|  |
| --- |
| Qualitative Study 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>>*[[1]](#footnote-1) 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*)* and the principles of the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95). |

Melbourne Health Acknowledges that elements of the NHS Health Research Authority Qualitative Protocol Development Tool were used in the development of this protocol template

# 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.

|  |  |  |
| --- | --- | --- |
| **For and on behalf of the Study Sponsor:** | | |
| Signature:  ...................................................................................................... |  | Date: ....../....../...... |
| Name (please print):  ...................................................................................................... |  |  |
| Position: ...................................................................................................... |  |  |
| **Chief Investigator:** | | |
| Signature: ...................................................................................................... |  | Date: ....../....../...... |
| Name: (please print):  ...................................................................................................... |  |  |

Table of Contents

[1. Signature Page 2](#_Toc82595103)

[2. Key Study Contacts 5](#_Toc82595104)

[3. Study Synopsis 7](#_Toc82595105)

[4. Study Flow Chart 9](#_Toc82595106)

[5. Glossary of Abbreviations & Terms 10](#_Toc82595107)

[6. Study Sites 11](#_Toc82595108)

[6.1 Study Location/s 11](#_Toc82595109)

[7. Introduction/Background Information 11](#_Toc82595110)

[7.1 Lay Summary 11](#_Toc82595111)

[7.2 Introduction 11](#_Toc82595112)

[7.3 Background information 11](#_Toc82595113)

[8. Theoretical Framework 12](#_Toc82595114)

[9. Study Objectives 12](#_Toc82595115)

[9.1 Research questions and/or hypothesis 12](#_Toc82595116)

[9.2 Study Aims 12](#_Toc82595117)

[9.3 Outcome Measures 12](#_Toc82595118)

[10. Study Design 13](#_Toc82595119)

[10.1 Study Type & Design & Schedule 13](#_Toc82595120)

[10.2 Study Setting 14](#_Toc82595121)

[11. Study Population 15](#_Toc82595122)

[11.1 Recruitment Procedure 15](#_Toc82595123)

[11.2 Inclusion Criteria 15](#_Toc82595124)

[11.3 Exclusion Criteria 15](#_Toc82595125)

[11.4 Consent 15](#_Toc82595126)

[12. Participant Safety and Withdrawal 16](#_Toc82595127)

[12.1 Sample Identification 16](#_Toc82595128)

[12.2 Risk Management and Safety 17](#_Toc82595129)

[12.3 Handling of Withdrawals 17](#_Toc82595130)

[12.4 Replacements 17](#_Toc82595131)

[13. Statistical Methods 18](#_Toc82595132)

[13.1 Sample Size Estimation & Justification 18](#_Toc82595133)

[13.2 Power Calculations 18](#_Toc82595134)

[13.3 Sampling technique 18](#_Toc82595135)

[13.4 Statistical Methods To Be Undertaken 18](#_Toc82595136)

[14. Data Security & Handling 18](#_Toc82595137)

[14.1 Details of where records will be kept & How long will they be stored 18](#_Toc82595138)

[14.2 Confidentiality and Security 19](#_Toc82595139)

[14.3 Ancillary data 19](#_Toc82595140)

[15. Consumer Involvement 19](#_Toc82595141)

[16. Appendix 20](#_Toc82595142)

[17. References 20](#_Toc82595143)

# Key Study Contacts

Insert full details of the key study contacts including the following

|  |  |
| --- | --- |
| Chief Investigator | *Full contact details including phone, email and fax numbers* |
| Study Co-ordinator | *Full contact details including phone, email and fax numbers* |
| Sponsor | *Full contact details including phone, email and fax numbers*  *The sponsor can be defined as the individual, company, institution, or organisation assuming overall responsibility for the initiation and management of the study, and is not necessarily the main funder. Sponsorship responsibilities may be shared by joint- or co-sponsors* |
| Joint-sponsor(s)/co-sponsor(s) | *Full contact details including phone, email and fax numbers of ALL organisations assuming sponsorship responsibilities as a joint- or co-sponsor/s (If applicable)* |
| Funder(s) | *Names and contact details of ALL organisations providing funding and/or support in kind for this study* |
| Key Protocol Contributors | *Full contact details including phone, email and fax numbers (If applicable)* |
| Committees | *Full contact details including phone, email and fax numbers* |

**ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS**

***Study Steering Groups***

*Aim: To outline any committees or groups involved in study coordination and conduct.*

*For each committee/group the protocol should state their roles and responsibilities and degree of independence from Sponsor and Investigators. If not included in the document the protocol should state where the information on the committee/group can be found.*

*Patient & Public Involvement Group*

*Public involvement plays an important role in study design and planning and can help reduce delays in approvals. Public involvement in study design and study documentation can help with the acceptability of a study to the public which in turn can assist with study set-up and recruitment. Ongoing involvement of the public can help understand blockages to recruitment and the acceptability and relevance of study findings.*

