**Section 1: General Information**

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| Reference Number (assigned upon receipt) | AU RED No *(Office Use Only)*: Click here to enter text. | VHIMS Q (RISKMAN Q) No:Click here to enter text. |
| Project Title |  |
| Short Title/Acronym (if applicable) |  |

**Northern Health Principal Investigator**

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| Title & Name |  |
| Position |  |
| Department |  |
| Mailing Address |  |
| Northern Health Phone E-mail |  |
| Alternative Phone & E-mail |  |

**Additional Personnel** (add additional tables if required)

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| --- | --- |
| Title & Name |  |
| Position |  |
| Department |  |
| Mailing Address |  |
| Phone & E-mail |  |
| Alternative Phone & E-mail |  |
| Role in this Project |  |

**Student Investigator** (if applicable)

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| --- | --- |
| Name |  |
| Role in this project |  |
| University |  |
| Supervisor at Northern Health |  |
| Postgraduate qualification being completed |  |
| Phone & E-mail |  |

**External Applicant** (If applicable)

This section is for applicants who are not employees of Northern Health but require access to health, personal or sensitive information from Northern Health including from medical records.

Please identify the position and organization that you are affiliated with below:

* University Student: [*Insert University*]
* Applicant: [*Insert University employed by or Research Institute*]
* Pharmaceutical Company/Institution: [*Insert name of Sponsor Company or Collaborating Organisation*]

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| Contact Phone No: |  |
| Email: |  |

**Documents for review** (please list all related documents including their version number and date in the footer)

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| **Document** | **Version number** | **Date** |
| (Data collection tool specific to this project **must** be attached, include version/date in footer**Note:** Data should be collected in a **non-identifiable manner**, i.e. anonymous (no label or a label that is not linked to the participant) or a **re-identifiable manner**, i.e. coded (with a unique code project number, not the UR number) if it is necessary to be able to re-identify the data) |  | Click here to enter a date. |
| (Attach surveys or questionnaires with version/date in footer, if being used) |  | Click here to enter a date. |
| List of acronyms if not included in this document |  | Click here to enter a date. |
|  |  | Click here to enter a date. |

**Description of proposed activity** (refer to the last page of this application for guidance, NHORE reserves the right to change the selected activity of this application)

 ***Quality Improvement:*** [ ]  Audit OR [ ]  Service Evaluation

 ***Research:*** [ ]  Audit [ ] Unsure

**At which Northern Health campus will this activity be conducted:**

[ ]  The Northern Hospital [ ]  Bundoora Extended Care

[ ]  Broadmeadows Health Service [ ]  Craigieburn Health Service

**Reason for undertaking this activity**

[ ]  Higher Degree or Postgraduate Qualification

[ ]  Part of employee’s professional duties/employment with Northern Health

[ ]  Undergraduate Degree

[ ]  Vocational or Qualification requirement

**Approximate project duration**

Expected project commencement date: Click here to enter a date.

How long is the project expected to take?

[ ]  less than 1 year [ ]  1 to 2 years [ ]  more than 2 years

**Section 2: Protocol**

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| **Rationale & Objectives** (max 300 words) |
| Click here to enter text. |
| **Methodology** - including how the activity will be conducted, timelines, number of participants, data collection & analysis (max 500 words) |
| Click here to enter text. |
| **Consent** |
| Will written informed consent be obtained from participants? If yes, please include a copy of the Information Sheet/Consent Form for review. | [ ]  Yes [ ]  No |
| Will verbal and/or implied consent be obtained from participants?  | [ ]  Yes [ ]  No |

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| **Risks & Burdens**The risk and/or burden to participants must be negligible for these activities. Risk and/or burden include extensive interviews, lengthy questionnaires, persistent reminders, and/or intrusive/personal questions. |
| Does the proposed activity impose any additional burden, harm or risk, beyond those associated with routine care? | [ ]  Yes [ ]  No |
| If participants are being asked to complete a survey/questionnaire, please detail:* Number of surveys/questionnaires the participant will have to answer Click here to enter text.
* The time required for each participant to answer the survey/questionnaire Click here to enter text.
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| **Staff survey** |
| Will you be interviewing or surveying staff?  | [ ]  Yes [ ]  No |

