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Protocol Template

Sponsored Clinical Trial Design

Version 3, May 2023

This document is intended to guide you in your protocol development.

Some sections may not be relevant to your project and you may delete these as necessary.

You may also remove this cover page if you wish.

Developed by the AHCL Research Office

Email: [research@sah.org.au](mailto:research@sah.org.au)

Adventist HealthCare Limited ABN 76 096 452 925

**FULL STUDY TITLE**

**SHORT STUDY TITLE**

**CONFIDENTIAL**

This document is confidential and the property of XXX

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STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007, update 2018) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95) as adopted in Australia.

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PROTOCOL SYNOPSIS

|  |  |
| --- | --- |
| **Title** |  |
| **Objectives** | **Primary:**  **Secondary:** |
| **Study Design** |  |
| **Planned Sample Size** |  |
| **Selection Criteria** |  |
| **Study Procedures** |  |
| **Statistical Procedures**  **Sample Size Calculation:**  **Analysis Plan:** |  |
| **Duration of the study** |  |

GLOSSARY OF ABBREVIATIONS

|  |  |
| --- | --- |
| **Abbreviation** | **Term** |
|  |  |
|  |  |
|  |  |

1. STUDY MANAGEMENT
   1. Principal Investigator

[Insert text – see comments for guidance]

* 1. Associate Investigators

[Insert text – see comments for guidance]

* 1. Statistician

[Insert text – see comments for guidance]

* 1. Internal Trial Committees

[Insert text]

* 1. Independent Safety and Data Monitoring Committee

[Insert text – see comments for guidance]

* 1. Sponsor

[Insert text – see comments for guidance]

* 1. Funding and resources

[Insert text – see comments for guidance]

1. INTRODUCTION AND BACKGROUND
   1. Background Information

[Insert text – see comments for guidance]

* 1. Research Question

[Insert text – see comments for guidance]

* 1. Rationale for Current Study

[Insert text – see comments for guidance]

1. STUDY OBJECTIVES
   1. Primary Objective

[Insert text – see comments for guidance]

* 1. Secondary Objectives

1. STUDY DESIGN
   1. Type of Study

.

[Insert text – see comments for guidance]

* 1. Describe the Study Design

[Insert text – see comments for guidance]

* 1. Standard of Care procedures

[Insert text – see comments for guidance]

* 1. Number of Participants at each study site

[Insert text – see comments for guidance]

* 1. Expected Duration of Study

[Insert text – see comments for guidance]

* 1. Primary and Secondary Outcome Measures

[Insert text – see comments for guidance]

1. STUDY TREATMENTS
   1. Treatment Arms

5.1.1 Description

[Insert text]

5.1.2 Dosage and Route of Administration

[Insert text]

5.1.3 Dose modification

[Insert text]

* 1. Preparation and administration of study drug

[Insert text]

* 1. Dispensing and Product Accountability

[Insert text]

* 1. Measurement of participant compliance

[Insert text]

* 1. Excluded medications and treatments

[Insert text]

1. PARTICIPANT ENROLLMENT AND RANDOMISATION
   1. Recruitment

[Insert text – see comments for guidance]

* 1. Eligibility Criteria

6.2.1 Inclusion Criteria

[Insert text – see comments for guidance]

6.2.2 Exclusion Criteria

[Insert text – see comments for guidance]

* 1. Informed Consent Process

[Insert text – see comments for guidance.]

[Either *Informed Consent* or *Waiver of Consent* (below) will be applicable to your study]

* 1. Waiver of Consent

[Insert text – see comments for guidance. Delete this section if not applicable]

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

[Response required]

1. *the benefits from the research justify any risks of harm associated with not seeking consent*

[Response required]

1. *it is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)*

[Response required]

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

[Response required]

1. *there is sufficient protection of their privacy*

[Response required]

1. *there is an adequate plan to protect the confidentiality of data*

[Response required]

1. *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)*

[Response required]

1. *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*

[Response required]

1. *the waiver is not prohibited by State, federal, or international law.*

[Response required]

1. *Please provide additional information regarding how the use and disclosure of personal health information in this project is reasonably necessary for research in the public interest.*

[Response required]

1. *Please confirm that reasonable steps will be taken to de-identify the information, or if the purpose of the research cannot be served by using or disclosing de-identified information, please provide additional information regarding the steps that will be taken to protect patient confidentiality. (please make clear that the data will be de-identified after collection.*

[Response required]

1. *Please provide additional justification for the use and disclosure of this information without patient consent. (with reference to the National Statement and Statutory Guidelines). Please ensure that all of the points in the national statement (2.3.10) are addressed with regard to your project.*

[Response required]

