## Site Specific Assessment/Research Governance – Principal Investigator Declaration

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| Study details |  |
| Project ID: |  |
| Study title: |  |
| Principal Investigator: |  |
| Sponsor/Project Lead: |  |
| Facility site: |  |

**Declaration by Principal Investigator**

* I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility for the sites for which I hold responsibility.
* I will only commence this research project after obtaining the required authorisations from the site/s and approval from the responsible Human Research Ethics Committee (HREC).
* I accept responsibility for the conduct of this research project according to the principles of the NHMRC National Statement on the Ethical Conduct in Human Research (2007; updated 2023) and the Australian Code for the Responsible Conduct of Research (2018) and Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)
* I undertake to conduct this research project in accordance with the protocol and other documentation approved by the HREC and the relevant policies and procedures of the organisation(s) involved and will adhere to the conditions of HREC approval.
* I undertake to conduct this research in accordance with relevant legislation and regulations.
* I agree to comply with the requirements of adverse or unexpected event reporting as stipulated by the HREC and NHMRC.
* I will inform the HREC and the participating sites if the research project ceases before the expected date. I will discontinue the research if the HREC withdraws ethical approval.
* I will adhere to the conditions of authorisation stipulated by the authorising authority at the site/s where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site/s where I am Principal Investigator.
* I understand and agree that study files and documents and research records and data may be subject to monitoring.

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| Name: |  |
| Position: |  |
| Department: |  |
| Signature: |  |
| Date: |  |