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| **Privacy and Confidentiality**Participants records (medical records, databases, data/tissue banks) used for these activities may only be accessed by those with usual access (through routine clinical care or professional practice) or by those with a directly related secondary purpose. |
| Will participant records/information be accessed by those with routine access through clinical care/professional practice **OR** by those with a secondary purpose which is directly related to the patient’s clinical care? | [ ]  Yes [ ]  No[ ]  N/A  |
| Will the confidentiality of participant records/information be maintained at all times? | [ ]  Yes [ ]  No |
| Are the rights, privacy, and professional reputation of any persons or institutions involved free from any risk of infringement? | [ ]  Yes [ ]  No |
| Will all data collected as part of the proposed activity be non-identified? Please note that data must be made non-identified as soon as possible following collection. | [ ]  Yes [ ]  No |
| How will the findings of this work be disseminated? *Comment:* Click here to enter text. | [ ]  Journal article[ ]  Conference[ ]  Internal presentation  (e.g. Research week)[ ]  Case study |
| In what format will data be published? Only non-identifiable data is able to be published.[ ]  Non-identifiable [ ]  Re-identifiable [ ]  Identifiable*Comment:* Click here to enter text. |

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| **Privacy and Data Storage** |
| Will the storage of such information be securely held within the department for a minimum period, in a non-identified format? If data is to be published it will need to be kept for 5 years from date of publication. | [ ]  1 year[ ]  5 years [ ]  No[ ]  Other: \_\_\_\_\_\_(specify) |
| How will this data be stored? *Comment:*  Click here to enter text. | [ ]  Paper copies in  locked office[ ]  Electronic copies, password protected file on the NH secure network |
| How will data be destroyed?  | [ ]  Secure shredding[ ]  Secure electronic file deletion |
| **Intellectual Property Considerations** |
| Is there a possibility of new Intellectual Property being developed from this project? | [ ]  Yes [ ]  No |
| Does the Collaboration Agreement state arrangements for the use of existing intellectual property and the parties’ rights in relation to ownership? | [ ]  Yes [ ]  No |
| Does the Collaboration Agreement describe arrangements for the use of all new intellectual property through this project? | [ ]  Yes [ ]  No |

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| **Overlap with Research**Activities must not involve a deviation from normal standard care, and must not include the assessment of safety/efficacy of a new intervention or device. Any requirement for additional testing, blood or tissue collection, physical or psychological testing, or longer interviews are not considered quality improvement. Similarly, activities must not involve randomisation, or the use of control groups/placebo. |
| Does the proposed activity involve any clinically significant departure from the routine clinical care provided to patients? | [ ]  Yes [ ]  No |
| Does the proposed activity involve randomisation, control groups, or the use of placebo? | [ ]  Yes [ ]  No |
| Does the proposed activity seek to gather information about the participant beyond that collected as part of routine care? If yes, please explain. Click here to enter text. | [ ]  Yes [ ]  No |

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| **Study Budget** (If you are receiving funds to support this project, please submit relevant documentation; for example contracts and/or the letter from the sponsor) |
| **Funding Type** | **Source of Funding** | **Funding Amount** |
| Commercially sponsored | Click here to enter text. | Click here to enter text. |
| Sponsored, other (eg: collaborative groups) | Click here to enter text. | Click here to enter text. |
| External funding (eg: NHMRC, Foundations, etc.) | Click here to enter text. | Click here to enter text. |
| Internal Departmental funding | Click here to enter text. | Click here to enter text. |
| Other (eg: in-kind) | Click here to enter text. | Click here to enter text. |
| **Which organisation will receive and manage this funding and/or will be the Administering Organisation:** (Please list organisation details and contact person)Click here to enter text. | Click here to enter text. |

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| How are the findings expected to result in a quality improvement? |
| Sample Text: The benefits of this project are to:1. Determine the level of compliance with a <insert clinical standard>.2. Increase awareness and understanding among the clinicians of the <insert clinical standard> and its importance.3. Improve the compliance with the <clinical standard>.All of which will improve the quality of care provided to *<insert the patient cohort information>* Northern Health. |

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| **Principal Investigator Declaration** |

* I confirm that the information provided in this application is true and correct and that I agree to adhere to all relevant legislation and guidelines during conduct of this activity.
* I am responsible for maintaining the confidentiality of the medical records accessed and any personal, health or sensitive information contained within those records by the external applicant.

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

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| **Head of Department Declaration** |

* I support the conduct of this activity being undertaken with the department.

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| **Name of Northern Health Head of Department** |  |
| **Signature of Northern Health Head of Department** |  |
| **Date** |  |

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| **External Applicant Declaration** |

In consideration of Northern Health agreeing to allow me to access, use, collect and disclose health, personal or sensitive information from health and medical records or directly from Northern Health patients or employees for the purposes of conducting the above named project, as the case may be I:

1. acknowledge that certain legislation relating to patient health care and medical records privacy including the Health Services Act 1988 (Victoria), the Health Records Act 2001 (Vic), the Information Privacy Act 2000 (Victoria), the Mental Health Act 1986 (Victoria) and the Privacy Act 1988 (Cth) impose on me duties of confidentiality.
2. agree to comply with those requirements as they apply to Northern Health and its patients and that I am not permitted to, and will not, collect, use or disclose to any other person beyond the research team personnel, directly or indirectly, any health, personal or sensitive information about any patient of Northern Health in identifiable format obtained by reason of my participation or connection with my conduct of this project.
3. agree to maintain the confidentiality of any health, personal and sensitive information from the health and medical records I source. I will not remove any original source material from Health Information Management. I agree to keep confidential any health, personal or sensitive information concerning persons and events that comes to my attention on the Northern Health campuses. Such information includes that concerning the research study noted above and any other information which comes my way, whether it be something I read, something I see, or something I hear.

