Central Adelaide Local Health Network
Research Services

Investigator Initiated Protocol Guideline – Intervention/Clinical Trial

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 (2023) (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.

All Protocols must meet the requirements of the National Statement on Ethical Conduct in Human Research 2023.

All SA Health projects must meet the requirements of the SA Health Research Ethics and Governance Policy.

For Clinical Trials the Protocol must comply with Therapeutic Goods Administration (TGA) regulations and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines.

For research involving Indigenous Australians, additional ethical guidelines must be followed, such as those in the NHMRC's Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders

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

PLEASE NOTE: Adelaide Health Medical School (AHMS) Clinical Research

For any project conducted at the University of Adelaide's Clinical Research Facility a risk mitigation plan is required. Please contact the University of Adelaide's Clinical Research Facility to discuss current requirements. Please ensure consultation occurs prior to submitting your ethics application. Please contact via crf@adelaide.edu.au

Government of South Australia
Health
Central Adelaide Local Health Network

Protocol Guide

Protocol Title:

Short Title: (if applicable)

Protocol Number:

Phase: (if applicable)

Sponsor Name:

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

Address: (address of institution)
Phone number:

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.

The monitor (if other than the sponsor) and the medical expert (or dentist when appropriate) must be listed in this section.

The Name, title, address, and telephone number(s) of the qualified physician (or dentist, if applicable), who is responsible for all trial-site related medical (or dental) decisions (if other than investigator) must be listed.

Principal Investigator:

The research project must have one designated Principal Investigator (PI) 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]

The study Monitor and medical representative must be included in this section.

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*

All Principal Investigators and other investigators need to provide evidence of Good Clinical Practice (GCP) for clinical trials in Australia when conducting human research. Please refer to Australian Clinical Trials Good Clinical Practice

Trial Site(s):

Address:
Phone Number:
The Name(s) and address(es) of the clinical laboratory(ies) and other medical and/or technical department(s) and/or institutions involved in the trial must be listed in the protocol.

Statement:

A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s).

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 relevance Please provide details of 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.

Endpoints

- A specific statement of the primary endpoints and the secondary endpoints, if any, to be measured during the trial.

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).

- Please describe the measures taken to minimize or avoid bias in your study. For example randomisation or blinding.
- 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.
- State whether the project is specifically identifying First Nations Persons as a cohort.

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 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?
- The type and timing of the data to be collected for withdrawn participants (if applicable).
- Whether and how participants are to be replaced (if applicable).
- Is there follow-up for participants that have withdrawn from investigational product treatment/trial treatment (if applicable).
- If the study is terminated early, outline and justify what will happen to the participants involved in the study and whether the treatment will continue to be provided. (if applicable)

Opt-out approach

Provide information about participant opt-out criteria and specify:

How participants can opt-out

- Whether prospective participants have been provided appropriate plain language information to make an informed decision.
- Has there been a reasonable time period between the provision of information to prospective participants and the use of their data so that they have the opportunity decline before research begins.
- What is the mechanism that will ensure that prospective participants can obtain further information before making an informed decision to opt-out?

Provide a statement that potential participants won ’t be disadvantaged regarding their ongoing treatment are care.

Study Discontinuation

The details and justification of any stopping rules or discontinuation criteria should be provided.

- How will information that the study has been discontinued be disseminated to participants?
- Provide details under what circumstances would the research be discontinued?

Early Termination

Outline what will occur if the trial is terminated prematurely.

- How will information that the study has been terminated prematurely be disseminated to participants?
- Provide details under what circumstances would the research be terminated early.

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.
- Recruitment strategy should be relevant to the research methodology, topic/subject matter, the potential participants and the context.
- Explain how participants will be recruited into the study e.g. indirectly, such as flyers, or directly, such as patient lists.
- 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?
- How will the recruitment strategy ensure that participants can make an informed decision about participation?
- Has culture, traditions and belief been considered regarding recruitment?
- 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 and 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?
- Has direct recruitment been free of coercion/exploitation?
- Has there been any pressure put on potential participants due to any payment in money or incentives of any kind?

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?
- How will informed consent be obtained from diverse cultures and backgrounds? Will information be translated into languages other than English?
- How will informed consent be obtained from First Nations persons? (if relevant)

- How will consent be obtained for future secondary use of data or tissue in research? For example, research activities outside of SA Health employment, such as University or Medical College activities.

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, medication(s)/treatment(s) permitted (including rescue medication) and not permitted before and/or during the trial.
- Outline all efficacy assessments and procedures.
- Outline any potential risks. How will these be managed?
- Does the research procedure depart from established practice? If yes, please explain.
- What is the procedure for managing any distress that might be experienced by participants during the process of data collection or research procedures?
- The treatment(s) to be administered, including the name(s) of all the product(s), the dose(s), the dosing schedule(s), the route/mode(s) of administration, and the treatment period(s), including the follow-up period(s) for participants for each investigational product treatment/trial treatment group/arm of the trial.
- Outline the procedures for monitoring participant compliance.