1. *Please confirm that information which could reasonably be expected to identify individuals will not be published in a generally available publication. (Please just make this statement in your protocol and HREA).*

[Response required]

* 1. Enrolment and Randomisation Procedures

[Insert text – see comments for guidance]

* 1. Blinding Arrangements

[Insert text – see comments for guidance]

* 1. Breaking of the Study Blind

6.7.1 On Study

[Insert text – see comments for guidance]

6.7.2 Following Completion of the Study

[Insert text – see comments for guidance]

* 1. Participant Withdrawal

6.8.1 Reasons for withdrawal

[Insert text – see comments for guidance]

6.8.2 Handling of withdrawals and losses to follow-up

[Insert text]

6.8.3 Replacements

[Insert text]

* 1. Trial Closure

[Insert text]

* 1. Continuation of therapy

[Insert text]

1. STUDY VISITS AND PROCEDURES SCHEDULE

Study Flow Chart

Diagram of the study design (example below)

Enrolment

Randomisation

Treatment Phase

(e.g. 12 weeks)

Group A Group B

Include all study visits and all study procedures conducted at each visit. This information can also be displayed in a table.

Example below

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| List Interventions | Enrolment Visit | Visit 1 | Visit 2 | Visit 3 | Final Study Visit |
| Informed Consent | ✓ |  |  |  |  |
| Inclusion / Exclusion critieria | ✓ |  |  |  |  |
| Physical examination |  | ✓ |  |  |  |
| CXR | ✓ |  |  |  | ✓ |
| Adverse Event & Serious Adverse Event Assessment |  | ✓ | ✓ | ✓ | ✓ |
|  |  |  |  |  |  |

[Insert text – see comments for guidance]

1. CLINICAL AND LABORATORY ASSESSMENTS

[Insert text]

1. ADVERSE EVENT REPORTING

[Insert text – see comments for guidance]

* 1. Definitions

[Insert text – see comments for guidance]

**Adverse event**

An adverse event for medicines is also referred to as an adverse experience, any untoward medical occurrence in a patient or clinical investigation participant administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment.

An adverse event can therefore be any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

**Devices Events**

An adverse event for devices is any undesirable clinical occurrence in a participant whether it is considered to be device related or not, that includes a clinical sign, symptom or condition and/or an observation of an unintended technical performance or performance outcome of the device.

For devices is any adverse medical occurrence that:

* led to a death;
* led to a serious deterioration in health of a patient user or other. This would include:
* a life threatening illness or injury;
* a permanent impairment of body function or permanent damage to a body
* structure;
* a condition requiring hospitalisation or increased length of existing hospitalisation;
* a condition requiring unnecessary medical or surgical intervention; or
* foetal distress, foetal death or a congenital abnormality/birth defect;
* might have led to death or a serious deterioration in health had suitable action or intervention not taken place.
* This includes: a malfunction of a device such that it has to be modified or temporarily/permanently taken out of service; or a factor (a deterioration in characteristics or performance) found on examination of the device.

* 1. Assessment and Documentation of Adverse Events

[Insert text]

* 1. Eliciting Adverse Event Information

[Insert text]

* 1. Serious Adverse Event Reporting

9.4.1 SAEs

[Insert text – see comments for guidance]

9.4.2 SUSARs

[Insert text – see comments for guidance]

* 1. Specific Safety Considerations (e.g. Radiation, Toxicity)

[Insert text – see comments for guidance]

1. STATISTICAL METHODS
   1. Sample Size Estimation

[Insert text – see comments for guidance]

* 1. Population to be analysed

[Insert text – see comments for guidance]

* 1. Statistical Analysis Plan

[Insert text – see comments for guidance]

* 1. Interim Analyses

[Insert text – see comments for guidance]

1. DATA MANAGEMENT
   1. Data Collection

[Insert text – see comments for guidance]

* 1. Data Storage and Study Record Retention

[Insert text – see comments for guidance]

*Please delete clauses that* ***do not*** *apply to your project:*

1. [As per the general data storage requirements for research, data will be stored for 5 years following publication] OR
2. [As per clinical trial data storage requirements, the data will be stored for 15 years post publication.] OR
3. [As the research relates to gene therapy, data will be stored permanently] OR
4. [As the research relates to community work, cultural or historical value the data will be stored permanently].
   1. Data Confidentiality

[Insert text – see comments for guidance]

* 1. Participant reimbursement

[Insert text – see comments for guidance]

* 1. Financial disclosure and conflicts of interest

[Insert text – see comments for guidance]

1. USE OF DATA AND PUBLICATIONS POLICY

[Insert text – see comments for guidance]

1. REFERENCES

[Insert text – see comments for guidance]

1. APPENDICES