|  |
| --- |
| protocol |
| [Insert Full study Title] |
| Protocol Number (if applicable):  Version: #  Date: DD/MM/YYYY |
| **Author/s:**  <<List Author/s>>  **Sponsor/s:**  <<Insert Sponsor/s>> |
| **CONFIDENTIAL**  This document is confidential and the property of Melbourne Health. No part of it may be transmitted, reproduced, published, or used without prior written authorization from the institution.  **Statement of Compliance**  This study will be conducted in compliance with all stipulation of this protocol, the conditions of the ethics committee approval, the NHMRC National Statement on ethical Conduct in Human Research (2007 updated 2018). Australian Code for the Responsible Conduct of Research, 2018 *(the Code)* and the principles of the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95). |

# Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

|  |  |  |  |
| --- | --- | --- | --- |
| **Chief Investigator:** | | | |
| Signature: |  | Date: |  |
| Name (please print): |  | | |
| Position: |  | | |

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# Study Synopsis

Provide brief information

|  |  |
| --- | --- |
| Title: |  |
| Short Title: |  |
| Design: |  |
| Study Centres: |  |
| Hospital: |  |
| Study Question: |  |
| Study Objectives: |  |
| Primary Objectives: |  |
| Secondary Objectives |  |
| Inclusion Criteria: |  |
| Exclusion Criteria: |  |
| Number of Planned Participants : |  |
| Investigational product: |  |
| Safety considerations: |  |
| Statistical Methods: |  |
| Subgroups: |  |
| Consumer Involvement | Confirm if there has been or will be consumer involvement and categorise as one of the following to align with OFR data collection requirements:   * Consultative * Co-design * Nil consumer involvement   Refer to section 12 for definitions and to provide details. |

# Glossary of Abbreviations & Terms

*Insert or delete information as required*

|  |  |
| --- | --- |
| **Abbreviation** | **Description (using lay language)** |
|  |  |
| CT | Clinical trial |
| GCP | Good Clinical Practice |
| HREC | Human Research Ethics Committee |
| MACH | Melbourne Academic Centers for Health |
| NHMRC | National Health and Medical Research Council |
|  |  |
|  |  |
|  |  |
| PMCC | Peter MacCallum Cancer Centre |
|  |  |
| RCH | Royal Children’s Hospital |
| REDCap | Research Electronic Data Capture electronic database |
| RMH | Royal Melbourne Hospital |
| RWH | Royal Women’s Hospital |
| UoM | University of Melbourne |
|  |  |
|  |  |
|  |  |

# Study Sites

### Study Location/s

[List all locations, their address & contact details this study or parts of the study will be conducted]

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Site** | **Address** | **Contact Person** | **Phone** | **Email** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Introduction/Background Information

### Lay Summary

[All information provided in this section must be in language that can be understood by an interested, intelligent person without a scientific background. Do not use scientific jargon, abbreviations and do not include journal citations in the lay summary. This summary should include information on the aims and importance of the study as well as briefly summarizing what will happen to the participants, the time commitment required by the participants and how their safety will be ensured.]

### Introduction

[The introduction is a very brief overview of the study (~250-500 words). The introduction should be concise but sufficient to orientate the reader to the main purpose of the study and how it will be conducted and its expected benefits. It should include details on (1) What the research question is (2) How the proposed study will fill a gap in the literature and (3) provide an understanding that this study is novel]

### Background information

[This section should give clarity on the research question being addressed. The information should convince the reader of why the study needs to be done. The following points may be used as a guide:

* Conduct a comprehensive literature search
* Critically appraise the relevant literature and discuss the current knowledge on the topic (include deficiencies). If applicable, discuss the current treatment options and the associated issues risks and benefits.
* Indicate how the research question has emerged and fits logically with the evidence detailed above.
* Explain how your study will contribute to existing research and benefit your target population.
* Discuss the importance of the topic (e.g., public health, clinical importance, community, incidence, prevalence, mortality and morbidity)

# Study Objectives

### Hypothesis

### Study Aims

### Outcome Measures

[This section of the protocol must clearly state what the variables to be measured are. The primary outcome measure should reflect the clinically relevant effects of the intervention and be based on the primary objective of the trial. There should only be one primary outcome.

The secondary outcome measures are other effects to be measured in the study, these may or may not be related to the primary objective and are based on the secondary objectives.

