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| **Research Protocol Template**  **Non-clinical research** |

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| **Instructions – delete this section once your protocol is complete** |
| * This protocol template is for non-clinical research, including qualitative research, research involving biological samples, research that only involves accessing patient data   If you are unsure whether this is an appropriate template please contact the HNE Research Office   * For clinical research please use the <SPIRIT> or <Transcelerate> templates * Not all sections of this template will apply to your research   Complete only those sections which apply  Mandatory sections are indicted by a \* |

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| **\* Protocol Information** | |
| **Scientific Title** | Title of your research project |
| **Short Title** | Acronym: Plain Language Title  e.g. TEST: The Ethical STudy |
| **Version control** | Current version number and date  Replicate this information in the document footer  Update with amendments and maintain version history in the following table |
| **Principal Investigator** | Name of PI for this project  Include email and telephone details |
| **Contact Person** | Name of contact for this application  Include email and telephone details |
| **Study sites** | List all sites where this project will run  Name a Principal Investigator for each site  Include position, project responsibilities, contact details, institutional affiliation |
| **Other Collaborations** | List any other institutions or services contributing to this research  e.g. CrediTTS, UoN, Joint Medical Program, HMRI |
| **Resources** | List any associated funding  If grant funded, list the grant associated with this project, including the total amount  If funding application is pending, list information in HREA, and update the protocol if application is successful |

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| **\* Document Control**  Update this table with protocol amendments    For each amendment  Retain a copy of the original document with tracked changes recorded  Save a clean version once the changes are complete  Keep both documents as an audit trail |

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| Version Number | Date | Author | Approval Date |
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| Add extra rows as needed |  |  |  |

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| 1. **\* Background Information**   Background summary  Referenced literature review  Rationale  How the knowledge gap addresses an aim / objective / hypothesis  Expected outcomes  Use plain language in this section; your scientific information is in section 2 |

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| **Background Summary** |
| * Plain Language summary of the background to your research question * Include a summary of any other research your project will build on, from your own or published research |
| **Referenced Literature Review** |
| * Targeted literature review demonstrating the background and justification for the research question * Use the referencing style appropriate to your discipline   Full references are listed in section 6 |
| **Rationale** |
| * Plain language paragraph explaining the gap in knowledge your research will address   This may be contribution to existing practices |
| **How Knowledge Gap addresses aim / objective / hypothesis** |
| * Plain language description of how you will link this knowledge gap to the study aims and objectives |
| **Expected Outcomes** |
| * State your expected outcomes in plain language   Write what you hope to happen in your research project   * Scientific outcomes will be listed in section 2 |

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| 1. **\* Research Plan**   Study Design  Purpose of the Study  Study Population |

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| **Study Design** |
| * State the study design   e.g. We are conducting a single site prospective cohort study at the Armidale Rural Referral Hospital   * Explain your choice of methodology * State the location(s) of the research   These may be physical sites, online, laboratories |
| **Purpose of the Study**  State the key research question/s by listing the aims, objectives, outcomes and hypothesis |
| * **Study Aims and Objectives**   Aims are broad statements of intent  In one sentence, what is your general research plan  Objectives are goals  In one or two sentences, what do you hope to achieve by your research   * **Expected Outcomes**   An outcome may be called an “event” or “endpoint”  An outcome is a measure of what has happened during and / or after a study  An outcome may be expected, and may also be unexpected (e.g. a side effect, a new finding)  There can only be one primary outcome  The primary outcome is the one considered most important to answer the research question  List any additional outcomes as secondary   * **Hypothesis**   A hypothesis is a statement about the relationship between two (or more) variables in the study - it is what you expect to happen in the research.  This statement must be specific, and it must be able to be tested  This statement would usually include your primary outcome   * For biology studies only – state the control arm if applicable |
| **Study Population**   * Describe your participants / study population * If there are multiple groups of participants, or different groups at different sites, describe each group separately |
| * **Number of participants**   If there is more than one phase of your study, state the number of participants in each phase   * **Age range**   State age range of participants   * **Inclusion criteria**   Clearly state and justify the inclusion criteria  Submission to the Aboriginal Health and Medical Research Council (AHMRC) HREC is required if:  Aboriginal people are a targeted participant group or  You plan to analyse data on Aboriginal and Torres Strait Islander peoples as a specific sub-group   * **Exclusion criteria**   Clearly state and justify exclusion criteria  Exclusion from research participation requires objective justification for safety  Researcher inconvenience or cost is not an appropriate exclusion  People who do not communicate in English can access the HNE LHD Interpreter service at no cost to facilitate research participation. Non-English language is not an appropriate point of exclusion.   * **Sample Size**   Provide evidence the sample size is appropriate and feasible  Include detail on consultation with statistician <refer to CredITTS>  Calculate sample size contingencies for participant withdrawal of consent   * **Describe what your participants will do**   Describe the activities the participant will contribute to in the research study  Include the duration  Include the follow up procedures and timing   * **Participant Withdrawal**   If applicable, include process for withdrawal from the research project  Provide details of any consequences for the participants including:  Safety issues and how these are mitigated  What happens to participant data  If data and samples will be retained after a participant withdraws this requires justification |

