CLINICIAN INVESTIGATOR

	Responsibility	Checklist
1	Use of your Organisational Clinical Governance framework policies, procedures, and the relevant 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	☐
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 clinical lead to assess your scope of practise, performance, and professional competencies at regularly scheduled intervals, as per your organisational standard practise	☐
5	Conduct clinical trials in line with relevant national 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, 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	Lead by example in: modelling responsible clinical trial conduct, focussing on safety and quality, and acting with integrity. Cultivate a culture of this amongst your clinical trial team members	☐
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	Develop strategies to engage and communicate with service users (particularly First Peoples, members of culturally diverse peoples, and those whose preferred language is not English) about participating in clinical trials	☐
10	Hold overall responsibility for the individual trials and research projects you conduct, by supervising the conduct and performance of your research/clinical trial team(s) and working with clinical and non-clinical managers to resolve performance concerns	☐

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11	Delegate clinical governance and/or clinical trial responsibilities to team members (where relevant)	☐
12	Involve participants, families, and decision makers in the decision-making process about their participation in a clinical trial and their overall care, to the extent that they choose, ensuring patient welfare and desires are prioritised and they receive concomitant care during and after the trial	☐
13	Assess the feasibility of new trials in partnership with clinical and non-clinical managers, and make your current trial portfolio and service user population primary considerations here	☐
14	Perform HREC and SSA submissions of new trials (including budget and contract negotiations), in partnership, and ensure trials have received all relevant approvals before starting	☐
15	Identify and report risks, issues, or anything that could compromise your ability to deliver care in a safe environment. Report using both clinical trial and research-specific systems and organisation processes and systems. Work with clinical leaders 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 and service user feedback and complaint. Work with clinical leads to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐
17	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐
18	Provide feedback on the functioning of the clinical trials service by using your organisational standard processes and channels	☐
19	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	☐