**PROTOCOL CONTRIBUTORS**

*Aim: To describe all the contributors to the protocol.*

*The protocol should:*

* *Explicitly outline the roles and responsibilities of the sponsor and any funders in study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.*
* *It is also important to state whether the sponsor or funder controls the final decision regarding any of these aspects of the study.*
* *Describe in what aspects of the protocol design have patients, service users, and/or their carers, or members of the public been involved.*

# Study Synopsis

*Complete brief information and, if required, add additional rows.*

|  |  |
| --- | --- |
| Study Title: |  |
| Short Title: |  |
| Study Design: |  |
| Study Centre/s: |  |
| Study Hospital/s: |  |
| Study Question: |  |
| Study Objectives: |  |
| Primary Objectives: |  |
| Secondary Objectives |  |
| Inclusion Criteria: |  |
| Exclusion Criteria: |  |
| Study Participants |  |
| Planned Size of Sample (if applicable) |  |
| Follow-up duration (if applicable) |  |
| Planned Study Period |  |
| 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 Consumer Involvement section for definitions and to provide details.* |

# Study Flow Chart

*Aim: To give readers a schematic overview of the study*

A flow diagram should be included.

Careful consideration must be given by the protocol authors to ensure that the protocol is sensibly structured and ordered to allow users of the document to follow the patient and study pathway accurately and with ease. Flow diagrams are helpful tools to guide users of the protocol through the patient and study pathway. A schedule of events can be included as an appendix to the protocol.

*For study designs using less complex methods a Gantt chart or timeline of activity outlining the timing of study management is helpful*

# 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 Ethis 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 |
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# 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** |
|  |  |  |  |  |
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# 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 question is worth asking.*

*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).*
* *Include a brief description of the population to be studied.*

*It should be written so it is easy to read and understand by someone with a basic sense of the topic who may not necessarily be an expert in the area. Some explanation of terms and concepts is likely to be beneficial.*

# Theoretical Framework

*This section describes the theoretical framework for the study.*

* *A clear explanation of the proposed approach and why it is suitable to address the gaps outlined in the BACKGROUND section.*
* *Briefly outline a system of concepts, from published literature, that frames your study.*
* *Can be presented either visually or textually.*

# Study Objectives

### Research questions and/or hypothesis

### Study Aims

### Outcome Measures

*[This section would not generally be applicable for entirely qualitative studies, consider removing if not applicable].*

*[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.*

# 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]*

*A suitable design should be chosen to reflect the aim(s) of the study and the chosen theoretical framework. A suitable design might include ethnography, interviews, focus groups, document analysis, and so on.*

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. *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. *Data collection methods should be described in detail. For example:*
   1. ***Observation****- What will be observed? What resources or equipment will be used if recording observation? Who will be observing?*
   2. ***In-Depth Interviews****- How will the prompt guide or interview schedule be developed? Who is conducting the interviews? By telephone or in person? How are the interviews being recorded? Consider a contingency plan if potential participants do not wish to be recorded i.e the researcher just needs to take detailed notes (making them illegible to participate in the study may introduce bias).*
   3. ***Focus Groups****-Who is leading the focus group? How are the focus groups being recorded?*
7. *Data analysis methods may include content analysis, the constant comparative method, framework analysis, interpretative phenomenological analysis, and so on.*

*The protocol should clearly describe how and by whom data will be (for example)*

* *Transcribed. (NOTE: If it is by a third party, detail how privacy is ensured)*
* *Coded.*
* *De-identified.*
* *Stored/Transferred.*
* *Accessed.*
* *Archived.*

*Any software to be used in assisting the analysis should be specified.*

1. *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.*
2. *Specify if the study requires any home visits, and what the home visit policy and procedures are.*
3. *Ensure you have included all information on all required contingency plans within your study outline i.e. funding shortfall, COVID restrictions*
4. *State if this protocol will be used towards a student project, and if so, state what course and degree the student will undertake.*
5. *Provide a flowchart or table of 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* |  |  |  |

### Study Setting

*State where the data will be collected, explain what activities will take place in that site, and justify the choice of site and any special requirements.*

*The protocol should address:*

* *Where and how you are accessing your participants?*
* *How the research setting is appropriate to address the research question/aim(s)?*
* *If it is a multicentre or single centre study.*
* *If there are any site specific requirements to run the study.*
* *Outline if there are different ‘types’ of activity being undertaken at each site (e.g. identifying or recruiting) and what the specific requirements are for each.*

# Study Population

### Recruitment Procedure

*[Define the group in which the study will be carried out on. Explain how participants will be identified and recruited.*

*This section should give details of the participant eligibility screening process for the project including methods of identifying eligible participants/sample.*

### 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...]*

The choice of criteria can affect recruitment and attrition to the study.

