RESEARCH OFFICE

	Responsibility	Checklist
1	Working familiarity of 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	Work within your defined role. Work with your manager to assess your performance and responsibilities at regularly scheduled intervals, as per your organisational standard practise	☐
4	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	☐
5	Advise and assist in the development, periodic review, and update of policies and procedures for the clinical trial service to ensure they stay up to date on relevant requirements. 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	☐
6	Develop relationships with key stakeholders (clinicians, colleagues at other sites, consumers, supporting departments, etc) to support clinical trial operations and service improvement	☐
7	Facilitate the provision and delivery of clinical trials, and clinical trial information, in languages, formats, and ways that reflect the needs of the service users, by making consideration of this part of the ethics and governance review process	☐
8	Provide information and education to researchers on GCP, how to responsibly conduct clinical trials, and research integrity, by working with and supporting researchers throughout the lifecycle of their research project, and implementing and managing systems for this	☐
9	Ensure the clinical trial workforce is appropriately credentialled and trained before conducting any research or clinical trial work (including GCP training) by making this part of the SSA review process	☐
10	Maintain records of work done and decisions made by entering and updating records in real time	☐

11	Manage conflicts of interest, complaints, risks, and incidents resulting from the functioning of the clinical trials service by implementing, resourcing, and managing systems and processes for this purpose	☐
12	Monitor and assess potential risks by using clinical trial risk assessments specific to clinical governance and, if relevant, use organisational systems and processes (including the organisational risk register) to record them	☐
13	Use the relevant processes and systems to receive and respond to consumer, service user, and workforce feedback and complaints (including the Australian Open Disclosure Framework). Work with management to resolve issues and implement preventative and corrective actions if feedback and/or complaints are received.	☐
14	Conduct audits to check clinical trials and research are operating in line with relevant requirements. Including clinical governance requirements, the National Statement, the Code, national and local guidelines, standards, regulations, and legislation, etc	☐
15	Monitor for, and report on, clinical trial activity and performance in the areas of the clinical trials service you are responsible for, by reporting on relevant metrics, using data collected at the trial unit level as per your organisation's standard practises	☐
16	Monitor for, and respond to, changes in the areas of the clinical trials service you are responsible for, by collecting and reporting on data collected at the trial unit level as per your organisation's standard practices.	☐
17	Provide feedback on the functioning of the clinical trials service by using your organisational standard processes and channels	☐
18	Contribute to the development, management, and review of clinical trials service governance (including the National Clinical Trials Governance Framework), where opportunities present themselves	☐
19	Look for opportunities to improve the areas of the clinical trials service that you are responsible for, and the care given to participants	☐