

NT Health

Research Governance Office (RGO)

**Site Specific Assessment**

**(SSA) Form**

# Purpose of the SSA form

The Site Specific Assessment (SSA) form is an information gathering tool used to assess the impact of the research project on each relevant NT Health site(s). The information provided will be reviewed by the appropriate authorising delegate(s) from the NT Health department. The responsible delegate(s) will provide the Research Governance Office (RGO) with their support or a reason why the research is not supported. All research must have a Site Principal Investigator (PI) that is employed by NT Health and the Site PI should be able to address any concerns with the authorising delegate(s), however if the issues are not adequately addressed, the authorising delegate(s) can refuse support.

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# When this form should be used

All research projects conducted with NT Health staff, patients, sites and/or data require an SSA as a component of research governance.

# Instructions for completion

The SSA must be completed by the Site Principal Investigator (PI) responsible for the research project at the nominated NT Health site(s). All questions on the form must be completed. All research projects conducted within NT Health must designate an individual, qualified by training and experience, to serve as the NT health Site PI. The PI must have sufficient authority, relevant scientific knowledge, and the requisite training to personally carry out or supervise all aspects of the project at NT Health.

The SSA should be submitted with all the supporting documents as separate attachments via email. It is the responsibility of the Site PI to provide evidence to support sections 16 and 20-22, as required. The checklist in section 18 has been designed to assist the applicant in ensuring a full and complete SSA package is submitted. Once completed, the SSA form plus electronic copies of all attachments (as listed in section 17) must be submitted separately to the RGO [nthealth.rgo@nt.gov.au](mailto:nthealth.rgo@nt.gov.au)

The RGO will assess the submitted form and attachments. If further information is required, the Site PI will be notified by the RGO. The Site PI **must receive organisational authorisation in writing** from the RGO prior to commencing research project at any NT Health site(s).

**Please note: The study can only commence at NT Health site(s) once both the HREC approval and SSA authorisation have been granted.**

The NT Health Site Specific Assessment (SSA) – Completion Guide can be accessed [here](https://health.nt.gov.au/data-and-research/nt-health-research/forms-and-process)

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| 1. **PROJECT DETAILS** | | |
| 1.1 | **SSA Submission Date** | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| 1.2 | **Reviewing Human Research Ethics Committee (HREC)** | |
|  | Name of HREC reviewing the research project | Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research, NT HREC (EC00153)  Central Australian Human Research Ethics Committee, CAHREC (EC00155)  Charles Darwin University Human Research Ethics Committee (EC00154)  National Mutual Acceptance (NMA) approving Human Research Ethics Committee: |
| Reviewing HREC Application Reference Number |  |
| If under NMA, NT HREC Reference number |  |
| 1.3 | **Project Title** | |
| Full/Scientific Title |  |
| Short Title |  |
| Acronym *\*if applicable* |  |
| 1.4 | **Brief Summary of Project in Plain Language** | |
|  | |
| 1.5 | **National Health & Medical Research Council (NHMRC) Broad Research Area** | *Choose an item.* |
| 1.6 | **NHMRC Field of Research** \*click [here](https://www.nhmrc.gov.au/about-us/resources/australian-standard-research-classifications-and-research-keywords) |  |
| 1.7 | **Project Type** | Clinical trial of a drug, drug trial phase  Clinical trial of a device, device trial phase  Clinical research (includes all other clinical research trialling new interventions and therapies not involving drugs / devices)  Qualitative research – disciplined inquiry that examines people’s lives, experiences and behaviours and the stories and meanings ascribed to them – through interviews, focus groups, observation, archival, on-line, and/or action research  Conducting non-invasive physical experiments or examinations  Research involving human tissue or biological samples  Research involving human genetics – studying the structure, location, function, expression, interaction, abnormalities and effects of the genes  Research involving human stem cells  Research involving exposure to ionising radiation above standard of care *(\*Attach certificate from ionising radiation expert*)  Establishment of or data contribution into a registry  Evaluation  Other, please specify: |
| 1.8 | **Anticipated Project Start Date** | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Start date refers to the anticipated first point of recruitment, i.e. the date when the advertising or screening for participants begins. | |
| **Anticipated Project Finish Date** | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |
| Finish date refers to when no further contact with participants and/or data source is foreseen including the data analysis and reporting period. | |