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 and Management

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?

Investigational Product(s)

Description of Investigational Product

The Name and description of all investigational products and placebos should be given.

A summary of findings from nonclinical studies that potentially have clinical significance and from clinical trials that are relevant to the trial.

Summary of the known and potential risks and benefits, if any, to human participants.

Outline the maintenance of trial treatment randomization codes and procedures for breaking codes

Dosage

Include a description of the trial treatment(s) and the dosage and dosage regimen of the investigational product(s).

Dose Justification

A justification for the dose of investigational product(s) should be provided.

Handling and storage of study drugs

All accountability procedures for the investigational drug, including placebo and comparators should be provided, with specific storage instructions.

- Describe how the drug will be packaged and labelled and by whom.
- Describe how labelling will maintain blinding for blinded studies.

- Describe when and how medication/study drug will be supplied to the site.
- Describe who has authority to dispense the drug (investigator, pharmacist, etc.) and any other significant dispensing requirements.
- Include step-by-step instructions including order of other medications, chest physiotherapy, etc. Include how the participant should administer the study drug and/or how the study site should administer the study drug.
- What are any potential risks? How will these be managed?

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.
- Will participants be able to access the research study results and outcomes? Please explain.

Data Analysis

- Clearly detail the statistical analysis methods that will be used to meet the study aims and/or test the study hypotheses.
- Describe the statistical methods that will be employed, including timing of any planned interim analysis.
- The number of participants planned to be enrolled. In multicentre trials, the numbers of enrolled participants projected for each trial site should be specified. Reason for choice of sample size, including reflections on (or calculations of) the power of the trial and clinical justification.
- The level of significance to be used.
- Criteria for the termination of the trial.
- Procedure for accounting for missing, unused, and spurious data.
- Procedures for reporting any deviation(s) from the original statistical plan (any deviation(s) from the original statistical plan should be described and justified in protocol and/or in the final report, as appropriate).
- The selection of subjects to be included in the analyses (e.g. all randomized participants, all dosed participants, all eligible participants, evaluable participants).
- What statistical tools will be used? Such as SPSS, Stata or NVivo. Please provide details

Note, if no statistical analysis will be performed, outline how the research results will be analysed.

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?
- How will the radiation be transported?
- How will the radiation be stored at the Site?
-

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.

Serious Breach

The following statement must be included:

A serious breach is a breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree the safety or rights of a trial participant, or the reliability and robustness of the data generated in the clinical trial. The principal investigator will use continuous vigilance to identify and report any suspected breaches to the sponsor within 72 hours of becoming aware of the event and report any serious breaches confirmed by the sponsor as occurring at the site to their institution (research governance office) within 72 hours of being notified of the serious breach.

Safety

Safety Monitoring and Reporting Responsibilities

A statement must be included to outline the Principal Investigator, HREC and Sponsors reporting responsibilities. The reporting responsibilities are dependent on the project sponsor.

CALHN as the project Sponsor for an intervention or drug trial: Click here

CALHN as the project Sponsor for a device trial: Click here

External project sponsor for an intervention or drug trial: Click here

External project sponsor for a device trial: Click here

Safety Consideration

Outline any safety monitoring and reporting responsibilities.

- How will the participants and researchers' safety be ensured?
- Has the participant been provided with a Participant Emergency Contact Card with details on whom to contact in case of an emergency?
- Define Adverse Events (AE) and Serious Adverse Events (SAE).
- How will AEs and SAEs be assessed?
- How will AEs and SAEs be documented?
- Outline the methods and timing for assessing, recording, and analysing safety parameters.
- Outline the procedures for eliciting reports of and for recording and reporting adverse event and intercurrent illnesses.
- Outline the type and duration of the follow-up of participants after adverse events.

Data Safety Monitoring Board

Provide information about the personnel and processes of the Data Safety and Monitoring Committee. Further information can be located on the NHMRC website.

Clinical Trial Monitoring

Sponsors-Investigators are responsible for ensuring that the clinical trial is conducted with utmost integrity and adherence to ethical and regulatory standards. This includes protecting participants' rights and well-being, ensuring the accuracy and completeness of trial data, and maintaining compliance with the approved protocol,

Good Clinical Practice (GCP), and relevant regulations. Outline the clinical monitoring plan specific to the trial, detailing arrangements for monitoring data and conducting quality assurance checks.

Risk Management

- Are there any risks associated with this research? Provide details.
- How will risks including potential risks be mitigated? Provide details.
- How will identified risks be managed? Provide details.
- How will you monitor risk throughout the life of the research study? Provide details.

Data and Sample Management

Secondary use of data

Data collected and used for any secondary purpose, must be disclosed for ethics and governance assessment and authorisation. Researchers cannot use data for any secondary purpose, such as for University or College activities including qualifications, unless authorised to do so. This applies to SA Health employees and external persons and organisations.

- Will data be used for secondary purposes?
- How will this data be stored?
- Who will have access to this data?
- How long will it be kept?
- How will this data be disposed of? Who will dispose of the data?