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| 1. **\* Recruitment Methods**   Refer to: The National Statement on Ethical Conduct in Human Research, 2007 (updated 2018)  Section 3 Element 2  Identify and Invite Participants  Consent  Reimbursements |

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| **Identify and invite participants** |
| * Explain how potential participants will be identified * Explain how and who will determine participant eligibility (sometimes called “screening”) * Who will and how will this person approach people to invite them to the research   The person identifying potential particpants must have legitimate and authorised access to hospital records or other documentation containing the potential participant’s contact information |
| **Consent** |
| * State who will obtain consent   Name this person and their role in the research project   * Describe the type of consent to be used   e.g. written / verbal / implied / opt out   * If you are requesting a waiver of consent   Provide a justification in terms of section 3.10 of the National Statement  Consider question 2.8.1 of the HREA     * Consider who needs to give consent   e.g. parents, guardians, carers   * State minimisation of coercion   Are treating clinicians involved in the consenting process?  If so, how will the potential for coercion be minimised   * List the time points consent will be re-visited during the study   Include this information in your study schema (Section 8)   * Ensure the timeframe for participants to consider participation is appropriate to:   Read the information sheets  Discuss the research with others (including family, friends and other medical care providers)  Ask questions and have answers provided   * Attach the Information Sheet as an appendix to this protocol   The Information Sheet and Consent Form will be provided as a separate document for HREC and Research Governance review |
| **Reimbursements** |
| * Explain any reimbursements offered to participants   See NHMRC Guidance <link to document>   * Describe the reimbursement: * What the reimbursement is for * What the reimbursement is (e.g. gift card, cash reimbursement) * The monetary value of the reimbursement * When this reimbursement will be offered * How the participant can claim the reimbursement |

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| 1. **\* Study Activities**   Describe the activities of this research project  If your project uses data only, this is detailed in Section 5  Participants  Collection Methods  Follow Up |

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| **Participants** |
| * Describe the activities participants will do in your research project   Detail the locations of these activities  Detail who will conduct and who will supervise these activities  Include a study schema as an appendix to this protocol (Section 8) |
| **Collection Methods** |
| * State how data will be collected from participants   Detail the specific role of the participant in data collection  Plain language summary - Section 5 is for detailed data information |
| **Follow Up** |
| * Explain any follow up of participants   Include what participants need to do at these Follow Up time points   * State when participation in this research ceases * State your plan for any unexpected findings from your research – especially with respect to participant safety and providing clinical information to relevant care providers |

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| 1. **\* Data Management Plan**     A data management plan should include information as per: The National Statement on Ethical Conduct in Human Research, 2007 (updated 2018), Section 3.1.45 Section 3.1.56  Data Collection  Data Linkage  Data Storage  Analysis of Data Plan  Reporting of Results  Access to Data  Research Data Storage  Sharing and Re-use of Data  Disposal of Data |