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| 1. **RESEARCH PROJECT STAFF** | | |
| 2.1 | **NT Health Site Principal Investigator (Site PI)** | |
| Title |  |
| First Name |  |
| Surname |  |
| Position in NT Health |  |
| Department |  |
| Phone |  |
| Email |  |
| 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 provide details and **complete Section 21** : |
| Research hours/week | hrspaid hrs in-kind |

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| 2.2 | **NT Health Associate Investigator(s)** – List all NT Health Staff that will be involved in the research project | | | | | | | |
| Researches Name  (including title) | | Research role | Qualifications | Division/Unit | GCP Certificate  (clinical trials only) | | Research hours/week | |
| Yes/No | Date (if yes) | Paid | In-kind |
|  | |  |  |  | *Choose an item.* | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |  |  |
|  | |  |  |  | *Choose an item.* | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |  |  |
|  | |  |  |  | *Choose an item.* | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |  |  |
|  | |  |  |  | *Choose an item.* | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* |  |  |

*\*Please add additional rows as required*

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| 2.3 | **External Staff (Non-NT Health)** – who will be involved in conducting research project at NT health site(s) (i.e. accessing NT Health data and/or facilities as part of this research project).  *For external staff accessing NT Health confidential data, please also sign the* [*Research Deed of Confidentiality and Compliance Form*](https://health.nt.gov.au/__data/assets/pdf_file/0017/1113920/PA-6-Research-Deed-of-Confidentiality-and-Compliance-Form.pdf)*. For students undertaking any research activities as part of their student placement/training, please sign the* [*Student Deed of Undertaking*](https://health.nt.gov.au/__data/assets/pdf_file/0018/1113921/PA-7-Student-Deed-of-Undertaking.PDF)*.* | | | |
| Researches Name  (including title) | | Research role | Employer/Organisation | Please indicate access type |
|  | |  |  | Confidential Data  Facilities  N/A |
|  | |  |  | Confidential Data  Facilities  N/A |
|  | |  |  | Confidential Data  Facilities  N/A |
|  | |  |  | Confidential Data  Facilities  N/A |

*\*Please add additional rows as required*

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| 2.4 | **Conflict of interest** | |
| Have any of the researchers involved with the research project 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 |

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| 2.5 | **Staff Training/Credentialing** | |
| Will any of the researchers at this site require extra training/credentialing to enable their participation in this project? | Yes  No  If yes, training/credentialing required:  If yes, who will provide the training/credentialing? |
| Do all of the researchers’ scopes of clinical practice cover the relevant aspects of their participation in this project? | Yes  No  If no, please provide details and **complete Section 21** : |

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| 2.6 | **Project Coordinator/Contact Person for this Research Project** (if different from Site PI) | |
| Name (including title) |  |
| Position |  |
| Department/Organisation |  |
| Phone |  |
| Email |  |

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| 1. **PROJECT SITE(s)** | | |
| 3.1 | **Project/Study Site(s)** | Single site  Multi-site within Northern Territory  Multi-site National  International |
| 3.2 | **Is this a teletrial?** | Yes  No |
|  | If yes, select one option relating to the site type:  \*NT Teletrial team will get in touch for additional requirement to conduct a teletrial | Teletrial primary site  Teletrial satellite site |

