Work with your manager to assess your scope of practise, performance, and professional competencies at regularly scheduled intervals, as per your organisations standard practise	☐
5	Conduct clinical trials in line with relevant national requirements and in a way that is responsive to change. Including: he National Statement and the Code, the National Clinical Trials Governance Framework, the Australian Open Disclosure Framework, National regulations, standards, codes of conduct, and legislation	☐
6	Conduct clinical trials in line with relevant local requirements. Including the trial protocol, Conditions of HREC and Governance approvals, Your organisational charter and clinical governance framework, Local policies and procedures, Contractual and sponsor requirements	☐
7	Conduct clinical trials responsibly, focussing on integrity, safety, and quality, and within the bounds of organisational systems Support other team members to do the same	☐
8	Develop relationships with key stakeholders (clinicians, colleagues at other sites, consumers, supporting departments, etc.) to support clinical trial operations, service improvement, and best clinical outcomes for participants	☐
9	Perform study, data management, and participant-related tasks, as delegated by the trial investigator and indicated by your skills, experience, and scope of practise	☐

10	Encourage participants, families, and decision makers to actively involve themselves in the decision-making process about their participation in a clinical trial, and their overall care (to the extent that they choose). Ensure participants welfare and desires are prioritised.	☐
11	Perform HREC and SSA submissions of new trials (including budget and contract negotiations), in partnership with the Investigator, and ensure trials have received all relevant approvals before starting	☐
12	Identify and report risks, issues, or anything that could compromise your ability to deliver care in a safe environment. Report using both clinical trial/research-specific and organisational systems and processes. Work with management to resolve issues and implement preventative and corrective actions if incidents occur	☐
13	Use the relevant processes and systems to receive and respond to consumer and service user feedback and complaints. Work with management to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐
14	Provide feedback on the functioning of the clinical trials service by using organisational processes and channels	☐
15	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐
16	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	☐