Since the outcome variables will be used to evaluate the success or otherwise of the intervention, they need to be carefully selected and clearly defined in the protocol. Ensure endpoints are obtainable. Efficacy variables are usually a quantitative measure of a clinical effect. Often the clinical effect to measure is obvious, but the method of measurement may be controversial. A surrogate endpoint does not measure the clinical effect, but is something that can be measured that is thought to relate to the clinical effect (e.g. bone density is related to a reduced fracture rate). Provide justification for any surrogate endpoints.

If a composite endpoint will be used explain its composite parts.

Primary and secondary outcome measures may be:

 Objective assessments (e.g. mortality rates);

 Subjective clinical assessments (e.g. validated rating scales);

 Measurements of various physiological functions (e.g. blood

pressure);

 Anatomical or histological assessments (e.g. tumour measurements)

 Biomarkers or biochemical markers (e.g. tumour markers, liver

function tests); or

 Pharmacokinetic tests.]

# Study Design

### Study Type & Design & Schedule

[The description of the study design should be capable of meeting the study objectives. A thorough description of **ALL** study procedures and assessments in a logical and sequential format]

1. Specify the type of study e.g., Cohort-study (retrospective or prospective), case-control study, cross-sectional study
2. Specify the basic design elements including the population to be studied (e.g., Adults aged 18-35), any risk factors present
3. Specify if this study will be a single-centre or multi-centre (national or international) study.
4. Specify how the design will achieve the aims and objective
5. Please state what data will be collected e.g., blood tests, MRI’s, genetic testing, videos, photos, questionnaires etc... For each item, specify if the data collected will be identifiable, re-identifiable or non-identifiable.
6. Describe how you will collect, handle and store all types of data collected.
7. Specify the time frame for each component of the study, this should include study visits, how long recruitment is open for and how long analysis will take etc..
8. Specify if the study requires any home visits, and what the home visit policy and procedures are.
9. Ensure you have included all information on all required contingency plans within your study outline.
10. State if this protocol will be used towards a student project, and if so, state what course and degree the student will undertake.
11. Provide a flowchart or table specifying visits, interventions and other relevant details

**EXAMPLE STUDY TABLE**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Example procedures | **Assessment/Procedure** | **Screening** | **Visit 1**  **(3 months)** | **Visit 2**  **(12 months)** | **Follow-up** |
| **Informed Consent** | **x** |  |  |  |
| **Demographic Information** | **x** |  |  |  |
| **Weight Measurement** | **x** |  |  |  |
| **MRI** |  | **x** | **x** |  |
| **QOL50- questionnaire** |  | **x** | **x** | **x** |
| **Blood Collection** | **x** | **x** | **x** |  |
| **Biopsy** | **x** |  |  |  |

### Standard Care and Additional to Standard Care Procedures

[In table format LIST all procedures, assessments, and tests (e.g., CT-scans, MRI, blood tests etc…) that form part of standard care and that are additional to standard care. Include testing times, dosages and volumes where applicable]

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Standard Care Procedures** | | |  | **Additional To Standard Care** | | |
| **Procedure** | **Time/Visit** | **Dosage/Volume** |  | **Procedure** | **Time/Visit** | **Dosage/Volume** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

### Randomisation

[Include a description on how your participants will be randomised, include any software that will be used. Where applicable, a description of the type of randomisation performed, ratio of assignment to group and stratification should be included. An explanation on the method used to conceal group allocations should be included and who will assign participants to their groups. This section should also discuss if the participants and/or investigators will be blinded to group allocations or if the study will be unblinded to the participants and/or investigators]

### Study methodology

[Describe each clinical or laboratory assessment/s that will be carried out as part of this study. This should include a procedures list that details what information will be collected. If you are using standardised surveys, questionnaires or other test please attach a copy of each of these tests to the appendix of the protocol]

# Study Population

### Recruitment Procedure

[Define the group in which the study will be carried out on. Explain how participants will be identified and recruited. You should make a distinction between how you will recruit control subjects compared to other groups.]

Cohort Studies: Describe sources and methods that will be employed in the identification and recruitment of potential participants e.g., clinics, referring doctors, advertisements etc…

Cross-sectional Studies: Describe the sources and methods that will be employed in the identification and recruitment of prospective participants (e.g., clinics, referring doctors, advertisements etc…) and retrospective data (e.g., medical records, registries, databases etc...)