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| 3.3 | **NT Health Site(s)**  Please note: an SSA is required for **each** Regional Heath Service where the project will be conducted | | | |
| **TOP END REGION (tick all that apply below)** | | |  | |
|  | Royal Darwin and Palmerston Hospital (RDPH) | | Royal Darwin Hospital, wards:  Palmerston Regional Hospital, wards:  Alan Walker Cancer Centre (AWCC)  Top End Renal Services, please specify:  Other, please specify: | |
| Mental Health, Alcohol and Other Drugs | | Please specify: | |
| Population and Primary Health care | | Please specify: | |
| Other, please specify | | Please specify: | |
| **BIG RIVERS REGION (tick all that apply below)** | | |  | |
|  | Katherine Hospital | | Wards: | |
| Mental Health, Alcohol and Other Drugs | | Please specify: | |
| Population and Primary Health care | | Please specify: | |
| Other, please specify | | Please specify: | |
| **EAST ARNHEM REGION (tick all that apply below)** | | |  | |
|  | Gove District Hospital | | Wards: | |
| Mental Health, Alcohol and Other Drugs | | Please specify: | |
| Population and Primary Health care | | Please specify: | |
| Other, please specify | |  | |
| **CENTRAL AUSTRALIA REGION (tick all that apply below)** | | |  | |
|  | Alice Springs Hospital | | Wards: | |
| Mental Health, Alcohol and Other Drugs | | Please specify: | |
| Population and Primary Health care | | Please specify: | |
| Other, please specify | |  | |
| **BARKLY REGION (tick all that apply below)** | | |  | |
|  | Tenant Creek Hospital | | Wards: | |
| Other, please specify | |  | |
| **NT DEPARTMENT OF HEALTH (NT DoH) (tick all that apply below)** | | | | |
|  | | Territory Pathology (NT DoH) | | |
|  | | Other, please specify | |  |

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| 1. **PARTICIPANTS** | |
| 4.1 | What categories of people will participate in this research project at this site? (i.e. children and young people, people with intellectual or mental impairment, pregnant women, Aboriginal and Torres Strait Islander Australians, other vulnerable groups, NT Health staff) |
| 4.2 | What is the total number of participants to be recruited for this research project at this site? |
| 4.3 | What is the expected number of participants to be recruited for each NT Health site covered by this SSA form?   |  |  |  | | --- | --- | --- | | Site | Number of participants/year | Number of years | |  |  |  | |  |  |  |   *\*Please add additional rows as required* |

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| 1. **RESOURCES** | | |
| 5.1 | **Site - HOSPITAL ACTIVITIES** or  N/A - go to Q5.2 | |
| 5.1.1 | What process will be used to identify potential participants for this research project? | |
| 5.1.2 | Please state all departments/wards/services at which research activities (recruitment/visit/follow-ups) will occur.  \*Please complete section 16 and support this with an email from the appropriate Nurse Manager/s of the listed wards/services | |
| 5.1.3 | Will your research require clinical equipment above that of normal care? | Yes  No |
| If yes, please specify what equipment and whether this will impact on the delivery of care to other patients: | |
| 5.1.4 | Will ward staff be required to conduct any protocol activities? | Yes  No |
| If yes, is this  In-kind or  Paid support  \*Please complete section 16 and support this with an endorsement email from the appropriate Nurse Manager ensuring that the expectations of ward staff are transparent | |
| 5.1.5 | Will your team be accessing an Aboriginal Liaison Officer for research purposes? | Yes  No |
| If yes, is this  In-kind or  Paid support  \*Please complete section 16 and support this with an endorsement email from the Manager of the Aboriginal Services and Support Unit | |
| 5.1.6 | Will your research require additional office or desk space? | Yes  No |
| If yes, has this been negotiated with the appropriate hospital delegates and agreed upon? Please provide details and attach the relevant correspondence: | |
| 5.1.7 | Please state whether any additional support or resources will be required to conduct this project at the hospital*:* | |
| 5.2 | **Site - PRIMARY HEALTH CARE ACTIVITIES** or  N/A - go to Q6.1 | |
| 5.2.1 | What process will be used to identify potential participants for this research project? | |
| 5.2.2 | How do you plan to locate participants and if required bring them to the Health Service? | |
| 5.2.3 | Will you require clinic space to see your project participants? | Yes  No |
| If yes, please provide details | |
| 5.2.4 | Will your research require using PHC clinical equipment? | Yes  No |
| If yes, please provide details | |
| 5.2.5 | Will PHC staff be required to conduct any protocol activities? | Yes  No |
| If yes, please provide details | |
| 5.2.6 | Please state whether any additional support or resources will be required to conduct this project at the hospital*:* | |
|  | Note: This form will be submitted for review to the PHC General Managers/Regional Managers and/or Clinic Managers for any research project occurring on-site at PHC centres. Please contact the RGO for further information. | |

