CLINICAL/NON-CLINICAL MANAGER

	Responsibility	Checklist
1	Identify, communicate to your team and, if relevant, be able to use your Organisational Clinical Governance framework, policies, procedures and related processes and systems	☐
2	Undertake all of your required training and education, as per your organisation's schedule	☐
3	Manage clinical trial workforce training, credentialling and professional competencies, scope of practise and performance by overseeing your team members keeping up to date on all their regular education and training, and assessing their performance at regularly scheduled intervals, as per your standard organisational schedule	☐
4	Conduct the clinical trials service in line with relevant requirements and in a way that is responsive to change. Including the National Statement and the Code, the National Clinical Trials Governance Framework, the Australian Open Disclosure Framework, your organisational charter and clinical governance framework, national and local guidelines, standards, regulations, and legislation	☐
5	Develop relationships with key stakeholders (team leaders, consumers, supporting departments, colleagues at other sites, etc) to support clinical trial operations, service improvement, and best clinical outcomes for service users	☐
6	Develop strategies to engage & communicate with service users about clinical trials (particularly First Peoples, members of culturally diverse peoples, and those whose preferred language is not English) Support team members to tailor their approaches to meet the differing needs of service users	☐
7	Cultivate a team culture where team members conduct clinical trials responsibly, focus on integrity, safety and quality, and work within the bounds of organisational systems	☐
8	Support team members to 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	☐
9	Support your team members to expand their scope of practise (eg by taking on leadership opportunities)	☐

10	Support team members and service users in identifying opportunities to be involved in the development and review of clinical trials service governance	☐
11	Manage clinical trial resourcing and budgeting, identify funding sources, assess whether your organisation has appropriate capacity and resources to support your clinical trials portfolio	☐
12	Appropriately resource your team members to deliver the clinical trials service. Including adequate staff numbers and appropriate workloads, working space, equipment, supplies (clinical and office), access to computers, EMR systems, etc	☐
13	Make your current trial portfolio and service user population primary considerations when assessing the feasibility of new trials. Periodically review trial recruitment to ensure your current trial portfolio is the best use of your resources	☐
14	Monitor and assess potential risk by undertaking clinical trial risk assessments, covering both staff and participants If relevant, use organisational systems and processes (including the organisational risk register) to identify and report risks as they occur	☐
15	Use the relevant processes and systems to manage safety and incident reporting responsibilities. Oversee your team members being trained in, aware of, and actively carrying out their responsibilities in this area. Work with team members to resolve issues and implement preventative and corrective actions if incidents occur	☐
16	Use the relevant processes and systems to receive and respond to consumer, service user, and team member feedback and complaints. Oversee your team members being trained in, aware of, and actively carrying out their responsibilities in this area. Work with team members to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐
17	Receive and respond to audit findings to monitor clinical governance compliance, clinical trial conduct, and take action to deal with any findings	☐
18	Monitor and report on clinical trial activity and performance, in the areas of the clinical trials service that you are responsible for, by reporting on relevant metrics, using data collected at the trial unit level as per your organisation's standard practises	☐
19	Monitor for, and respond to, changes in the areas of the clinical trial service you are responsible for by collecting and reporting on data collected at the trial unit level as per your organisation's standard practise	☐

20	Provide feedback on the functioning of the clinical trials service by using organisational processes and channels	☐
21	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐
22	Look for opportunities to improve the areas of the clinical trials service that you are responsible for	☐