AMENDMENT TO AN EXISTING GOVERNANCE APPROVAL

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| **PROJECT DETAILS** | | | | | | | | |
| Project Title | Click or tap here to enter text. | | | | | | | |
| MyIP Reference Number | Click or tap here to enter text. | | | | | | | |
| HREC Reference Number | Click or tap here to enter text. | | | | | | | |
| Authorised SSA Reference Number | Click or tap here to enter text. | | | | | | | |
| New SSA Reference Number (if applicable) | Click or tap here to enter text. | | | | | | | |
| **NEW CALHN SITE** | | | | | | | | |
| Additional CALHN Site | Click or tap here to enter text. | | | | | | | |
| Principal Investigator (PI) | Name | Click or tap here to enter text. | | | | | | |
| Phone | Click or tap here to enter text. | | | | | | |
| Email | Click or tap here to enter text. | | | | | | |
| Employer | Click or tap here to enter text. | | | | | | |
| Department | Click or tap here to enter text. | | | | | | |
| CV | | | GCP  (Mandatory for Clinical Trials) | | | Study Team Declaration | |
| Site Team | Have all site team details been provided to CALHN Research Services including study team declarations, CVs, GCP, Police Check (Non-SA Health Investigators on CALHN site) & Confidentiality Deed (Non-SA Health Investigators accessing patients/data)? | | | | | | | |
| Yes | | No | | | | | N/A |
| How will this project be funded at this site? | Click or tap here to enter text. | | | | | | | |
| *Greater than low risk:* Will a Site-Specific Assessment (SSA) be submitted on GEMS? | Yes | | No | | | | | N/A |
| If no or N/A, explain why.  Click or tap here to enter text. | | | | | | | |
| Head of Department approval has been provided | Yes  (attach approval) | | | | | No (provide an explanation)  Click or tap here to enter text. | | |
| **CHANGES FROM EXISTING PROJECT** | | | | | | | | |
| Change Principal Investigator | Name | | | | | Click or tap here to enter text. | | |
| Phone | | | | | Click or tap here to enter text. | | |
| Email | | | | | Click or tap here to enter text. | | |
| Employer | | | | | Click or tap here to enter text. | | |
| Department | | | | | Click or tap here to enter text. | | |
| CV | | | GCP  (Mandatory for Clinical Trials) | | | Study Team Declaration | |
| Change of budget/funding | Yes  *(attach budget and financial endorsement)* | | | | No | | | |
| **Changes to Project Application:**  (Please give summary of changes/additions to the plan/protocol if applicable, and provide supporting documentation) | Click or tap here to enter text. | | | | | | | |
| **Is further ethical review required?** | Yes | | | | No | | | |

I, Click or tap here to enter text. certify that:

1. All information in this Amendment Form is truthful and as complete as possible.
2. I have had access to and read the NHMRC National Statement on Ethical Conduct in Human Research 2023 (National Statement) and the Australian Code for the Responsible Conduct of Research 2018 (the Code).
3. The research will be conducted in accordance with all ethical and research governance arrangements of the organisations involved.
4. I have no conflicts of interest or have disclosed any conflicts of interest to the ethics review committee and CALHN Research Office and will manage them in accordance with the National Statement and the Code.
5. I will maintain the confidentiality, integrity, privacy and security of information in accordance with the SA Health Privacy Policy Directive.
6. I have consulted any relevant legislation and regulations, and the project will be conducted in accordance with these.
7. I will only commence this research project after obtaining ethics approval and governance authorisation.

Name of Principal Investigator: Click or tap here to enter text.

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Signed: Click or tap to enter a date.

#### For more information

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| CALHN Research Services |
| T: (08) 7117 2223 |
| E: Health.CALHNResearchMonitoring@sa.gov.au |
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