CALHN Research Services

Investigator Initiated Protocol Guideline – Clinical Research

Overview

Health/Medical Research Projects conducted at a Central Adelaide Local Network (CALHN) site that are greater than low/negligible risk, and/or that include participating sites outside of South Australia, require ethical review and approval by a full Human Research Ethics Committee (HREC).

Ethical review is conducted in accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007) (incorporating all updates) (herein the National Statement), available here.

All studies submitted to the CALHN HREC must have a study protocol. The study protocol provides the background, rationale and objectives of the research and describes the design, methodology, organisation and under which it is to be performed and managed. Research proposals should be clear and comprehensive and written in lay language.

Researchers who are planning to submit a research application for clinical research that involves greater than low risk should refer to this guideline for guidance and instructions.

PLEASE NOTE: All documents submitted for review must follow the CALHN HREC submission guideline.

Recommended document Formatting:

Logos: The institution/organisation that will own the study results

Font: Arial (default)

Size: 12pt

Footer format: <Document type>, Version XX, Dated XX XXX XXXX Page X of X

Protocol

Protocol Title:

Short Title: (if applicable)

Sponsor Name:

The sponsor is the institution responsible for the ownership of the protocol/results.

Address: (address of institution)

Phone number:

Funding Body:

Provide information about how the project will be funded.

Project Team – Roles and Responsibilities

If investigators have multiple affiliations, list the affiliation/capacity the investigator will be using for the duration of this project. One affiliation must be nominated.

Principal Investigator:

The research project must have one designated Principal Investigator responsible for the overall project coordination. In cases where the research project involves multiple sites, clearly state the Principal Investigators for each site and the Co-ordinating principal Investigator for the project.

Name:

Qualification:

Institutional affiliation and Department/Academic unit:

Email address (*institutional email address*):

Phone number:

Responsibilities/duties:

Investigator(s)/other personnel:

[add/delete as required]

Name:

Qualification:

Institutional affiliation and Department/Academic unit:

Email address:

Phone number:

Role: *e.g. investigator, administrative contact*

Responsibilities/duties: *e.g. study design, analysis, recruitment etc*

Abbreviation List

Recommended if the protocol contains numerous acronyms.

Project Overview

Ensure that you refer to the National Statement Chapter 3.1 Elements of Research for guidance on how to conduct this research in accordance with core ethical principles.

Introduction

Provide a brief overview that introduces the main topic and provides context for the research. This will help the reader understand the purpose of the study and what they can expect to learn from it.

Background

Provide a brief description of the background of the study including its theoretical basis, any relevant previous studies, and any relevant contextual information.

Include appropriate references relating to the literature.

Purpose

The purpose of the study should be clearly connected to the background information and gaps in the current research literature.

Aims

- Your aim(s) should arise from your literature review and state what the study hopes to accomplish.

Objectives

- Your focused research question(s) may need to be further refined as one or more study objectives. The study objective(s) should be single and quantifiable statement(s) that will allow you to answer your research question(s).

Hypothesis (if applicable)

- A clear and testable statement of your prediction or expectation that can be validated by the research.

Study Design

The study design is an important component of any research project.

- Provide an overview of the study design.

- State the design of the research (e.g. prospective, retrospective, randomised controlled study, etc).
- Explain how the study design will answer the research question or aims.
- Include the anticipated duration of the study (months/years). And the anticipated data collection period.

Study Population and Setting

- State whether the project is a single or multi-site study.
- State the location(s) the study will be conducted.
- Provide a comprehensive list of all sites and departments that are involved in the study, along with a brief description of the activity occurring at each location.
- Provide a description of the population to be studied. Include, for example, age, sex, condition, and any additional participant descriptors, the number of participants required and/or expected and duration of the study.

Eligibility Criteria

The inclusion and exclusion criteria for the potential participants in a project must be justifiable and should be fair.

Inclusion criteria

- Describe the characteristics that clearly describe the study population required for a participant to be included in the study.

Exclusion criteria

- Describe the characteristics/basis on which prospective participants will be excluded from the study, and the rationale for the exclusion.

Withdrawal Criteria

Provide information about the participant withdrawal criteria and specify:

- How the participants can withdraw.
- What happens to the data collected prior to withdrawal?
- How would the data be affected by a participant's withdrawal, and what measures would be taken in response to it?

Recruitment

- Describe in detail the sources and methods that will be used in the identification, recruitment, and selection of potential participants and/or historical data.
- Explain how participants will be recruited into the study e.g. flyers, direct approach.
- Explain the pre-screening processes that will be used to identify eligible participants
- How will participants be approached? E.g. face to face, via email etc.

- Who will make the first approach?
- How long will potential participants be given to consider participation?
- What is the period expected to recruit the required number of participants?
- For studies involving health service employees as participants, how will recruitment be managed to ensure there is no coercion to participate? Consider who will recruit participants, what method will be used to recruit, how much time employees have to consider participation, and whether employees consenting/declining to be involved will be identifiable to their management?