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| **\* Data Collection** |
| * Provide an outline of your research method(s)   e.g., survey, interview, focus group   * List all databases you will access and use   + Internal LHD data   + External to LHD   + Creation of a project specific database * Include all data points and variables that will be collected   Include a data collection sheet as an appendix to this protocol  Listing every data collection point in your project  Justify the collection of sensitive data points (e.g. ethnicity, socio-cultural, gender/sexuality)   * Refer to questionnaires/surveys you will use   Note if these are validated tools  Include as appendix/ces to this protocol   * Detail how the data will be collected, and by whom * Detail access to the data within your team   Who will have access to the data  The type of data they have access to (identified, identifiable or deidentified)  Why they need that access   * Detail the physical and electronic location of where you will store your data * Include contingency for data withdrawal request by participant |
| **Data Linkage** |
| * If your project will include data linkage, describe this here * Name the person or entity who owns this data before it becomes part of your project   Sometimes called the “data custodian”   * Indicate how you will request access to this data * Include what data will be linked   Focus on what data is identifiable at the point of linkage |
| **\* Data Storage** |
| * Name the person responsible for this data once it is part of your project      * Include details of any transfer of data from its original location * State the location where research data will be stored:   During the project  After publication  Note the identification status of the data (identified, re-identifiable, de-identified)   * Describe how data security will be ensured.   **If a waiver of consent is requested, researchers should de-identify participant information as soon as possible, preferably as the data is extracted from the original source. All data must be de-identified before removal from site. Please contact the Research Ethics Office for consultation if the research project proposes disclosure of identifiable information under a waiver of consent.** |
| **\* Analysis of Data Plan** |
| * Detail your plan for data analysis   Include any data linkages planned  State how you will use the information you collected to report on your outcomes  Address any biases   * State the statistical analysis planned   Do not name the software as this may change  Refer to any statistical consultation   * Include plan for withdrawal of consent to data by participant * Note how you will secure the privacy of research participants if your data analysis is by parties who: Are not the original data custodian; or   Are not named investigators on this project |
| **\* Reporting of Results** |
| * Explain how and where you will report the results of this research   Explain how and when you will offer participants access to their individual results  Include your plan to return the results of the research to participants, as a plain language summary (see Section 1.5 3.1.65, 3.2.15, 3.3.36 - 3.3.61 of the National Statement)  Include plans to disseminate and/or publish project results   * Match this to the outcomes you have listed in Section 2 * State how privacy is ensured in this distribution * Do you plan to make your data available on open access |
| **\* Access to data** |
| * Describe who will have access to data at each location and each time point of the project   Include details of any secondary use of your data   * Explain the data lifecycle   + Who will     - Collect     - Collate     - Manage     - Distribute   + When will the data be:     - Identifiable     - re-identifiable     - non-identifiable   + Include who will have access to the data in each of its forms   Individually identifiable data - the identity of an individual can reasonably be ascertained. Examples of identifiers include name, image, date of birth and address. Patients' identifiable information cannot be accessed for research without specific consent or waiver granted.  Re-identifiable data - identifiers have been removed and replaced by a code, but it remains possible to re-identify an individual. This may occur by linking data sets or when the research is conducted in a small population (by geography or rarity).  Non-identifiable data - have never had individual identifiers or from which identifiers have been permanently removed. No individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person’s identity remains unknown |
| **\* Research Data Storage** |
| * State the length of time you will store this data after you have used it   The storage is usually a minimum of 5 years after the completion of non-clinical research   * Describe your data archiving plans * Audio and video recordings are not required to be retained, only the transcripts |
| **\* Sharing and Re-use of Data** |
| * Do you plan to re-use your data   State whether the data will be re-used  State whether your data will be shared with others   * If planning to re-use or share data:   State the purpose of sharing/re-use  Name who will be involved in the re-use  Detail the process for application to share the data  Demonstrate how participants are aware of these processes  Ensure ethical considerations including consent processes are clearly articulated |
| **\* Disposal of Data** |
| * State how data will be destroyed at the completion of the study   Refer to HNE LHD Policy and NSW Health Policy  Note the timeframe of disposal  Note the manner of disposal  Name who will be responsible for destruction of data  Detail where the data will be stored between completion of the study and destruction of data |

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| 1. **Biospecimen Research**   Complete this section if your project will include any bio-specimens  \* If you project will not use any bio-specimens, state this here and delete the rest of this section  Specimen Collection  Link to Clinical Data  Specimen Storage  Transport of Specimens  Analysis of Specimens  Reporting of Results  Access to Specimens  Research Specimen Storage  Sharing and Re-use of Specimens  Disposal of Specimens |