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| 1. **ACCESS TO INFORMATION AND DATA** | | |
| Site PI will need to contact RGO to organise system(s) access request. | | |
| 6.1 | What patient information systems (if any) will external researchers require access to for this research project?  No external researchers - go to Q7.1  External researchers but access not required - go to Q7.1  Acacia - Territory-wide electronic health record (currently read-only)  Acute Care Information System (ACIS) - Hospital sites electronic health records  Primary Care Information System (PCIS) - Used by rural/remote PHC sites  Community Care Information System (CCIS) - Used by urban PHC sites  Jadecare/CWS - Clinical pathology and imaging results  Caresys - Patient admission, discharge, transfers and outpatients appointments.  eMMa - Medication management (electronic medchart)  Synapse - Medical imaging access (only available on NT Health computers)  Hard copy medical records  Other, please specify: | |
| 6.2 | Will the associated access fees for external researchers for the above patient information systems be paid for by the: | Project  In-kind (relevant department conducting the research) |
| 6.3 | How long do the research project documents need to be kept (i.e. site investigator files, data collection forms)? years,  years post publication or  N/A | |
| 6.4 | Does this include hard copy medical records of participants?  years,  years post publication or  N/A | |

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| 1. **PHARMACY – INVESTIGATIONAL DRUGS** | | | |
| 7.1 | Will the research project include administration of medications? | | Yes  No – go to Q8.1 |
| 7.2 | Is the research project being conducted under the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) schemes? | | CTN  CTA  N/A, add comment: |
| 7.3 | Does this research project require additional pharmacy services above the standard of care at this site? | | Yes  No |
| If yes, what additional services will NT Health Pharmacy Department be providing for this project (tick all that apply):  \*Please complete section 16 or provide an endorsement email from Head of Department as part of governance approval requirement.  Procurement or  Standard hospital imprest  Storage, please list any specific requirements including temperature control:  Distribution  Dispensing:  Within hours and/or  Out of hours  Trial medication/s labelling or potentially re-labelling  Accountability of trial medication  Reconstitution  Compounding  Monitoring and adverse event recognition, management and reporting  Other, please specify, | | |
| 7.4 | Will project funds cover the costs of the trial medications and/or additional services at this site? | | Yes  No |
| If no, please comment on who will cover additional costs? | | |
| 7.5 | Will a Non-NT Health pharmacy perform some or all of the above services? | Yes  No  N/A | |
| If yes, please provide the name of the external organisation and details of their involvement at this site: | | |
| 7.6 | Will the trial medication/s be prescribed/ordered by medical officer? | Yes  No | |
| If yes, prescribe/order via  eMMa (electronic medchart) or  Paper based  Please describe process: | | |
| If no, please provide comment on the process of how the trial medication/s will be prescribed/ordered: | | |

Pharmacy fees may be applicable to the research project, please [click here](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules)

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| 1. **RADIOLOGY – MEDICAL IMAGING AND NUCLEAR MEDICINE** | | | | | |
| 8.1 | Does this research project require additional medical imaging above the standard of care at this site? | | Yes  No  N/A - go to Q9.1 | | |
| 8.2 | What additional services will NT Health Radiology Department be providing for this project:  \*Please complete section 16 or provide an endorsement email from Head of Department as part of governance approval requirement. | | | | |
| 8.2.1 | Tests  **(tick all that apply below)** | Number of additional tests above standard of care/year | | Number of years | Is this covered by the project funds |
| MRI scans |  | |  | Yes  No |
| CT scans |  | |  | Yes  No |
| Ultrasound |  | |  | Yes  No |
| X-ray |  | |  | Yes  No |
| Fluoroscopy x-ray |  | |  | Yes  No |
| PET/SPECT scans |  | |  | Yes  No |
| Radiation Therapy |  | |  | Yes  No |
| Angiography |  | |  | Yes  No |
| Other, please specify |  | |  | Yes  No |
| \*If project funds don’t cover any of the above, please comment on who will cover additional costs? | | | | |
| 8.2.2 | Does this trial require pulling or duplicating images? | | Yes  No | | |
| Will you require de-identified images or images in bulk? | | Yes  No | | |
| If yes to any of the above, please provide details (i.e. number of images/duplicates across how many participants): | | | | |