Informed Consent

Where possible, informed consent should be sought from individuals to participate in research or to access their data for research purposes.

- Outline what information will be provided to the participant.
- Which investigator(s) will be responsible for explaining the research project?
- Which investigator(s) will be responsible for obtaining consent?
- How will consent be documented? (e.g. signature, verbal)
- If potential participants are unable to give their own consent, outline if third party consent will be sought.
- Will there be an opportunity to confirm or renegotiate consent during the research project? Who will be confirming or renegotiating consent with participants and what process will be undertaken?
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Waiver of Consent

If informed consent of participants will not be sought and the researchers who will access data and/or conduct study procedures are not in the direct care of each participant, provide justification with reference to the provisions in Chapter 2.3.10, a) through i), of the National Statement. Please use the CALHN Waiver of Consent Template - Appendix 1: Waiver of Consent Information and Template.

Study Procedures

Provide clear and detailed descriptions of the specific procedures or techniques that will be utilised to answer the research question and achieve the project aims. Include exactly what will happen to any participant once they enrol in the study and what is expected from them.

- Outline the study procedures and techniques that will be used.
- Outline the participants commitments. For example, what occurs at each study visit.
- Outline how participants will be monitored during and after the study.
- Multiple Phases: Clearly detail each phase of the project including the projected timeline for each phase.
- Outline any study restrictions. E.g. live vaccines.

A Schedule of activities is highly recommended.

Methods of data collection

If **existing data** will be used:

- Identify the source.
- Specify what data will be extracted (whole record, specific elements or information).
- Which investigators/research personnel will be responsible for extracting the data?
- Use the below Access to existing data table template*:

Name/Description of data	*e.g. RAH Electronic Medical Records*
Data Custodian	*Which institution? e.g. CALHN*
Database Name	*e.g. Sunrise*
Agency Type State	*(State / Commonwealth / Private Sector)*
Data Collection Format	*Identifiable (identifiable / re- identifiable / non-identifiable)*
What variables will be collected from the database?	*e.g. Name, age, etc*
Which investigator(s) will access the database?	*<insert name(s), affiliation>*

**Mandatory if accessing existing data. A table must be included for each database that will be used.*

Data Collection

- Outline what data will be collected.
- Describe how the data will be collected (e.g. patient survey, focus group etc.).
- Specify what format the data will be collected in (written notes, audiotape, questionnaire responses etc.).
- Who will be responsible for data collection?

REDCap is the CALHN preferred method of building and managing investigator-initiated research data bases and surveys.

Sample Collection

Access to **existing tissue/samples**

- Identify the source and data custodian.
- Who will access the samples?

Sample collection

- Outline which samples are standard of care and which samples are being collected for research purposes.
- Explain who will be responsible for collecting the samples.
- Explain how samples will be collected.
- Is consent being sought for the samples?

Study Outcomes

- What do the investigators anticipate the outcomes of this research will be?
- How will the outcomes be measured?
- Specify any potential implications of the potential results.

Data Analysis

Outline how the research results will be analysed.

Clearly detail any statistical analysis methods that will be used to meet the study aims and/or test the study hypotheses.

Radiation

If the research involves ionising radiation methods, you are required to document:

- What procedures and apparatus will be used?
- What are the radioactive sources?
- What is the number and frequency of procedures per participant? Include the frequency per year and over the course of the project.
- Where will the procedures be carried out?

CALHN specific requirements:

Clearly outline which procedures are standard of care and which procedures are research specific.

All research involving exposure to ionising radiation above standard medical care amounts requires a radiation dose and risk assessment report sent to the Human Research Ethics Committee. A medical physicist will calculate the radiation dose from the procedure and provide statements to the committee on the risks associated with the radiation exposure/dose.

Protocol Deviation

The following statement must be included:

Protocol deviations occur when an investigator conducts a procedure or task that is not detailed in the study protocol and/or the Participant Information and Consent Form. It may comprise participant contact, laboratory work or management of data/documentation. Protocol deviations must be reported to the reviewing ethics committee as soon as practicable following the investigators becoming aware of the deviation.

Safety Consideration

Provide information about how the safety of research participants and researchers will be ensured. Outline any safety monitoring and reporting responsibilities.

Data and Sample Management

Data storage during the study

- State whether data collected will be de-identified, re-identifiable, identifiable but confidential or anonymous.
- How will data be de-identified and who will be responsible for this?
- Outline how data re-identification will occur (e.g. enrolment log).
- Outline which investigator(s) will have access to de-identified data and/or identifiable data.
- Where will data be stored and how will it be secured?
- Who will have access to the data?

*Please note: **REDCap is mandatory** for data management purposes for all **CALHN studies.** For further information: The Standard Operating Procedure – "P0032: Source Documents, Case Report Forms, Data Management and Archiving" is available to CALHN staff via eCentral.*

REDCap

- To create a new CALHN REDCap account visit https://redcap.had.sa.gov.au/ and select New User Request Form
- REDCap Help is available here: https://redcap.had.sa.gov.au/index.php?action=help
- REDCap Training is available here: https://redcap.had.sa.gov.au/index.php?action=training
- CALHNs REDCap server has following limitations.
    - It can only be accessed using a HAD account
    - It is not publicly accessible and can only be accessed from SA Health computers or via a VPN connection.
    - Once your application is submitted it will be reviewed and processed. REDCap staff should be in contact within 2 days.

