**For researchers using this process for the first time we strongly recommend booking an appointment with the NH Research Development and Governance Unit (RDGU) staff prior to submission.**

Please email a copy of the completed and signed form and any attachments to ResearchDGU@nh.org.au

## PROJECT RISK SCREEN

*A key characteristic of projects eligible for the non-HREC approval pathway is that they must be* ***low risk.*** *To prevent completion of this form for ineligible projects, please consider the following research risk-related characteristics and certify that these are not relevant to your project.*

By signing below, I certify that I have considered the following statements related to research risk, and confirm that **none** are relevant to the project described in this form:

* Physical risk to participants, e.g.
	+ invasive procedures or investigations
	+ investigations involving radiation outside routine clinical care
	+ non-routine drug therapy – indication, dose, route, risk of interactions
	+ collection of data for genetic analyses
* Psychological distress to participants, e.g.
	+ risk of arousing significant anxiety
	+ psychological stress
	+ questions regarding psychological illness or sexuality
* Spiritual or social harm or distress to participants
* Risk to organization, e.g.
	+ collection of commercially sensitive data
	+ intellectual property
	+ identified data

|  |  |
| --- | --- |
| **Name of Northern Health Principal Investigator** |  |
| **Signature of Northern Health Principal Investigator** |  |

## INVESTIGATIONAL TEAM

**Northern Health Principal Investigator**

|  |  |
| --- | --- |
| **Title and name** |  |
| **NH appointment** |  |
| **NH Department/Unit** |  |
| **NH site(s)** |  |
| **Phone** |  |
| **Email (nh.org.au)** |  |

**Associate Investigator** *(Copy/paste cells as required for additional investigators)*

|  |  |
| --- | --- |
| **Title and name** |  |
| **NH appointment** |  |
| **NH Department/Unit** |  |
| **NH sites(s)** |  |
| **Phone** |  |
| **Email (nh.org.au)** |  |

*Note: A representative from each department involved in the project should be included.*

**Student Investigator** *(If applicable)*

|  |  |
| --- | --- |
| **Name** |  |
| **University** |  |
| **Role in this project** |  |
| **Email address** |  |
| **Qualification being undertaken** |  |
| **Has a student confidentiality agreement been signed?** | [ ]  Yes, provide signed agreement [ ]  No, provide details of reasons not required  |
| **Student signature & date** |  |
| **Student Academic Supervisor Name & Position** |  |
| **Academic Supervisor signature & date**  |  |

**External Investigator** (*if applicable* *- copy/paste cells as required for additional investigators*)

|  |  |
| --- | --- |
| **Name** |  |
| **Position** |  |
| **External Organisation** |  |
| **External Department** |  |
| **Role in this project** |  |
| **Email address** |  |
| **Signature & date**  |  |
| **Has an agreement been signed?** | [ ]  Yes, provide signed agreement [ ]  No, provide details of reasons not required |

## PROJECT OVERVIEW

### **3.1 Project title**

|  |
| --- |
|  |

### **3.2 Description of proposed activity**

|  |  |
| --- | --- |
| **Protocol Version Date:**  | **Protocol Version Number:**  |
| * + 1. **Project Protocol**

**Please attach a project protocol. Do not insert your protocol here.** *We recommend the use of the RDGU Low Risk Protocol Template which can be obtained from our* [*website*](https://www.nh.org.au/research/research-development-governance-unit-rdgu/project-types-approval-pathways/non-hrec-pathway/) *or by contacting* *ResearchDGU@nh.org.au**. If using a different template, please ensure all sections of the RDGU Low Risk Protocol Template are addressed.*  |
| * + 1. **Data management Plan**

**Please provide a data management plan for retention and archiving and destruction** *Ensuring compliance with the Health Records Act (Vic) (2001)* [*Here*](https://www.legislation.vic.gov.au/in-force/acts/health-records-act-2001/047) *& Australian Code for the Responsible Conduct of Research (2018) as applicable* [*Here*](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)*.* *If the data management plan is fully addressed in your project protocol, you can refer to it here.* |

## SUMMARY OF ETHICAL CONSIDERATIONS

**A full description of the ethical issues should be provided in the protocol. Please summarise the key issues below.**

|  |
| --- |
| **4.1 What are the public benefits of this project and relevance to clinical care?** *i.e. will this project generate new information that will have direct implications for patient clinical management?* |
| **4.2 Please specify the possible risks, burdens or inconveniences that the participants may experience, and what your strategies to mitigate possible risk, burden and inconvenience?** *Describe any foreseeable ethical issues and how they will be addressed, including any risks to privacy.* |

## GOVERNANCE CONSIDERATIONS

|  |
| --- |
| * 1. **Involved parties**

**5.1.1 Are other organisations involved in this project?**[ ]  Yes; please list (*and consider requirement for approvals and agreements* [*section 5.3.*](#_4.3_Agreements)) [ ]  No **5.1.2 Have all organisations involved, as listed above, agreed to participate in the project and have/will obtain local governance authorisation?**[ ]  Yes [ ]  In progress; please provide status:[ ]  No; please explain: [ ]  N/A (no other organisations)**5.1.3 Will NH data be provided to a third party (external) organisation?***If there is a transfer of data, ensure appropriate agreement is put in place with all external parties. See* [*section 5.3*](#_4.3_Agreements)*.*[ ]  Yes [ ]  No **5.1.4 If yes, in what format will that data be provided to the third party?**[ ]  Identifiable (or potentially identifiable) [ ]  De-identified with the potential to re-identify by NH site staff only[ ]  De-identified and unable to be re-identified [ ]  N/A (no data transfer)**5.2 Resources and Finance** **5.2.1 Are there any resourcing or financial implications associated with undertaking this project?** *E.g. obtaining grant or external/internal funding to undertake the project*[ ]  Yes; please provide details (*NH Research Budget Template may be used for this purpose*)[ ]  No  |