Nuclear medicine and Radiology fees may be applicable to the research project, please [click here](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules)

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| 1. **PATHOLOGY – TERRITORY PATHOLOGY** | | |
| 9.1 | Does this research project require additional pathology service/s (i.e. collection, storage, processing) above the standard of care at this site? | Yes  No  N/A - go to Q10.1 |
| 9.2 | If yes, what additional services will Territory Pathology be providing for this project (tick all that apply):  \*Please complete section 16 or provide an endorsement email from Territory Pathology Operations Manager as part of governance approval requirement.  Pathology results (data)  Specimen holding and storage  Tissue pathology, holding and storage  Additional services (i.e. slides/stains or histology)  Transport of samples  Other, please specify | |
| 9.3 | Will project funds cover the costs of the additional services at this site? | Yes  No |
| If no, please comment on who will cover additional costs? | |

Pathology fees may be applicable to the research project, please [click here](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules)

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| 1. **RESEARCH AGREEMENT** | | |
| If your research project involves an agreement between NT Health and any other party, this agreement must be submitted to the RGO for review. | | |
| 10.1 | Does this research project have a written research agreement? | Yes  No  N/A |
| If no or N/A, please add comment and go to Q11.1: | |
| 10.2 | Type of research agreement:  Medicine Australia Research Agreement Template, please specify:  Non-Standard Agreement, please specify: | |
| 10.3 | Name of organisation(s) entering into the agreement with NT Health: | |

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| 1. **INDEMNITY AND INSURANCE** | | | |
| NT Health employees conducting a research project in the capacity of their employment with NT Health are automatically covered by NT DoH self-insurance arrangements where HREC approval has been obtained. For research projects sponsored by an external party, including commercially sponsored clinical trials or collaborative research organisations (acting on behalf of the sponsor), the sponsor must supply evidence of its insurance cover. | | | |
| 11.1 | Is there evidence of adequate indemnity coverage for the scope of the research project attached? | | Yes  No  N/A |
| If no or N/A, please add comment: | | |
| 11.2 | If yes, type of indemnity form provided:  Medicine Australia Standard Indemnity  Collaborative Research Group (Administering Institution/Organisation) providing indemnity  Other: | | |
| 11.3 | Is there evidence of adequate and current insurance cover attached? | | Yes  No  N/A |
| If no or N/A, please add comment: | | |
| 11.4 | If yes, Name of Insurer |  | |
| Certificate of Currency Expiry Date | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* | |

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| 1. **BIOSAFETY, CHEMICAL AND RADIATION SAFETY - Complete only if relevant to this site** | | |
| It may be necessary for research organisations to complete notification, registration or licence requirements for research involving biosafety, regulatory issues and/or radiation. If so, evidence of this is required. If "Yes" is marked below against any of these items, appropriate documentation of approval must be attached to this form upon submission. | | |
| 12.1 | Is Institutional Biosafety Committee (IBC) notification and/or licence application to the Office of the Gene Technology Regulator (OGTR) for approval of genetically modified organisms required? | Yes  Approval attached  No |
| 12.2 | Will the project require NHMRC Gene and Related Therapies Research Advisory Panel (GTRAP) assessment? | Yes  Assessment attached  No |
| 12.3 | Will the project require application for a license to the NHMRC Licensing Committee to conduct embryo research? | Yes  License attached  No |
| 12.4 | For projects where Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code compliance is required, is additional State Specific radiation safety approval and registration required? | Yes  Approval and registration attached  No |