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| **Name of External Applicant** |  |
| **Signature of External Applicant** |  |
| **Date** |  |

***Submit application and relevant documents to:*** ***ethics@nh.org.au***

**Background Information**

Quality Improvement (QI) is an organised process that evaluates, assesses and seeks to improve health service delivery to improve patient and population outcomes and health service efficiency. It is also known as Quality Assurance. QI activities often involve the collection, use and disclosure of health, personal and sensitive information for the purpose of funding, management, planning, monitoring, improvement or evaluation of health services. Common QI activities include sentinel event monitoring, incident monitoring, root cause analysis, medical record review, and clinical audit. QI activities may include activities involving staff, patients or members of the community.

An audit is defined as an activity instigated by a Northern Health principal investigator involving a retrospective or prospective (occasionally) review of information that has been or will be collected for clinical purposes (e.g. a review of a medical record). ***An audit can be considered research if the intent is to attempt to drive generalizable new knowledge. Negligible risk research is reviewed by NHORE.*** The expression 'negligible risk research' describes research in which there is no foreseeable risk of harm or discomfort; and any foreseeable risk (even if unlikely) is no more than inconvenience, eg: research involving the use of information from existing datasets, documents, records pathology or diagnostic specimens which the researcher would already have access to that information or research involving only questionnaires and surveys on non-controversial, non-personal issues that also include only basic demographic data where respondents ae not identified.

**Differences between Research and Quality Improvement projects.1**

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|  | **Quality Improvement Activity** |
| **Research – Negligible, high or low risk ethical review required** | **Service Evaluation – HREC review not required (review performed by Northern Health)#** | **Clinical Audit – HREC Review not required (review performed by Northern Health)#** |
| The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them. | Designed and conducted solely to define or judge current care. | Instigated by Northern Health. Designed and conducted to produce information to inform delivery of best care, ie: Are we doing what we should be and how well |
| Quantitative research – designed to test a hypothesis | Designed to answer the question: What does this service achieve?” | Generally retrospective reviews; however prospective can be conducted.  |
| Qualitative research – identifies/explores themes following established methodology. |  | Does **not** involve collection of new raw data. |
| Addresses clearly defined questions, aims and objectives in a rigorous manner. | Measures current\* service\*\* without reference to a formal standard or regulation. | Measures against a standard or audits an already current practice. |
| Quantitative research may involve evaluating or comparing interventions, particularly new ones. This may be social research. | Involves an intervention in use ONLY (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.) | Involves an intervention in use ONLY |
| Qualitative research – usually involves studying how interventions and relationships are experienced. | Measures current\* service\*\* without reference to a formal standard or regulation. | Measures against a standard or audits an already current practice. |
| Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. | Usually involves analysis of existing data which has been routinely collected as part of the **service**, but may involve administration of simple interview or questionnaire. | Usually involves the analysis of information which has been routinely collected as part of the **practice**, but can include the administration of interview or questionnaire. |
| Quantitative research – study design may involve allocating patients to intervention groups. | No allocation to intervention: The clinician and patient have chosen intervention before service evaluation. | No allocation to intervention: The clinician and patient have chosen intervention before audit. |
| May involve randomisation | No randomisation | No randomisation |
| Although any of these three may raise ethical issues, under current guidance: |
| Research requires ethical review.Negligible via NHORELow & High via an external Human Research Ethics Committee (Austin Health is recommended) | Service evaluation does not require ethical review, however at NH if you wish to publish and present externally the NHORE must review PRIOR to implementation of the project. | Audit does not require ethical review, however at NH if you wish to publish and present externally the NHORE must review PRIOR to implementation of the project. If an audit is considered research, then ethical review is required. |

1 Adapted from Table 4.1 Differences between research, audit and service evaluation, D.K Sokol, Doing Clinical Ethics, 2012, pg58

#Quality Improvement projects must still follow basic ethical principles.

\*The service must be already available at the time that the evaluation is conducted.

\*\*If you wish to evaluate a service which has been generated as part of a research project, you should seek approval to evaluate this service as part of the ethical approval for the research element of your project.