**Instructions for creating a research protocol**

**What is a research protocol and why is it important?**

A research protocol is a detailed plan of your proposed study or research project. Preparing a detailed research protocol is an important first step in the research process. The protocol ensures that your research project is well planned from the outset, providing a platform to define your target population, describe how participants will be sampled and recruited, detail the study intervention/exposure, and outline the study procedures, including specifying the roles and responsibilities of study investigators. The protocol also provides the opportunity to specify the number of participants required to ensure study findings are likely to be meaningful (referred to as study power). A research protocol should be written with enough detail to enable anyone who reads the protocol to understand, undertake or replicate your research project. This level of detail is important as there can be changes to study investigators during a research project and having a single, detailed source providing a step-by-step guide for the study is crucial for describing how the project should be carried out.

A research protocol is a living document that can be referred to at any stage of the research project. It is important that it remains up to date as it represents the “source guide” to ensure your project is being conducted as you had planned.

**The research protocol and Ethical review**

The North Coast NSW Human Research Ethics Committee (NCNSW HREC) provides scientific and ethical review of human research ethics applications for research that takes place at any institutions governed by Northern New South Wales (NNSW) and/or Mid North Coast (MNC) Local Health Districts (LHDs); and/or external institutions/organisations and/or for research that is undertaken by independent researchers within the geographical boundaries of NNSW and MNC LHDs as approved by a HREC Co-Chairperson.

Submitting a new ethics application to the North Coast NSW Human Research Ethics Committee (NCNSW HREC) requires the following elements:

* A Human Research Ethics Application (HREA) completed in the [Research Ethics Governance Information System (REGIS)](https://regis.health.nsw.gov.au/); and
* All supporting documents – e.g., study protocol, participant information sheet, consent form, etc. These documents are to be uploaded and submitted through REGIS.

**Protocol template**

This is a generic protocol template that can be used for any research project. Some subsections will not be appropriate to your research and can be deleted/modified. For specific guidance as to what to include in your protocol, refer to the [EQUATOR network](https://www.equator-network.org/) and select the guideline that matches your study design. While these guidelines are designed to assist with reporting for publication, they do provide good guidance on what to include in your protocol.

**Delete this information page, all prompts and instructions (*grey italics*) from the final document.**

**Resources:**

For more information on how to undertake ethical research and write a research protocol:

* [National Statement on Ethical Conduct in Human Research (2007) – Updated 2018](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)
* Aboriginal Health & Medical Research Council of NSW [(AH&MRC)](https://www.ahmrc.org.au/health-topic/ethics/)
* Enhancing the Quality and Transparency of Health Research ([EQUATOR network](https://www.equator-network.org/))
* World Health Organisation. [Recommended format for a ‘research article’](https://www.who.int/groups/research-ethics-review-committee/recommended-format-for-a-research-protocol) includes a link to “[A practical guide for health research](https://apps.who.int/iris/rest/bitstreams/527138/retrieve)” (book), which can be freely downloaded.

|  |
| --- |
| **protocol** |
| [Insert Full Study Title] |
| Version Number: INSERTDate: DD/MM/YYYY |
|  |
|  |
| **Statement of Compliance**This document is a protocol for a research project. This study will be conducted in compliance with all stipulations of this protocol, the conditions of the ethics committee approval, the National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research (2007) – Updated 2018*, and the NHMRC and Universities Australia *Australian Code for the Responsible Conduct of Research (2018)*. If the project is a clinical trial, it will comply withthe *Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95)*. If the project relates to Aboriginal and/or Torres Strait Islander health, it will comply with the NHMRC *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders (2018)*, the *Australian Institute of Aboriginal and Torres Strait Islander Studies* *(AIATSIS) Code of Ethics for Aboriginal and Torres Strait Islander Research (2020*), and the *Aboriginal Health & Medical Research Council of NSW Ethical Guidelines: Key Principles (2020) V2.0*.  |

Study Investigators

*Add as many co-investigators as required. If this research will be used as part of a student project/course requirement, note this in the “Role in Study” and include the course/degree being undertaken.*

