|  |
| --- |
| **PRINCIPAL INVESTIGATOR DECLARATION** |
| **Declaration to Central Adelaide Local Health Network by Principal Investigator****Any capitalised terms have the same definitions as in the Medicines Australia Clinical Trial Research Agreements (CTRA) and Medical Technology Association of Australia Clinical Investigation Research Agreements (CIRA)** |
|  |  |  |  |
|  |
|  |  |  |  |
| **Study title** | Enter text |
|  |  |  |  |
| **I certify that:**1. All information in the Site Specific Assessment Form is truthful and complete as possible.
2. I will not commence the Study until the Study has received Reviewing HREC approval and governance authorisation to commence.
3. I have read, understood and accept the responsibilities of the Principal Investigator as outlined in the CTRA or CIRA as applicable and will sign the Principal Investigator Acknowledgement in the CTRA or CIRA.
4. I will conduct the Study in accordance with the Protocol or Clinical Investigation Plan (CIP) as may be amended from time to time, current ICH GCP and/or ISO14155 guidelines and with all ethical and research governance and applicable regulatory requirements.
5. I will provide all Study Personnel involved in conducting the Study with a copy of the Protocol/CIP and any amendments to it and corresponding approvals from the Reviewing HREC.
6. I will supervise the Study and inform the Study Personnel and other employees and subcontractors assisting in the conduct of the Study, of their obligations in meeting these commitments.
7. I will only deviate from Protocol/CIP after notifying and receiving approval from the Sponsor and the Reviewing HREC, except when necessary to protect the safety, rights, or welfare of Study Participants.
8. I have had access to and read the [NHMRC National Statement on Ethical Conduct in Human Research 2023](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) and the [Australian Code for the Responsible Conduct of Research 2018](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018).
9. I have no conflicts of interest or have disclosed any conflicts of interest to the Reviewing HREC and CALHN Research Services and will manage them in accordance with the National Statement and the Code.
10. I will maintain the confidentiality, integrity, privacy and security of information in accordance with the relevant Privacy Laws including but not limited to [Health Care Act (2008)](https://www.legislation.sa.gov.au/lz?path=%2FC%2FA%2FHealth%20Care%20Act%202008), [Mental Health Act (2009)](https://www.legislation.sa.gov.au/lz?path=%2FC%2FA%2FMental%20Health%20Act%202009) and [Department of the Premier and Cabinet (DPC) Circular 12 (PC012) Information Privacy Principles Instructions,](https://www.dpc.sa.gov.au/resources-and-publications/premier-and-cabinet-circulars)[.](https://www.sahealth.sa.gov.au/wps/wcm/connect/60b8550041526f138c0d8ee8f09fe17d/Directive_Privacy_30052017.pdf?MOD=AJPERES&CACHEID=ROOTWORKSPACE-60b8550041526f138c0d8ee8f09fe17d-lNmOOny)

**Signature:****Name:****Date:** |