

Subproject Application

Research Protocol

# Who should use this form?

Please complete this protocol for each new project being added as a subproject under an umbrella approval.

Each student should have a separate protocol.

This form must be ***approved*** and ***submitted to the ethics team*** (ie emailed) by the Chief Investigator of the overarching umbrella project.

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| --- | --- | --- | --- |
| Approved by: |  | Date: |  |

Please provide the following information for review:

**SECTION A**

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| --- | --- |
| **1** | **UMBRELLA PROJECT ETHICS ID:** |
|  | H13567 |
|  |  |
| **2** | **UMBRELLA PROJECT TITLE:** |
|  | START (Student TrAnsition and ReTention)  Program of Research |
|  |  |
| **3** | **SUB-PROJECT TITLE:** |
|  |  |
|  |  |
| **4** | **NAME/S OF INVESTIGATORS/STUDENTS:** |
|  |  |
|  |  |
| **5** | **BACKGROUND** |
|  | Literature review with citations: |
|  |  |
|  |  |
| **6** | **RATIONALE/JUSTIFICATION** (i.e. how the research will fill any gaps, contribute to the field of research or contribute to existing or improved practice): |
|  |  |
|  |  |
| **7** | **RESEARCH QUESTION/AIMS/HYPOTHESIS:** Provide a researchable question that clearly links to the rationale given in the background section |
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|  |  |
| **8** | **HOW DOES THE SUBPROJECT ALIGN WITH THE UMBRELLA APPROVAL?** |
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|  |  |
| **9** | **EXPECTED OUTCOMES:** |
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|  |  |
| **10** | **STUDY DESIGN:*** What type of project is it? (qualitative, quantitative, mixed methods)
* What is the design? (E.g. cross- sectional study, intervention study, audit, quality assurance, semi-structured interviews, focus group etc.)
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| **11** | **SITES:**Name the specific sites in which your data will be collected and the location  |
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|  |  |
| **12** | **PARTICIPANTS AND/OR DATA SOURCE:** *copy the table for each participant group* |
|  |

|  |  |  |
| --- | --- | --- |
| **A** | **Participation Group Number (eg 1, 2 etc)** |  |
| **B** | **Group name** |  |
| **C** | **Characteristics of the group that are relevant to the aims of the project** |  |
| **D** | **Inclusion criteria** |  |
| **E** | **Exclusion criteria** |  |
| **F** | **Expected number and age of participants** |  |
| **G** | **Sample size and statistical power issues** |  |
| **H** | **Describe what these participants will be asked to do** |  |
| **I** | **Follow up plans** |  |
| **J** | **Recruitment**How will you identify and recruit participants? Include whether screening takes place before or after consent; who will initially approach the participants; how participants will receive the recruitment documentation; how much time a participant will have to consider participation.**Will participants be offered any form of reimbursement?** |  |
| **K** | **Consent type**If you are seeking a waiver of consent for the use of pre-existing data, you must complete Section B of this form.  | [ ]  Written [ ]  Implied[ ]  Verbal [ ]  Waiver (complete section B below)  |
| **L** | **Summary of consent process**  |   |
| **M** | **Summary of project risks**(do not respond with N/A or ‘none’) |  |

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|  |  |
| **13** | **METHODS (DATA COLLECTION AND ANALYSIS):** |
|  | Describe the data collection instrument/s and the types of information will you collect to answer your research question (e.g. interviews, survey, audit etc.) |
|  |  |
|  | Provide a rationale for the selected data collection instrument – including:* + Are you using a published and validated instrument? Provide reference
	+ Are you modifying a validated instrument? Explain why and how? Provide reference
	+ Are you developing an instrument? Explain why and how?
	+ Have you piloted the instrument?
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|  |  |
|  |  |
| **14** | **ETHICAL CONSIDERATIONS:** * What ethical issues does your project raise?e.g. privacy/confidentiality, sensitive topic, emotional risk, special training required, researcher/participant relationship
* How will you address them?
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|  |  |
| **15** | **ATTACHMENTS:**Please list the names of any attachments (eg Participant Information Sheet, Consent Form etc) |
|  |  |

**SECTION B**

**WAIVER OF THE REQUIREMENT TO SEEK CONSENT**

Researchers should refer to Section 2.3 of the National Statement on Ethical Conduct in Human Research <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>

*Qualifying or Waiving Conditions for Consent* and any relevant State or Federal legislation before completing this form.

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| --- | --- |
| [ ]  | A de-identified dataset that it is not possible to re-identify (Under the Privacy Act, personal information is de-identified if the information is no longer about an identifiable individual or an individual who is reasonably identifiable.) |
|  |  |
| [ ]  | Identifiable data |
|  | [ ]  | Participant/s involvement in the research is low risk  |
|  | [ ]  | The dataset does not contain health information  |
|  | [ ]  | The research does not aim to expose illegal activity |
|  | [ ]  | There is no reason to think that participants would not have consented if they had been asked |
|  | Why isn’t it possible to use de-identified data? |
|  | Why isn’t it possible to seek consent for the use of the data? |
|  | How will the participant’s privacy and confidentiality be protected? |
|  | Why does the public interest in the research substantially outweigh the public interest in privacy? |