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| 1. **FUNDING** | | |
| 13.1 | Name of Sponsor |  |
| 13.2 | Sponsor Type | Commercial/Industry Sponsor  Collaborative Research Group  Investigator Initiated Group  Institution  University  Other: |
| 13.3 | Has the research project received funding? | Yes  No - If no, go to Q14.1 |
| 13.4 | Type of funding source (i.e. NHMRC, External Sponsor, Internal/Department) |  |
| 13.5 | Estimated funding for the project at this site (Amount: $/year or $/participant) | $or still negotiating |
| 13.6 | Is the funding received expected to cover the costs of the research: | Yes  No - If no, please state how the shortfall costs will be absorbed: |
| 13.7 | Please refer to the [fee schedule](https://health.nt.gov.au/data-and-research/nt-health-research/fee-schedules) for SSA review and ensure the details below are completed prior to submission of your SSA, for billing purposes. | |
| Name of the business |  |
| ABN |  |
| Business address |  |
| Billing contact name |  |
| Phone number |  |
| 13.8 | **FINANCIAL OVERSIGHT AND AUTHORISATION** | |
| 13.8.1 | **Responsible person (i.e. Finance Officer)**  Please identify who will be locally responsible for the management of funding provided for the project, and what cost centre/s funds will be paid into and drawn from. | |
| Name |  |
| Position |  |
| Department |  |
| Phone |  |
| Email address |  |
| 13.8.2 | Cost centre/s |  |
| 13.8.3 | **Financial Authorisation (i.e. Divisional Performance Managers)**  Cost allocations and sources at this site have been agreed  Yes  No | |
| Name |  |
| Position |  |
| Signature |  |
| Date | \_\_\_\_/ \_\_\_\_/ \_\_\_\_ |
| Site PI name |  |
| Signature |  |
| Date | \_\_\_\_/ \_\_\_\_/ \_\_\_\_ |

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| 1. **INTELLECTUAL PROPERTY (IP)** | | |
| 14.1 | Is it likely that new Intellectual Property will be developed as a result of this project being undertaken at this site? | Yes  No – go to Q15.1 |
| 14.2 | Please outline the agreement stating arrangements for the use of existing and/or new intellectual property and the parties’ rights in relation to ownership | |
| 14.3 | If intellectual property rights will be retained by the site Principal Investigator/NT Health Service, please indicate who will be responsible for financially supporting the development of this IP should the research generate new knowledge or breakthroughs (e.g. Drug Development costs or patents) and please attach evidence or  N/A | |

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| 1. **DISSEMINATION OF OUTCOMES** | |
| 15.1 | How will the research results be disseminated/implemented to relevant staff within the NT Health services? |
| 15.2 | How will the research results be fed back to the participants (tick if applicable)?  Urban:  Remote: |

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| 1. **DEPARTMENTS/SERVICES INVOLVED IN THE RESEARCH PROJECT AT THIS SITE** | | | |
| Note that endorsement from the Head/s of Department/s or Service/s is required, signature below or an email of support should be submitted with this application. If endorsed via email, their email should include full project title and describe all resources and support agreed to be provided by the relevant department for this research project (i.e. pharmacy, pathology, radiology, wards nursing managers, etc).  Where the Principal Investigator for the research project is also the Head of Department, support must be sought from the person to whom the Head of Department is responsible. Investigators must not approve their own research on behalf of the Health Service. | | | |
| **Unit/Department/Service** | **Unit Manager/Head of Department** | **Signature and date** | **Endorsement email attached**  **(if not signed)** |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* | Yes  No |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* | Yes  No |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* | Yes  No |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* | Yes  No |
|  |  | *\_\_\_\_/ \_\_\_\_/ \_\_\_\_* | Yes  No |

*\*Please add additional rows as required*

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| 1. **SUPPORTING DOCUMENTS SUBMITTED WITH THE SSA FORM** | | | |
| Please attach each supporting documents separately with the completed SSA form. Files should be named consistently to include project title/acronym, document type, version and date (ddmmyyyy). | | | |
| **Documents** | **Version** | **Date** | **RGO Only** |
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*\*Please add additional rows as required*