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| **Specimen Collection** |
| * Include specimens that will be collected   Method of collection  Size required  What part/s of the specimen will be used for research purposes   * Provide an outline of your specimen collection process   Add Specimen Collection SOP as an appendix   * List all sources of specimens you will use   + Prospective from patient   + Retrospective from biobank   + Prospective from biobank   + Collected separately to clinical care   + Collected at time of clinical care   + “Leftover samples” * Detail who will collect the specimens * Detail the annotation of the specimen * Detail who will have access to the specimens * Brief description of who will process the specimens (detail included below) * Detail the physical location where the specimens will be stored * Include contingency for specimen withdrawal request by participant |
| **Link to clinical data** |
| * If your project will include data linkage to the specimens, describe this here * Name the person or entity who owns this data before it is part of your project   Sometimes called the “Data Custodian”   * Indicate how you will request access to this linking data * Include what data will be linked   Focus on what data is identifiable at the point of linkage to specimen  Consider what specimens may become identifiable at the point of data linkage |
| **Specimen Storage** |
| * State the location where specimens will be stored:   During the project  After publication  Note how bio security will be ensured  Note at what times the specimens will be identified, re-identifiable and de-identified   * Name the person responsible for these specimens once they are part of your project   Include details during transfer of specimen from its original location below  **If a waiver of consent is requested, researchers should de-identify participant information as soon as possible, preferably as the data is extracted from the original source. All data must be de-identified before removal from site. Please contact the Research Ethics Office for consultation if the research project proposes disclosure of identifiable information under a waiver of consent.** |
| **Transport of Specimen** |
| * Detail the transport plans for specimens   Include the identification status of specimens at all points  If you are using a courier, name the company |
| **Analysis of Specimen** |
| * Detail your plan for specimen analysis   Include any data linkages planned  State how you will use the information you collected to report on your outcomes  Address any biases   * State the statistical analysis planned   Do not name the software as this may change  Refer to any statistical consultation   * Include plan for withdrawal of consent to specimen use by participant * Note how you will secure the privacy of research participants if your specimen analysis is by parties who:   Are not the original data custodian  or  Are not named investigators on this project |
| **Reporting of Results** |
| * Explain how and where you will report the results (outcomes) of the research   Include planned return of results to participants  See Section 3.1.65, 3.2.15, 3.3.36 - 3.3.61 of the National Statement  Explain how you will offer participants access to their individual results  Include plans to disseminate or publish project outcomes   * Match this to the outcomes you have listed in Section 2 * How is privacy ensured in this distribution * Any other use of specimens   Do you plan to make your specimens available to other researchers  Do you plan to re-use the specimens |
| **Access to specimen** |
| * Describe who will have access to specimens at each location and each time point of the project   Include details if you intend to allow secondary use of your specimens   * Explain the specimen use   + Who will     - Collect     - Prepare     - Distribute     - Analyse     - Destroy or Store   + When will the specimen be:     - Identifiable     - re-identifiable     - non-identifiable   + Include who will have access to the specimen in each of its forms   Individually identifiable - the identity of an individual can reasonably be ascertained. Examples of identifiers include name, image, date of birth and address. Patients' identifiable information cannot be accessed for research without specific consent or waiver granted.  Re-identifiable - identifiers have been removed and replaced by a code, but it remains possible to re-identify an individual. This may occur by linking data sets or when the research is conducted in a small population (by geography or rarity).  Non-identifiable - have never had individual identifiers or from which identifiers have been permanently removed. No individual can be identified. A subset of non-identifiable data are those that can be linked with other data so it can be known that they are about the same data subject, although the person’s identity remains unknown |
| **Research specimen storage** |
| * State the length of time you will store this specimen after initial use * Describe the storage facility * Note the security |
| **Sharing and re-use of specimen** |
| * State whether the specimen will be shared or re-used * If planning to share or re-use specimens:   State the purpose of sharing/re-use and who will be involved  Demonstrate how participants are aware of this process  Ensure ethical considerations including consent processes are clearly articulated  Describe how access to these specimens will be requested |
| **Disposal of specimen** |
| * State how specimens will be destroyed   Note  The timeframe of disposal  The manner of disposal  Who will be responsible for destruction of specimen  Address the consequences for clinical care if the specimen is destroyed |

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| 1. **\* References**   Include your reference list: |

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| **Reference List** |
| * Per standard academic referencing * Use the referencing style appropriate to your discipline |

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| 1. **\* Study Schema**     Include schema of research activities in table format  This reads best in landscape view  Add schemas for all groups of participants |

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| 1. **\*Appendix 1**     Data Collection Spreadsheet/s |

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| 1. **Appendix 2**   Participant Information Sheet  Include participant information sheets for each group in your research |

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| 1. **Surveys / Questionnaires**   Include any questionnaires / surveys you will use |

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| 1. **Specimen Collection SOP**   Include SOPs for specimen collection and processing  Refer to LHD policy if appropriate |