Data storage during the study

- State whether data collected will be de-identified, re-identifiable, identifiable but confidential or anonymous.
- Describe the method for de-identifying. What criteria and mechanisms will be used to ensure that each code is unique and maintains patient confidentiality? Who will be responsible for de-identifying the data? Who will have access to the re-identifiable data?
- 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? How will it be secured?
- Who will have access to the data?
- Will the data be accessed/used by non-SA Health employees? For example, Universities, Non-Government Organisations (NGOs) or other organisations.
- Identify any data to be recorded directly on the CRFs (i.e., no prior written or electronic record of data), and to be considered to be source data.

*Please note: Use of **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.*

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 otherwise.

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?

Direct Access to Source Data/Documents

The sponsor should ensure that it is specified in the protocol or other written agreement that the investigator(s)/institution(s) will permit trial-related monitoring, audits, HREC review, and regulatory inspection(s), providing direct access to source data/documents.

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.

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.

Finance, Indemnity and Compensation for injury (if applicable).

- Include information about who is indemnifying the study and any relevant compensation schemes.
- Address financing if not addressed in a separate agreement.

Disclosure 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.

- For additional information regarding ethical issues in human research refer to the National Statement on Ethical Conduct in Human Research.

Consumer and Community Engagement

As per the National Clinical Trials Governance Framework, Partnering with Consumers standard 2, Investigators are strongly encouraged to consult with Consumer and Community groups regarding 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 updates) 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.

Please 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?

Appendix 2: Safety Reporting Example Statements

CALHN Sponsor: Intervention or Drug Trial

A significant safety issue (SSI) is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. An Urgent Safety Measure (USM) is a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety. A serious adverse event (SAE) is any untoward medical or psychological occurrence that results in death, is life threatening, requires inpatient hospitalisation or prolongation of existing hospitalization, or results in persistent of significant disability or incapacity.

A Suspected Unexpected Serious Adverse Reaction (SUSAR) is an adverse reaction that is both serious and unexpected.

The principal investigator will report all SAEs, any occurrences of congenital anomaly/birth defect arising from any pregnancy of a participant (or partner) and all USMs instigated by the site within 24 hours of becoming aware of the events to CALHN Research Services. The principal investigator will report as specified in the protocol all safety critical events and any additional requested information relating to reported deaths to CALHN Research Services.

The principal investigator will use continuous vigilance to identify and report all SSIs within 72 hours of identification of the event to all approving HRECs and the relevant Research Governance Officers.

The principal investigator will report all SUSARs within 72 hours of identification of the event to the relevant Research Governance Officers.

CALHN Sponsor: Device Trial

A significant safety issue (SSI) is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. An Urgent Safety Measure (USM) is a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety. A serious adverse event (SAE) is any untoward medical or psychological occurrence that results in death, is life threatening, requires inpatient hospitalisation or prolongation of existing hospitalization, or results in persistent of significant disability or incapacity.

Unanticipated Serious Adverse Device Effect (USADE) is a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

The principal investigator will report all SAEs, any occurrences of congenital anomaly/birth defect arising from any pregnancy of a participant (or partner) and all USMs instigated by the site within 24 hours of becoming aware of the events to CALHN Research Services. The principal investigator will report as specified in the protocol all safety critical events and any additional requested information relating to reported deaths to CALHN Research Services.

The principal investigator will use continuous vigilance to identify and report all SSIs within 72 hours of identification of the event to all approving HRECs and the relevant Research Governance Officers. The principal investigator will report all USADEs within 72 hours of identification of the event to the relevant Research Governance Officers.

External Sponsor: Intervention or Drug Trial

A significant safety issue (SSI) is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. An Urgent Safety Measure (USM) is a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.

A Suspected Unexpected Serious Adverse Reaction (SUSAR) is an adverse reaction that is both serious and unexpected. The principal investigator will use continuous vigilance to identify and report all SSIs to all approving HRECs and the relevant Research Governance Officers. SSIs that meet the definition of an urgent safety measure will be notified within 72 hours, and all other significant safety issues will be notified within 15 calendar days of the sponsor instigating or being made aware of the issue. The principal investigator will report all SUSARs within 72 hours of identification of the event to the relevant Research Governance Officers.

External Sponsor: Device Trial

A significant safety issue (SSI) is a safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. An Urgent Safety Measure (USM) is a measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.

Unanticipated Serious Adverse Device Effect (USADE) is a serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.

The principal investigator will use continuous vigilance to identify and report all SSIs to all approving HRECs and the relevant Research Governance Officers. SSIs that meet the definition of an urgent safety measure will be notified within 72 hours, and all other significant safety issues will be notified within 15 calendar days of the sponsor instigating or being made aware of the issue.

The principal investigator will report all USADEs within 72 hours of identification of the event to the relevant Research Governance Officers.

For more information

Documents and Links:

National Statement on Ethical Conduct in Human Research 2023

Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders.

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines.

SA Health Research Ethics and Governance Policy

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