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| 1. **DOCUMENT SUBMISSION CHECKLIST** | | |
|  | **Person Completing Form** | **RGO**  **Only** |
| Have all sections on the form been completed? | Yes  No |  |
| Has a site Principal Investigator for this research project (NT Health employee) been nominated? | Yes  No |  |
| If there is a perceived conflict of interest for the PI and/or AIs, has a conflict of interest declaration form been attached? | Yes  No  N/A |  |
| Are the qualifications listed and GCP certificate attached for each researcher? | Yes  No  N/A |  |
| For external staff accessing NT Health confidential data, has the copy the Deed of Confidentiality and Compliance Form been attached? | Yes  No  N/A |  |
| For students undertaking any research activities as part of their student placement/training, has the Student Deed of Undertaking been attached? | Yes  No  N/A |  |
| Has a copy of the HREC application been attached? | Yes  No  N/A |  |
| Has a copy of the HREC approval letter been attached? (including approval to include NT Health site/s) | Yes  No  Pending |  |
| If under NMA, has a copy of the HREC reciprocal approval letter been attached? | Yes  No  Pending |  |
| Has a copy of the Protocol been attached? | Yes  No  N/A |  |
| Have all Master and Site Specific Participant Information and Consent Form(s) been attached? | Yes  No  N/A |  |
| Have all Site Specific Participant Information and Consent Form(s) attached showing the NT Health logo, contact details of the Site Principal Investigator and contact details of RGO for any concerns/feedback? The version number, date and standard institution name should be in the footer. | Yes  No  N/A |  |
| Has a copy of the Investigators Brochure/drug information/device been attached? | Yes  No  N/A |  |
| Has a copy of project advertising been attached? | Yes  No  N/A |  |
| Has a copy of any questionnaires been attached? | Yes  No  N/A |  |
| Is a Research Agreement attached? (All research agreements must be reviewed by the RGO and signed on behalf of NT Health) | Yes  No  N/A |  |
| Is evidence of indemnification attached? (i.e. Medicines Australia Standard Indemnity Form or other indemnity signedby the sponsor) | Yes  No  N/A |  |
| Is evidence of adequate and current insurance cover attached (Certificate of Currency)? | Yes  No  N/A |  |
| Is CTN or CTA form signed by the approving HREC and Site PI been attached? (clinical trials **ONLY)** | Yes  Pending  No  N/A |  |
| Has evidence of an application for NHMRC Cellular Therapies Advisory Committee (CTAC) been attached? | Yes  No  N/A |  |
| Has evidence of an application for a licence to the NHMRC Embryo Research Licensing Committee to conduct embryo research, been attached? | Yes  No  N/A |  |
| Has the Institutional Biosafety Committee (IBC) approval been attached? | Yes  No  N/A |  |
| Has evidence of Radiation Safety approval been attached? | Yes  No  N/A |  |
| If receives funding, has the financial authorisation and oversight section (13.8) been completed and signed? | Yes  No  N/A |  |
| Have the endorsements email/s from Head/s of all participating Departments or Services involved in the project been attached? (i.e. Divisional Head, Nurse Managers, ALO, Pharmacy, Radiology Pathology, etc.) | Yes  No  N/A |  |
| Has the Site PI notified the Clinical Nurse Manager/s of wards where research activities will occur and attached the relevant correspondence? | Yes  No  N/A |  |
| Has the data custodian/s provided permission to allow the study investigator/s to use any data required for the study? (For data collection involving large data sets ONLY) | Yes  No  N/A |  |