**Coordinating Principal Investigator**

|  |  |
| --- | --- |
| Title & name: |  |
| Institution: |  |
| Position: |  |
| Contact phone: |  |
| Contact email: |  |
| Role in study: |  |

**Study Contact Person**

|  |  |
| --- | --- |
| Title & name: |  |
| Institution: |  |
| Position: |  |
| Contact phone: |  |
| Contact email: |  |
| Role in study: |  |

**Co-Investigator**

|  |  |
| --- | --- |
| Title & name: |  |
| Institution: |  |
| Position: |  |
| Contact phone: |  |
| Contact email: |  |
| Role in study: |  |

Study Synopsis

*The study synopsis should summarise all the central elements of the research protocol. It should be able to be read on its own, and not refer the reader to the main protocol.*

|  |  |
| --- | --- |
| Title: | *Use a descriptive, informative title that succinctly describes the study including the main research idea and the study design* |
| Short Title: |  |
| Study Site/s: |  |
| Study Aims / Objectives / Hypothesis: |  |
| Study Design: |  |
| Study Population:  |  |
| Study Exposure / Intervention: |  |
| Study Outcome Variables: |  |
| Number of Participants: |  |
| Key Ethical and Safety Considerations: |  |
| Translation to Clinical Practice: |  |

Glossary of Abbreviations, Terms, and Acronyms

*Add additional rows as required.*

|  |  |
| --- | --- |
| Abbreviation, term, acronym | Definition (using lay language) |
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Background and Rationale

* *Provide an introduction to the study. This may include a description of the problem, a brief, critically appraised literature review of the area, and rationale/justification for the project (i.e., Why is it important that you undertake this project? What is the evidence-practice gap you are trying to address?). It is equivalent to the introduction in a research paper, and it puts the proposal in context.*
* *Typically, the background and rationale are 1-2 pages and includes 10-20 references.*
* *Contact the NNSW or MNC LHD Library for support if required.*

Research Question and Aims/Objectives/Hypothesis

* *State the research question and/or the aims/objectives of your study. The research question should include all relevant elements of the PICO framework (Population, Intervention, Comparator and Outcome). State the aim (an aim describes the overall goal/intention of the project) and objectives of the activity/project (the objectives are the specific steps you will take to achieve your aim).*
* *A hypothesis may or may not be required depending on the aims of your research. A clearly defined hypothesis is required if your study is testing a relationship between two or more variables.*

Methods

*The scientific integrity of the study and the credibility of the study data depend substantially on the study design and methodology.*

**Study Design**

* *Qualitative methods (e.g., action research, focus groups, interviews). Qualitative studies are undertaken to explore/gain an insight into a topic/subject/phenomenon through the observations, views, thoughts, opinions, understandings, etc of study participants and can be hypothesis generating. It is important that you describe your approach to data and or thematic analysis in detail*
* *Quantitative methods (e.g., surveys, case study, cohort study, cross-sectional study, case-control study, randomised controlled trial). Quantitative studies should, ideally, be underpinned by an epidemiological study design (e.g., please refer to the section ‘Robust Study Designs for Research’ –* [*https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-support/education-methods*](https://nnswlhd.health.nsw.gov.au/our-organisation/research/research-support/education-methods)*) and be either descriptive or inferential in nature.*
* *If the study is made up of multiple components or phases, e.g., mixed methods study/multi-modal, please describe each component/phase of the study and, for mixed methods studies, how they relate to each other. If ethical approval is being sought for only selected stages, make clear what stage this protocol is for and whether an amendment or separate submission will be made for future stages.*
* *Please visit the* [*Centre for Evidence-Based Medicine*](https://www.cebm.ox.ac.uk/resources/ebm-tools/study-designs) *for information on study design nomenclature and their uses.*
* *For studies involving an intervention (e.g., randomised controlled trial) or study factor/exposure, please describe this in detail (to a sufficient level to enable the study to be replicated by another investigator or research team) in the study exposure/intervention section below.*

**Study sites/settings**

*Describe the setting of interest (e.g., ED/inpatient/outpatient/community/home-visit) including the number of sites (single- or multi-site), locations (e.g., hospital site(s)) and relevant dates (e.g., July – September 202X) e.g. period of recruitment, follow up and data collection (e.g., July – September 202X).*