The following are examples:

* *Gender.*
* *Age range.*
* *Ethnicity.*
* *Socio economic grouping.*
* *Clinical**condition.*
* *Location.*

### Exclusion Criteria

*[These are usually dependant on the inclusion 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].*

The following are examples:

* *Outside of stated age range.*
* *Outside stated of location.*
* *Gender.*

### Consent

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

*The protocol should fully describe the process of gaining informed consent which could involve:*

* *discussion between the potential participant or his/her legally acceptable representative and an individual knowledgeable about the research, about the nature and objectives of the study and possible risks associated with their participation*
* *the presentation of written material (e.g., information leaflet and consent documents) which must be approved by the HREC, local regulatory requirements and legal requirements*
* *the opportunity for potential participants to ask questions*
* *getting verbal consent prior to recording participants (even if they have already given written consent for the study)*
* *assessment of capacity. For consent to be ethical and valid in law, participants must be capable of giving consent for themselves. A capable person will:* 
  + *understand the purpose and nature of the research*
  + *understand what the research involves, its benefits (or lack of benefits), risks and burdens*
  + *understand the alternatives to taking part*
  + *be able to retain the information long enough to make an effective decision.*
  + *be able to make a free choice*
  + *be capable of making this particular decision at the time it needs to be made (though their capacity may fluctuate, and they may be capable of making some decisions but not others depending on their complexity)*
  + *where participants are capable of consenting for themselves but are particularly susceptible to coercion, it is important to explain how their interests will be protected*

*For a very limited range of activities – such as some ethnographic observations – individuals in a research setting may not be deemed to be research “participants” and it may not be possible to gain consent from each individual observed. In such instances, a full explanation should be given of how the rights and privacy will be protected for those observed or otherwise involved in some way in a research activity for which it is not proposed to gain individual consent.*

# Participant Safety and Withdrawal

### Sample Identification

*The following should be described in the protocol:*

*• Who will identify the participants and what method will be used?*

*• Who will identify participants/sample?*

*• What resources will be used?*

*• Will any participants be recruited by publicity; posters, leaflets, adverts or websites?*

*• Details of the sources of identifiable personal information that will be used to identify potential participant. In the case of healthcare research on patients usually only a member of the patient’s existing clinical care team should have access to patient records without explicit consent in order to identify potential participants, check whether they meet the inclusion criteria or make the initial approach to patients. If the research proposes to use someone outside the clinical team to identify suitable participants or as first contact with the participant, the reason for this should be explained.*

*• The arrangements for referral if the participants are to be identified by a separate research team.*

*• If patient or disease registers are used to identify potential participants a brief description of the consent and confidentiality arrangements of the register should be included.*

*• The protocol should also detail all intended payments to participants e.g. reasonable travel expenses for any visits additional to normal care.*

*• Please include the details of any statistical analysis that will be conducted.*

### Risk Management and Safety

*[Identify all areas where participant safety may be compromised, safety such examples may include, but are not limited to 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.]*

* + *A clear explanation of any risk/potential risks of the study.*
  + *A risk management plan for dealing with any potential risk/harm to the participant. For example whilst undertaking an interview the researchers obtain information that the participant is suicidal. What mechanisms for safeguarding the participant would be put in place? Who should the information be shared with to mitigate harm to the participant?*
  + *A management plan for dealing with safeguarding issues for potential harm to others. For example if the participant discloses information about intention to harm others. What mechanisms for safeguarding others outside of the research would be put in place? Who should the information be shared with to mitigate harm to others?*

### 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., questionnaires, 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. NOTE: There comes a point with interviews/focus groups etc when it isn’t possible to withdraw data (once it’s been combined in analysis), so the study team should provide a clear time frame (e.g. 2 weeks post interview, 1 month post interview) etc, within which participants are able to withdraw their data]*

### 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

**[ONLY INCLUDE THIS SECTION IF RELEVANT]**

### Sample Size Estimation & Justification

*[Specify the sample size and technique.*

*Provide justification for the sample in terms of size and technique.*

*Specify how participants will be recruited at Melbourne Health]*

### Power Calculations

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

However it may not always be possible to estimate the size of a sample e.g. if you continue sampling until you reach saturation. This section should describe and justify how your sampling strategy answers your research question/aim(s) and ensures minimisation of bias.

### Sampling technique

*This section should detail the methods of selection used for example:*

* + *At random, snowball, convenience sampling, purposive sampling?*
  + *Where has the sample been derived from?*
  + *What is the rationale for this sampling strategy? The rationale should reflect the methodological and theoretical framework for the study.*

### 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.]*

*[NOTE: If this is protocol is for purely qualitative, then this section is not applicable. Unless, you may convert qualitative data into quantitative and then it is relevant. This section may also be substituted with analysis methods section]*

# 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 should be kept for a minimum of 5 years post study closure.]*

*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.*

*Where REDCap is to be used, the Melbourne Health instance should be used and this should be confirmed in the protocol. Refer to the Office for research website (*[*https://www.thermh.org.au/research/researchers/redcap-royal-melbourne-hospital*](https://www.thermh.org.au/research/researchers/redcap-royal-melbourne-hospital)*) for information on REDCap including Examples of text to include in Ethics and Research Governance Applications and protocols.*

### 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/participatory*
* *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/participants 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

1. Authors of this protocol may change to their relevant institution if they are not Melbourne Health employees – prior to submission delete this footnote. [↑](#footnote-ref-1)