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| 1. **DECLARATION BY SITE PRINCIPAL INVESTIGATOR**   **(PLEASE REFER TO** [**RESPONSIBILITIES OF NT HEALTH SITE PRINCIPAL INVESTIGATORS**](https://health.nt.gov.au/data-and-research/nt-health-research/site-principal-investigator-responsibilities)**)** |
| I declare the information in this form is truthful and accurate to the best of my knowledge and belief and I take full responsibility at this site.  I will only start this research project after obtaining authorisation from the Research Governance Office (RGO) 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 *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 undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved.  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 adhere to the conditions or approval stipulated by the HREC and RGO. I will cooperate with HREC and RGO monitoring requirements.  I will inform the HREC and the RGO if the research project ceases before the expected date. I will discontinue the research if the HREC or RGO withdraws approval.  I will adhere to the conditions of authorisation stipulated by the authorising authority at the site where I am Principal Investigator. I will discontinue the research if the authorising authority withdraws authorisation at the site where I am Principal Investigator.  I understand and agree that study files and documents and research records and data may be subject to inspection by the HREC, RGO, the Sponsor or an independent body for audit and monitoring purposes.  I understand that information relating to this research, and about me as a researcher, will be held by the HREC and RGO. This information will be used for reporting purposes and managed according to the principles establishing in the Privacy Act 1988 (Cth) and relevant laws in the States and Territories of Australia.  I accept responsibility for the oversight of research staff activities.  I will ensure all Investigators have declared any conflicts of interested with their involvement in the research.  **Name (including title):**  **Position:**  **Department:**  **Signature:**  **Date:** \_\_\_\_/ \_\_\_\_/ \_\_\_\_ |
| 1. **RECOMMENDATION BY MOST RELEVANT: CO-DIRECTOR/DIRECTOR OF MEDICAL SERVICES/DIRECTOR OF NURSING/DIRECTOR OF ALLIED HEALTH** |
| I certify that:   * I have read the research project application associated with this SSA. * I have discussed this research project and the resource implications for the relevant department/division with the Site Principal Investigator (Site PI). * There are suitable and adequate facilities and resources for the research project to be conducted at this site. * The Site PI and associated investigators, including all researchers/students from my Department/Division involved in this research project have the skills, training and experience necessary to conduct research safely within their scope of practice. * The proposed research aligns to institutional and/or departmental strategic plans and objectives. * The institutional benefit of participating in the research is consistent with the resource contribution. * There is no conflict of interest for the researchers or that the declared conflict of interest is acceptable.   **SSA authorisation is therefore:**  **Supported**  **Not supported**    If not supported, please state reasons below:    **Name:**  **Position:**  **Department:**  **Signature:**  **Date:** \_\_\_\_/ \_\_\_\_/ \_\_\_\_ |

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| 1. **RECOMMENDATION BY RELEVANT PROFESSIONAL LEAD (EDONM/EDMS/EDAH ETC.)**   **FOR RESEARCH ACTIVITIES OUT OF SCOPE OF PROFESSIONAL PRACTICE ONLY – see Q2.5** |
| I certify that:   * I have read the research project application associated with this SSA. * I have discussed this research project and the resource implications for the relevant department/division with the Site Principal Investigator (Site PI). * There are suitable and adequate facilities and resources for the research project to be conducted at this site. * The Site PI and associated investigators, including all researchers/students from my Department/Division involved in this research project have the skills, training and experience necessary to conduct research safely within their scope of practice. * The proposed research aligns to institutional and/or departmental strategic plans and objectives. * The institutional benefit of participating in the research is consistent with the resource contribution. * There is no conflict of interest for the researchers or that the declared conflict of interest is acceptable.   **SSA authorisation is therefore:**  **Supported**  **Not supported**    If not supported, please state reasons below:    **Name:**  **Position:**  **Department:**  **Signature:**  **Date:** \_\_\_\_/ \_\_\_\_/ \_\_\_\_ |

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| 1. **RECOMMENDATION BY INSTITUTIONAL HEAD: EXECUTIVE DIRECTOR/GENERAL MANAGER/REGIONAL EXECUTIVE DIRECTOR** |
| I certify that:   * I have read the research project application associated with this SSA.   • There is a clear institutional benefit of participation in the research.  • The proposed research aligns to institutional strategic plans and objectives.  • The research project and resource implications are within the allocated budget of the service.  **SSA authorisation is therefore:**  **Supported**  **Not supported**    If not supported, please state reasons below:    **Name:**  **Position:**  **Signature:**  **Date:** \_\_\_\_/ \_\_\_\_/ \_\_\_\_ |

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| 1. **FINAL AUTHORISATION BY THE RESEARCH GOVERNANCE OFFICE (EXECUTIVE DIRECTOR)** |
| **I hereby confirm that I am:**  **Satisfied** that the proposed research project meets all research governance requirements of this site. I therefore **authorise** the commencement of this project.  **Not satisfied** with one or more components of this submission, and am therefore **unable to authorise** the commencement of this project and will seek further information from the site Principal Investigator.  If not authorised, please state reasons below:    **Name:**  **Position:**  **Signature:**  **Date:** \_\_\_\_/ \_\_\_\_/ \_\_\_\_ |