|  |
| --- |
| **Internal and External Support (Agreements and Approvals)**Internal Support**5.3.1.1 Does this project involve supporting departments\* at Northern Health?** *\*any department at Northern Health that is providing support or services to the research project, and is not a member on the research team.*[ ]  Yes; please provide names and positions/departments:*Head of Supporting Department/s (or delegate) will be required to provide their signature in section 6.*[ ]  No; please explain:**5.3.1.2 Does your project intend to use translated documents or interpreters?** [ ]  Yes; please provide further information including letter of support from TALS (if applicable)[ ]  No; please explain:**5.3.1.3 Does your project intend to involve consumers+\*?** [ ]  Yes; please provide further information [ ]  No.*+ Collecting this information assists the office to track and build consumer engagement in research.* *\*Consumer Involvement, in this context, refers to the active collaboration of consumers with researchers to help shape the research project (as an investigator or through involvement in study design through to conduct).* *(This is distinct from research participation, where individuals provide data as a study participant).*5.3.2 External Support**Do you require an agreement with any external organisations listed for this project regarding transfer of data, transfer of material, ownership of potential intellectual property, ownership of data, stepping out of publication rights?**[ ]  Yes; please attach the agreement (*examples of pre-approved NH agreement templates can be provided on request)*[ ]  No; please provide brief explanation: |

## DECLARATIONS AND SIGNATURES

**Declaration by the Principal Investigator**

**I certify that:**

1. The information provided in this application is true and correct.
2. This research project will be conducted in accordance with the Northern Health Research Policy and all applicable Northern Health Standard Operating Procedures.
3. This research project adheres to the principles in the most recent [NHMRC Statement on Ethical Conduct in Human Research](https://www.nhmrc.gov.au/research-policy/ethics/national-statement-ethical-conduct-human-research), [Australian Code for the Responsible Conduct of Research](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018), and [The Declaration of Helsinki](https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/).
4. The project will not commence until institutional governance authorisation is obtained from the Northern Health Research Development & Governance Unit.
5. The following documentation has been completed (where relevant) and included in the local Investigator Site Master File/study site folder:
6. Evidence of support from all relevant parties
7. Detailed study budget and confirmation of funding
8. Executed research agreements
9. Evidence of project team research credentials
10. Additional information about the project, for the purposes of ensuring ethical conduct, will be provided if requested by the NH Research Governance and Development Unit.
11. The NH Research Development and Governance Unit will be notified in writing immediately if any changes to the project are proposed that would impact on its ethical consideration and the project will not proceed until approval is obtained.
12. Principal Investigators must expect to remain employed within the department specified in this form for the entire duration of the project. If there is any change to these circumstances, an amendment must be submitted. Failure to do so may result in the suspension of the project.
13. As the Principal Investigator I take responsibility for maintaining the confidentiality of the medical records accessed and any personal, health or sensitive information contained within those records. Any patient personal information collected, used and disclosed will be done so in accordance with the Northern Health Privacy Policy. No data capable of identifying a particular individual will be published without the specific written consent of the participant or person(s) with authority to consent on their behalf.
14. All named investigators have read, understood and agreed to provide the resources required to carry out the project as described.
15. Reporting to the Research Development and Governance Unit (RDGU) is a condition of ongoing ethics and governance approval. Annual Progress reports are due each year on 31 July. A Final Report must be provided on the completion of the project. To submit an annual progress/final report, please visit our [website](https://www.nh.org.au/research/research-development-governance-unit-rdgu/project-types-approval-pathways/non-hrec-pathway/?preview_id=26008&preview_nonce=399540dea6&_thumbnail_id=-1&preview=true).

|  |  |
| --- | --- |
| **Name of Northern Health Principal Investigator** |  |
| **Signature of Northern Health Principal Investigator** |  |
| **Date of signature**  |  |

|  |
| --- |
| **Declaration by Head of Department (or delegate) responsible for Principal Investigator** *• A Head of Department may delegate responsibility to an appropriate staff member.**• An investigator must not approve their own research on behalf of their department. If an investigator is also Head of Department, certification must be sought from the person to whom the Head of Department is responsible.* |

**I, the Head of Department (or delegate) identified below, certify that:**

* I have read the research project application named above.
* I have discussed this research project, and the resource implications for this department with the Principal Investigator.
* All investigators/students from my department involved in the research project have the skills, training and experience necessary to undertake their role.
* There are suitable and adequate facilities and resources for the research project to be conducted at this site.
* I support this research project being carried out using such resources.

|  |  |
| --- | --- |
| **Name of Northern Health Head of Department (or delegate)** |  |
| **Department and Position** |  |
| **Signature of Northern Health Head of Department (or delegate)** |  |
| **Date of signature**  |  |

*(Copy/paste Table above if more than one department is directly supporting this project)*

|  |
| --- |
| **Declaration by Head of Supporting\* Department** *\*any department at Northern Health that is providing support or services to the research project, and is not a member on the research team.** *If you have selected “Yes” at section 5.3.1.1, please complete for each supporting department.*
* *A Head of Department may delegate responsibility to an appropriate staff member*
 |

 **I, the Head of** *[name of supporting department]* **Department (or delegate) identified below, certify that:**

* I have read the research project application named above.
* I have discussed this research project, and the resource implications for this department with the Principal Investigator.
* I support this research project being carried out using such resources.

|  |  |
| --- | --- |
| **Name of Northern Health Head of Department (or delegate)** |  |
| **Department and Position** |  |
| **Signature of Northern Health Head of Department (or delegate)** |  |
| **Date of signature**  |  |

*(Copy/paste Table above if more than one supporting department is involved in this project)*