Data storage post project completion

- What format will data be stored in?
- Where will data be stored?
- Who will have access to the data and for what purpose?
- What strategies will be put in place to ensure data security?
- How long will data be stored, who will be responsible for its disposal, how will disposal occur?

Please note: Data must be stored at the institution that owns the study results. If data is identifiable, it must be stored at CALHN unless consented.

Electronic data should be stored on a 'shared departmental drive with password protection' and hard copy data should be stored in locked filing cabinets (or similar) only accessible to the study team.

Electronic copies of research data bases and documents containing confidential information must be stored on the institutional server and not on a personal drive/USB.

Sample management

- Where will they be stored during and after the project?
- Will samples be identifiable, de-identified or re-identifiable?
- Which institution owns the samples?
- Which Institution will be responsible for analysing samples?
- How long will samples be stored, who will be responsible for its disposal, how will disposal occur?

Publication

- Outline the authorship and publication policy.
- What is the plan for reporting, publishing or otherwise disseminating the outputs/outcomes of the research?
- Will participants in the research be informed of the study findings?

Ethical Considerations

Benefits

- Identify and explain the expected outcomes and potential benefits of the study.

Risks

- Identify and explain any potential risks of the study.
- Explain the level and likelihood of risks during and after participation.
- Include any risks that may result from the dissemination of study findings.

Risk mitigation

- Explain any strategies that will be put in place to manage the listed risks.

Indemnity and Compensation for injury (if applicable)

- Include information about who is indemnifying the study and any relevant compensation schemes.

Conflicts of interest

- Describe any possible conflicts of interest (actual or potential) of the researcher(s). Consider:
  - Dependent or unequal relationship issues between investigators and participants.
  - Whether investigators have any affiliation or involvement in any organisation or entity with direct or indirect interest in the subject matter of this research.
  - Any restrictions on publication or dissemination of research findings.

Any other ethical issues.

- e.g. participant reimbursement, site payments.

Consumer and Community Engagement

Investigators are encouraged to consult with Consumer and Community groups with the design of their research. Please outline any consultation that has occurred.

References

Include all references used throughout the application.

Attachments

All Participant Information Sheets/Consent Forms, copies of all questionnaires, recruitment flyers or information brochures and any other documents relevant to the study must be submitted as separate attachments.

Appendix 1:

Appendix 1: Waiver of Consent Information and Template

Before deciding to waive the requirement for consent (other than in the case of research aiming to expose illegal activity), an HREC or other review body must be satisfied that the project meets all requirements of Chapter 2.3.10 of the NHMRC National Statement on Ethical Conduct in Human Research (2007) (incorporating all changes) as set out below.

Using the below proforma, address each point of the NHMRC National Statement on Ethical Conduct in Human Research 2007, (incorporating all updates), 2.3.10.

Justify the Waiver of Consent request in the study protocol by listing the points 'a-i' with responses provided below each point of the Waiver. The CALHN HREC will not accept references to sections of the Protocol as a response.

Include an introduction sentence to the waiver, stating what type of waiver is being requested (for example Pre-screening for eligibility or retrospective medical records looking at years from XXXX to XXXX) and who will be accessing the medical records.

Please note: Where possible, informed consent should be sought from individuals to participate in research or to access their data for research purposes.

Template

Pre-screening: A waiver of consent for pre-screening is sought for this project. In order to identify suitable participants for this research project, <investigator> will be required to access <specify what is being accessed>, prior to obtaining consent from the patient.

Access to records: A waiver of consent for retrospective access to medical records is sought for this project. <investigator> will be required to access <specify what database(s) is being accessed>.

a) involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants

b) the benefits from the research justify any risks of harm associated with not seeking consent

c) it is impracticable to obtain consent.

d) there is no known or likely reason for thinking that participants would not have consented if they had been asked

e) there is sufficient protection of their privacy

f) there is an adequate plan to protect the confidentiality of data

g) in case the results have significance for the participants' welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)

h) the possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled

i) the waiver is not prohibited by State, federal, or international law.

Essential Tips

For part C, address:

- Why is it impractical to gain consent?
- Time period (MM/YYYY to MM/YYYY).
- How many records will be accessed? (estimate is suitable)
- Are there limitations to resources?
- Mortality rate of participants (estimate is suitable).
- Lost to follow up - inability to contact participants due to access to contact details or due to likelihood of contact details having changed due to time or due to characteristics of participant groups (estimate is suitable).

For part F, please include the following information:

- What format will data be stored in?
- Where is data being stored?
- Who will have access to identifiable data?
- Will data be re-identifiable?
- Which investigator is responsible for de-identifying data?
- Will the research team using REDCap?

For more information

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