*Please note: Progress reports are due on the****anniversary of the reviewing HREC approval****. RGO Progress Report must be provided to the RGO within 30 days of each anniversary of the initial reviewing HREC approval for the duration of the HREC approval period.*

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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 |  |
| HREC annual report acceptance/continued approval letter attached | Yes  HREC continued approval pending (Forward to RGO once received) |

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| 1. **PROJECT TIMELINE** | |
| Site authorisation date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Site commencement date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Site expected completion date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Report period date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* to *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |

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| 1. **STATUS OF THE PROJECT** | |
| **Status of the project**  \*overall NT Health site(s) | Not yet commenced (please add details in summary below)  Active – Recruiting  Active – Closed to Recruitment (Follow-up continuing)  On hold (please add details in summary below)  Discontinued or abandoned (please add details in summary below)  Completed |
| **Summary of progress at NT Health site(s)**  (Please attach a brief summary below in plain English of the project outcomes or progress to date including all important findings and/or conclusions at NT Health site/s) | |
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| 1. **RESEARCH STAFF AT NT HEALTH SITE(s)** | |
| Have any investigator/research staff changed in the past 12 months or since the previous report? | Yes  No |
| If yes, was RGO Amendment Form completed? | Yes  No |
| If no, complete and attach RGO Amendment Form with HREC approval letter | Yes  No |

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| 1. **PARTICIPANTS AT NT HEALTH SITE(s)**   (Please note if more than one site, list hospitals/PHC sites numbers individually) | |
| Not recruiting | *Go to section 6* |
| Planned number of participants at NT Health site(s) |  |
| Date of first participant recruitment | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Number of participants screened to date |  |
| Number of participants recruited to date |  |
| Number of participants withdrawn |  |
| Reason for withdrawal or  N/A | Safety concerns  Participant complaint  Other, details: |
| Numbers of participant completed the project |  |
| Is site participant recruitment on target? | Yes  No |
| If no, please specify details |  |

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| 1. **POST-ORGANISATIONAL AUTHORISATION REPORTING** | | |
| 6.1 | Has there been any Amendments submitted since authorisation or the last site progress report? | Yes  No |
| If yes, was RGO Amendment Form completed? | Yes  No |
| If not reported to the RGO, please complete and attach RGO Amendment Form with the relevant HREC correspondence | |
| 6.2 | Has there been any safety reports submitted since authorisation or the last site progress report? | Yes  No |
| If yes, was this reported to the RGO? | Yes  No |
| If not reported to the RGO, please add details of safety concerns/issues, the implications for this site and steps taken to address it (attach the relevant HREC correspondence as applicable): | |
| 6.3 | Has there been any complaints regarding the conduct of the project at NT Health site(s) since authorisation or the last site progress report? | Yes  No |
| If yes, was this reported to the RGO? | Yes  No |
| If not reported to the RGO, please add details of the circumstances surrounding the complaint and steps taken to address it (attach the relevant HREC correspondence as applicable): | |

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| 1. **INSURANCE** (if applicable (clinical trials)) | |
| Is a current certificate of insurance available? | Yes  No  N/A *(Go to Section 8)* |
| If yes, was this submitted to the RGO? | Yes  No – If No, please attach |
| If no, please specify details |  |

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| 1. **AUDIT** (if applicable) | |
| Has the project undergone and audit in the past 12 months? | Yes  No  N/A *(Go to Section 9)* |
| If no, please specify details |  |
| If yes, Audit date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Auditing organisation |  |
| Is there a report for the audit? | Yes  No |
| If yes, attach Audit report | Yes  No |

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| 1. **CLOSE-OUT SECTION**   (To be completed if project status at NT Health site(s) is **completed, discontinued or abandoned** in this period) | |
| Actual site completion date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Date of last participant recruitment | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Outcomes of project | |
| What impact/contribution do you think your research has delivered? | |
| Where there any barriers identified that prevented you from reaching the research outcomes? | |
| How will the research outcomes be translated into practice, policy or further research? Who in NT Health could be responsible for the translation of research findings into updated practices? | |
| How will participants be informed of the outcomes of the project? | |
| Please provide a list of publications to date resulted from this project, including any pending publications, conference presentations, posters, etc. or  N/A | |
| Is there any Intellectual Property that has been developed or could be developed through the conduct of this research project?  Yes  No  N/A  If yes, please add details stating arrangement in regards to ownership: | |
| Are there any additional research transfer activities planned? | Yes  No |
| If yes, please add details: | |
| Is the study close-out checklist attached? | Yes  No |
| If no, please add comment: | |
| Is the PI declaration form – archiving research documents attached? | Yes  No |
| If no, please add comment: | |

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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 (RGO) at [nthealth.rgo@nt.gov.au](mailto:nthealth.rgo@nt.gov.au) and attach any relevant documents.