**Study Population (including eligibility/inclusion and exclusion criteria)**

Study population

* *Define the study population in which the research project will be carried out in terms of demographics, disease/condition of interest etc.*

Inclusion criteria

* *Specify inclusion criteria (e.g., age range, gender, specific diagnosis and stage of disease, previous treatment history)*

Exclusion criteria

* *Specify exclusion criteria (e.g., an inability to give informed consent, or understand English, contraindications of the study treatment and/or procedures, conditions that will hinder the interpretation of results from the study, or participant’s inability to comply with the study protocol)*

**Study procedures: sampling, recruitment, consent, data sources and/or collection**

* *Provide a detailed description of how the study is to proceed. This includes detailing the steps you will take to identify/sample, recruit, consent, collect data from and follow up participants, including how often data will be collected, by whom and the estimated time involved.*
* *A flow chart may be used.*

Sampling

* *Describe how participants will be sampled (e.g. random, consecutive, purposive, convenience sampling) and from where (e.g. clinics, presentation to ED, flyers) and over what time period.*

Recruitment

* *Describe the process you will undertake to enrol/recruit people into the study.*
* *If you are undertaking a randomised controlled trial please include a subheading on randomisation, blinding and allocation concealment as appropriate.*

Consent

* + - *Describe the type of consent being sought (e.g. individual consent, implied consent, waiver of consent; refer to the* [*National Statement on Ethical Conduct in Human Research (2007) - Updated 2018*](https://www.nhmrc.gov.au/_files_nhmrc/file/publications/national-statement-2018.pdf)*, addressing the requirements of section 2.3.10), the process potential participants will go through to provide consent, who is responsible for obtaining consent from participants and the process on how participants can withdraw their consent.*
		- *Detail if consent will be specific (for this study only), extended (for use of data and/or tissue in future research that is an extension of, or closely related to this study, or in the same general field), or unspecified (use of data and/or tissue in any future research).*

Main study exposure/intervention

* *Provide information on the main study exposure/intervention variable(s), how it is defined (e.g. diagnostic/treatment codes, descriptive definition, a pharmacological intervention, a non-pharmacological intervention), the source of data and how it will be assigned to study groups (e.g. by the study investigators if experimental or self-report/assigned by choice/circumstance if non-experimental).*
* *The* [*TIDieR checklist*](https://www.equator-network.org/reporting-guidelines/tidier/) *for intervention description and replication may be a useful tool for reference. This checklist itemises information about the intervention according to name, the ‘why’ (e.g. rationale behind its use), the ‘what’ (e.g. materials and procedures used for intervention delivery), the ‘who’ (e.g. personnel responsible for the intervention), the ‘how’ (e.g. modes of intervention delivery), the ‘where’ (e.g. location), the ‘when’ (e.g. schedule of intervention delivery and accompanying dose), tailoring and modifications (e.g. if the intervention is to be personalised or adapted). Writing to each of these sections will facilitate the describing of the intervention to a level expected in a study protocol.*
* *Add additional rows as required*

|  |  |  |  |
| --- | --- | --- | --- |
| Exposure/intervention  | Definition/description | Assignment/Data source | Data collection time points |
| *e.g. Mobile health app for enhancing recovery following orthopaedic surgery* | *Mobile health app to help manage pain, prompt the patient to engage in relevant rehabilitation activities and provide evidence-based recommendations for self-management in accordance with accepted guidelines.* | *e.g. Assigned by study statistician with information on treatment allocation securely stored in the master participant list.* | *e.g. Data on mobile app use will be assessed monthly (up to 6-months)* |
|  |  |  |  |
|  |  |  |  |

Main study outcome variable(s), covariates, predictive factors, confounding factors and assessment time points

* *Provide information on the main outcome variable(s), how it is defined (e.g. diagnostic/treatment codes), descriptive definition, the source of data, and how often it will be assessed/measured.*
* *Add additional rows as required*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outcome *(Primary/secondary or covariate)* | Outcome measure | Definition/description | Data source | Data collection time points |
| *e.g. Pain score (primary outcome)* | *e.g. 0-10 Visual analogue scale* | *e.g. Pain score at 7 and 14 days* | *e.g. Participant self-report or telephone call by lead investigator* | *e.g. Baseline, 2 and 6 months* |
|  |  |  |  |  |
|  |  |  |  |  |

