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| 1. **PROJECT DETAILS** | |
| Project SSA Reference number | EFILE |
| Project Full Title |  |
| Project Short Title/Acronym |  |
| Site Principal Investigator (PI) |  |
| Reviewing HREC |  |
| HREC Reference Number |  |
| **Type of amendment**  \*If a major change is being proposed, a full SSA might be required | Change of site PI *(Also complete Section 2)*  Adding new research staff at NT Health site *(Also complete Section 3)*  Removing research staff at NT Health site *(Also complete Section 4)*  Adding/removing NT Health site *(Also complete Section 5)*  Change to project documentation *(Also complete Section 6)*  Other, |
| **Summary of changes/impact on NT Health site(s)** | |
|  | |
| HREC approval attached | Yes  HREC approval pending (Forward to NT Health RGO once received) |

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| 1. **CHANGE OF SITE PRINCIPAL INVESTIGATOR (SITE PI)**   (New Site PI declaration form will be required – see NT Health SSA Form Section 19. New Site PI will be contacted by the RGO if research project has an executed Clinical Trial Research Agreement) | | |
| New Site PI Title and Name | |  |
| New Site PI Position | |  |
| Department | |  |
| Relevant site(s) | |  |
| Phone number | |  |
| Email address | |  |
| New PI has agreed to take the responsibilities as NT Health Site PI? | | Yes  No |
| Does your scope of clinical practice cover all the relevant aspects of the principal investigator’s participation in this project? | | Yes  No  If no, please add comment: |
| Have you received adequate training in the project including the current status? | | Yes  No  If no, please add comment: |
| CV and GCP attached (if clinical trial) | | Yes  No  N/A |
| Do you have a conflict of interest to declare? | | Yes  No  N/A  If yes, Conflict of Interest Declaration Form completed and attached?  Yes  No  N/A |
| New PI signature and date | | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Unit Head/General Manager/Co-Director (or equivalent) has been advised of the change of PI? | | Yes  No |
| Unit Head | Name |  |
| Positon |  |
| Signature |  |
| Date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Co-Director/General Manager | Name |  |
| Positon |  |
| Signature |  |
| Date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |

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| 1. **ADDING NEW RESEARCH STAFF AT NT HEALTH SITE** (Please add additional rows as required) | | | | |
| **NT Health staff** | | | | |
| Name (including title) | Position | Unit/Division | Role in research project | Research hrs per week |
|  |  |  |  | Paid:hrs  In-kind:  hrs |
|  |  |  |  | Paid:hrs  In-kind:  hrs |
| **External (Non-NT Health) staff** | | | | |
| Name (including title) | Employer/Organisation | | Role in research project | Required access |
|  |  | |  | Confidential data  Facilities  N/A |
|  |  | |  | Confidential data  Facilities  N/A |

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| 1. **REMOVING RESEARCH STAFF AT NT HEALTH SITE**  (Please add additional rows as required) | | | |
| Name (including title) | Role in Research Project | Exit date | External researchers ONLY  Previous access |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* | NTG Service centre informed  ID badge returned  N/A |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* | NTG Service centre informed  ID badge returned  N/A |

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| 1. **ADDING/REMOVING NT HEALTH SITE** (Please add additional rows as required) | | |
| Site name | Adding/Removing | Summary of the research activities and impact on the proposed new site(s) |
|  | Adding  Removing |  |
|  | Adding  Removing |  |
|  | Adding  Removing |  |

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| **RECOMMENDATIONS** | | |
| Unit Head/District Manager | Name |  |
| Positon |  |
| Signature |  |
| Date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Health Centre Managers  (if applicable-PHC) | Name |  |
| Positon |  |
| Signature |  |
| Date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Co-Director/General Manager | Name |  |
| Positon |  |
| Signature |  |
| Date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |

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| 1. **CHANGE TO PROJECT DOCUMENTATION** (Please add additional rows as required) | | |
| Please list all supporting documents and the relevant HREC correspondence submitted with this amendment form | Version | Date |
| Study Protocol |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Investigator Brochure or Product Information |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Master Participant Information Sheet |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Master Participant Consent Form |  |  |
| NT Site-specific Participant Information Sheet |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| NT Site-specific Participant Consent Form |  |  |
| Research Agreement/Contracts |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Indemnity |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Certificate of Currency (CoC), expiry date *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| GCP certificate - |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |

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| 1. **DECLARATION OF SITE PRINCIPAL INVESTIGATOR (SITE PI)** | |
| * The information provided is complete and correct. * The project is being conducted in keeping with the conditions of approval of the reviewing HREC and RGO (and subject to any changes subsequently approved). * The project is being conducted in accordance with the protocol. Any further changes to the project documentation, timeline, personnel or sites will be notified in writing to the reviewing HREC(s) and/or the relevant RGO. * I am aware that the health service reserves the right to monitor the progress of projects more intensively. This monitoring may include site visits, audits, interviews and/or documentation checks. * The project is being conducted in compliance with the *NHMRC National Statement on the Ethical Conduct in Human Research* (2018), *NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* (2018)*, NHMRC Keeping Research on Track ll* (2018), *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (2016), the *Australian Code for the Responsible Conduct of Research* (2018) and *Note for Guidance on Good Clinical Practice* (CPMP/ICH/135/95). * I am aware of my responsibilities and obligations as the Site PI for this research project, this includes oversight of all research related activities and research staff performing those activities. | |
| Name |  |
| Phone Number |  |
| Email address |  |
| Signature |  |
| Date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |

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| 1. **RESEARCH CONTACT PERSON**  (if different from Site PI)   (Responsible for the submission of ongoing site authorisation to the Research Governance Office) | |
| Name |  |
| Phone Number |  |
| Email address |  |

Submit completed form to the NT Health Research Governance Office at [nthealth.rgo@nt.gov.au](mailto:nthealth.rgo@nt.gov.au) and attach any relevant documents.