

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

Protocol Template

Observational or Experimental Design (not sponsored clinical trial)

Version 2.1, December 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

Adventist HealthCare Limited ABN 76 096 452 925

**FULL STUDY TITLE**

**[Insert study title, see comments for guidance]**

**SHORT STUDY TITLE**

**CONFIDENTIAL**

This document is confidential and the property of XXX

No part of it may be transmitted, reproduced, published, or used without prior written authorisation from the institution.

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 (2023) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95) as adopted in Australia.

**LIST OF CONTENTS**

[STATEMENT OF COMPLIANCE 1](#_Toc136332369)

[GLOSSARY OF ABBREVIATIONS 3](#_Toc136332370)

[1. STUDY INVESTIGATOR(S) 3](#_Toc136332371)

[2. INTRODUCTION 3](#_Toc136332372)

[3. BACKGROUND 3](#_Toc136332373)

[4. AIM(S) OF STUDY 3](#_Toc136332374)

[5. OBJECTIVES 3](#_Toc136332375)

[6. HYPOTHESIS 4](#_Toc136332376)

[6a. Primary Hypothesis 4](#_Toc136332377)

[6b. Secondary Hypotheses 4](#_Toc136332378)

[7. STUDY DESIGN 4](#_Toc136332379)

[8. STUDY SETTING/LOCATION 4](#_Toc136332380)

[9. STUDY POPULATION 4](#_Toc136332381)

[10. ELIGIBILITY CRITERIA 4](#_Toc136332382)

[10a. Inclusion criteria 4](#_Toc136332383)

[10b. Exclusion criteria 4](#_Toc136332384)

[11. STUDY OUTCOMES 4](#_Toc136332385)

[11a. Primary Outcome 4](#_Toc136332386)

[11b. Secondary Outcome(s) 4](#_Toc136332387)

[12. STUDY PROCEDURES 4](#_Toc136332388)

[12a. Recruitment of participants 5](#_Toc136332389)

[12b. Randomisation 5](#_Toc136332390)

[12c. Study procedure 5](#_Toc136332391)

[12d. Measurement tools used 5](#_Toc136332392)

[12e. Safety considerations/Patient safety 5](#_Toc136332393)

[12f. Data monitoring 5](#_Toc136332394)

[12g. Data Storage and Study Record Retention 5](#_Toc136332395)

[13. STATISTICAL CONSIDERATIONS AND DATA ANALYSIS 5](#_Toc136332396)

[13a. Sample size and statistical power 5](#_Toc136332397)

[13b. Statistical methods 5](#_Toc136332398)

[14. ETHICAL CONSIDERATIONS 6](#_Toc136332399)

[14a. Informed Consent 6](#_Toc136332400)

[14b. Waiver of Consent 6](#_Toc136332401)

[15. OUTCOMES AND SIGNIFICANCE 7](#_Toc136332402)

[16. REFERENCES 7](#_Toc136332403)

GLOSSARY OF ABBREVIATIONS

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

1. STUDY INVESTIGATOR(S)

Principal Investigator: [Insert name]

 Ph: [Insert]

Email: [Insert]

Address: [Insert Institution, street, suburb, state, post code]

Co-Investigator (A): [Insert name]

 Ph: [Insert]

Email: [Insert]

Address: [Insert Institution, street, suburb, state, post code]

Co-Investigator (B): [Insert name]

 Ph: [Insert]

Email: [Insert]

Address: [Insert Institution, street, suburb, state, post code]

Co-Investigator (C): [Insert name]

 Ph: [Insert]

Email: [Insert]

Address: [Insert Institution, street, suburb, state, post code]

1. INTRODUCTION

[Insert text – see comments for guidance]

1. BACKGROUND

[Insert text – see comments for guidance]

1. AIM(S) OF STUDY

[Insert text – see comments for guidance]

1. OBJECTIVES

[Insert text – see comments for guidance]

1. HYPOTHESIS

6a. Primary Hypothesis

[Insert text – see comments for guidance]

6b. Secondary Hypotheses

[Insert text – see comments for guidance]

1. STUDY DESIGN

[Insert text – see comments for guidance]

1. STUDY SETTING/LOCATION

[Insert text – see comments for guidance]

1. STUDY POPULATION

[Insert text – see comments for guidance]

1. ELIGIBILITY CRITERIA

[Insert text – see comments for guidance]

10a. Inclusion criteria

[Inset text – see comments for guidance]

10b. Exclusion criteria

[Insert text – see comments for guidance]

1. STUDY OUTCOMES

11a. Primary Outcome

[Insert text – see comments for guidance]

11b. Secondary Outcome(s)

[Insert text – see comments for guidance]

1. STUDY PROCEDURES

[Insert text – see comments for guidance]

12a. Recruitment of participants

[Insert text – see comments for guidance]

12b. Randomisation

[Insert text – see comments for guidance]

12c. Study procedure

[Insert text – see comments for guidance]

12d. Measurement tools used

[Insert text – see comments for guidance]

12e. Safety considerations/Patient safety

[Insert text – see comments for guidance]

12f. Data monitoring

[Insert text – see comments for guidance]

12g. 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].
5. STATISTICAL CONSIDERATIONS AND DATA ANALYSIS

13a. Sample size and statistical power

[Insert text – see comments for guidance]

13b. Statistical methods

[Insert text – see comments for guidance]

1. ETHICAL CONSIDERATIONS

[Insert text – see comments for guidance]

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

14a. Financial disclosure and conflicts of interest

[Insert text – see comments for guidance.]

14b. Informed Consent

[Insert text – see comments for guidance.]

14c. 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. *Please confirm that a permitted health situation exists in relation to the use or disclosure by an organisation of health information about an individual by addressing the below points [Privacy Act S16B(3)]:*
2. *the use or disclosure is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety.*

[Response required]

1. *it is impracticable for the organisation to obtain the individual's consent to the use or disclosure.*

[Response required]

1. *the use or disclosure is conducted in accordance with guidelines approved under section 95A for the purposes of this paragraph*

[Response required]

1. *in the case of disclosure--the organisation reasonably believes that the recipient of the information will not disclose the information, or personal information derived from that information [NB: confirm that you will not disclose the information].*

*[Response required]*

1. *A permitted health situation exists in relation to the secondary use or disclosure of the personal information (APP 6.2(d)”*

[Response required]

1. OUTCOMES AND SIGNIFICANCE

[Insert text – see comments for guidance]

1. REFERENCES

[World Medical Association Declaration of Helsinki](http://www.who.int/bulletin/archives/79%284%29373.pdf) (1964)

[Note for guidance on good clinical practice (CPMP/ICH/135/95 - Annotated with TGA comments)](http://www.tga.gov.au/docs/pdf/euguide/ich/ich13595.pdf)

[National Statement on Ethical Conduct in Human Research (2023)](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)

[Insert additional references]