Case-Controlled studies: Describe how controls will be identified and recruited (e.g., advertisements, letters from GP’s, family members etc...), and describe how they will be matched. Describe how the study population will be identified and recruited, and then provide a justification for how bias has been avoided.

### Inclusion Criteria

[Clearly describe the study population that is required for a subject to be included in the study. The criteria may be based on factors such as age, gender, type and stage of disease, previous treatment history etc...]

### Exclusion Criteria

[Provide details of participants that will be considered ineligible to participate and justify why they have been excluded. Exclusion criteria may include an inability to give informed consent, understand English, contraindications of the study treatment and/or procedures, conditions that will hinder the participant’s ability to comply with the study protocol].

### Consent

[Describe if individual consent will be obtained or if a waiver of consent is required, or if no consent is required]

[If a waiver of consent is being requested this must be justified against the National Statement on Ethical Conduct in Human Research Section 2.3.10a-i]

# Participant Safety and Withdrawal

### Risk Management and Safety

[Identify all areas where participant safety may be compromised, safety such examples may include, but are not limited to exposure to radiation and invoking psychological or physical distress. Safety considerations are not just physical, they can also be psychological, therefore, you must ensure for psychological distress you have arranged an appropriate contingency plan.]

### Handling of Withdrawals

[Participants may withdraw from the study for the following reasons: participant has chosen to withdraw from the study, protocol violation, or participant has experienced an adverse event. Describe the procedures to be followed when a participant is withdrawn from the study. This should include what happens to all collected data (e.g., blood samples, scans, photos, etc…) that have already been collected, if the participant needs to have any follow-up, all administrative requirements to withdraw a subject to ensure their information isn’t inappropriately used after their withdrawal from the study]

### Replacements

[Describe if withdrawn participants will be replaced in the study and if not, describe what impact this will have on the statistical significance of the sample size for the study]

# Statistical Methods

### Sample Size Estimation & Justification

[Specify the estimated sample size and justify how this sample size will ensure that your study numbers will reach statistical significance. Please also specify how participants will be recruited at Melbourne Health]

### Power Calculations

[Describe and detail how the power calculations were obtained.]

### Statistical Methods To Be Undertaken

[Describe the statistical methods that will be undertaken for this study. It is recommended this section is written in collaboration with a statistician.]

# Storage of Blood and Tissue Samples

### Details of where samples will be stored, and the type of consent for future use of samples

[Describe what samples are taken, how long you will store each sample, where you will store the sample and state if any samples will be used for genetic testing. Finally describe if samples will be entered into a biobank, and if consent from participants will be for this research project only, for future projects related to this, or if participants have given unspecified consent.]

# Data Security & Handling

### Details of where records will be kept & How long will they be stored

[List the location/s where records will be held. If there are multiple locations, list the exact data to be held at each location. All records for non drug trials should be kept for a minimum of 5 years post study closure, if your study contains a CTN drug/device, then records must be kept for a minimum of 15 years.]

Data Management: How will you store, provide access to, disclose, use/re-use, transfer, destroy or archive the information that you collect/gather?

* Include a data management plan in accordance with National Statement 3.1.45 and 3.1.56.

### Confidentiality and Security

[Describe how confidentiality of all study data will be ensured via security mechanisms in place.]

### Ancillary data

[Describe how where and for how long you will store data such as videos, photographs and images, also describe how confidentiality will be ensured].

# Consumer Involvement

[This section of the protocol should confirm if there has been consumer involvement as:

* Consultative
* Co-design
* Nil consumer involvement

Where there have been consultative and co-design processes:

* Provide details on which aspects of the research process have actively involved, or which will involve, patients, service users, and/or their carers, or members of the public.
* Provide a brief summary of the outcomes of consumer involvement in the study.

**Consultative** - consumers are usually only involved in providing review specific documents such as the informed consent forms, advertising etc.

**Co-design** - consumers are involved in one or more of the following activities:

* The acceptability of the research
* Design of the research
* Management of the research
* Undertaking the research
* Analysis of results
* Dissemination of findings]Appendix

[Attach any questionnaires, functional and/or cognitive tests, surveys, telephone scripts, advertisements, photographs of devices etc….].

**List of Attachments included:**

|  |  |  |
| --- | --- | --- |
| **Document Name** | **Version Number** | **Date** (eg. 18 January 2012) |
|  |  |  |
|  |  |  |
|  |  |  |

# References