Data Governance

Data collection procedures

* *Describe the data collection procedure/s. For example, how will focus groups/interviews be conducted e.g. face-to-face or online? How long will focus groups/interviews with patients be? Will these be audio recorded? How will survey/focus group/interview questions be developed? Will they be piloted?*

Data management and access procedures

* *Describe how the data will be managed. For example, how will questionnaire data, interviews, pictures, blood test, imaging results be recorded as data? Will this be entered into a database? When and how will the data be cleaned?*
* *Specify who will have access to the data and how the data will be accessed.*
* *Describe how data will be transferred between study investigators if going offsite.*
* *Note whether participants will be able to access or request their own data.*
* *Describe any plans for secondary use of data or information (e.g. data sharing between sites).*

Data storage and security

* *Describe how participants’ privacy and confidentiality will be protected. For example, in what format will participant data be stored (e.g. identifiable, re-identifiable or non-identifiable). If applicable, please outline how data identifiers will be removed and by who, and whether a list of identifiers will be kept and where that will be stored.*
* *Where and how will consent forms, recorded transcripts and study data be stored, and how long will study data be retained following completion of the project.*
* *When, how and who will destroy the data at the end of the data retention period.*

Statistical considerations

Sample size and statistical power

* *Provide a description of the sample size required to address the study aims and objectives.*
* *For quantitative analyses, please base this on power calculations guiding the sample sizes needed to detect effect sizes (e.g. difference in means) at specified confidence levels (e.g. 95%) and power (e.g. 80%).*
* *For qualitative projects this could include any practical considerations, budgetary constraints, data saturation.*

Data/Statistical analysis

* *Provide a description of the statistical methods that will be used.*
* *For Qualitative projects e.g. coding (inductive/deductive), single or multiple coders. Define the theoretical framework underpinning your proposed thematic analysis and comment on approach to data saturation*
* *For Quantitative projects e.g. descriptive statistics: count, percentage, frequency, median, mean, standard deviation; inferential statistics: statistical models and significance tests (e.g. student-tests, chi-square tests, linear regression). It is good practice to express your results as a point estimate and 95% confidence intervals, as appropriate, and describe how you will calculate each.*

Ethical Considerations

*Consult the* [*National Statement in Ethical Conduct in Human Research*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018)*.*

*Determine the level of risk associated with the proposed activity (inconvenience, discomfort, harm).*

*If any risks are identified, indicate how they will be mitigated and/or addressed.*

*Consider whether your study population proposes to include specific participants as outlined in Section 4 of the National Statement and address an ethical consideration specific to them. These include:*

* *Women who are pregnant and the human fetus*
* *Children and young people*
* *People in dependent or unequal relationships*
* *People highly dependent on medical care who may be unable to give consent*
* *People with a cognitive impairment, an intellectual disability, or a mental illness*
* *People who may be involved in illegal activities*
* *Aboriginal and Torres Strait Islander Peoples*
* *People in other countries*

*Consider the ethical considerations for culturally and linguistically diverse communities.*

Outcomes and Significance

Translation to clinical practice

*Provide information on the potential benefits of the research for clinical practice including extent of the changes e.g. hospital wide, national or international. Highlight the potential significance of the findings (e.g. to inform future research, policy, planning and/or practice). How will the new knowledge be disseminated to relevant stakeholder groups? What knowledge translation mechanisms will you use to ensure findings influence policy and practice?*

Dissemination plan

Where do you plan to disseminate the findings of the project*: (check all that apply and provide details as appropriate)*

[ ] Internal report (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] External report (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Presentation (please provide details e.g. unit/department/organisation level, scientific conference): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Publish in a peer-reviewed journal (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  Other (please provide details): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note that you will be asked to report upon your dissemination plan in your final report.*

Timeline

* *Provide a timeline of activities described in this protocol. You may like to consider using a Gantt chart.*

Funding and resources

* *Give details of any funding received or sought for this project. Name the funding organisation, the size of the grant, period of funding, nature of peer review, and date of application.*

References