Document 2

BETA Ethical Risk Assessment Form

All BETA projects undergo an internal ethics review process to determine the risk to participants and researchers. The appropriate level of ethical review of a project is determined in accordance the National Statement on Ethical Conduct in Human Research (the National Statement).

The National Statement identifies the following three types of risk (refer Chapter 2.1):

1. **More than low**—where the foreseeable impact on participants is greater than discomfort (even if it is unlikely) or reaching distress. Examples include psychological harm such as feelings of worthlessness, distress or guilt.
2. **Low**—where the foreseeable impact on participants is discomfort only involving body and/or mind (even if it is unlikely), for example anxiety induced by participating in an interview.
3. **Negligible**—where the foreseeable impact on participants is not discomfort or harm and is no more than inconvenience, for example filling in a form, participating in a survey or giving up time to participate in a research activity. If the risk is more than inconvenience (even if it is unlikely), the research is not negligible risk.

Based on these types of risk and data considerations, the appropriate ethical review pathway can be determined. This form will BETA officers through this process – please complete Parts 1, 2, 3 and 4.

Need assistance? If you need assistance using this form or arriving at an assessment, please contact the s47F **.**

s47E(a), s47E(d)

Part 1 – Project information

Complete the table below with high level information.

Project name	
Responsible partner agency	
BETA project lead	
Names and institutions of academic co-authors *[Is your research being conducted in partnership with a researcher affiliated with an academic institution?]*	
Summary of project scope	

Part 2 – Identification of Potential Risks

Core principle: When completing Part 2, the best practice is to err on the side of caution and identify a higher level of risk if it's a 'close call'.

Summary: Part 2 identifies the level of risk associated with the project. It includes four steps:

Step 1: Identifying any foreseeable harms for participants (indicative of 'More than low risk')

Step 2: Identifying any discomfort for participants (indicative of 'Low risk')

Step 3: Identifying inconvenience for participants (indicative of 'Negligible risk')

Step 4: Prospective data collection (determines whether project is exempt from ethical review) – applicable only for research with 'Negligible risk'.

Please see Attachment A for a flow chart summarising the risk assessment process.

Step 1: Does the research involve certain foreseeable harms, vulnerable groups or certain topics specified in the National Statement? Complete the tables below.

Foreseeable harms (refer section 2.1 of the National Statement)

Are any of the following harms foreseeable (even if unlikely)…	**YES**	**NO**
Physical harm, including injury, illness, pain? *If yes, please explain:*	☐	☐
Psychological harm, including feelings of worthlessness, distress, guilt, anger or fear-related? *If yes, please explain:*	☐	☐
Devaluation of personal worth, including being humiliated, manipulated or in other ways treated disrespectfully or unjustly? *If yes, please explain:*	☐	☐

Are any of the following harms foreseeable (even if unlikely)…	YES	NO
Social harm, including damage to social networks or relationships with others; discrimination in access to benefits, services, employment or insurance; s47F social stigmatisation and findings of previously unknown paternity status? *If yes, please explain:*	☐	☐
Economic harm, including direct or indirect costs on participants? *If yes, please explain:*	☐	☐
Legal harm, including discovery and prosecution of criminal conduct? *If yes, please explain:*	☐	☐
Other harm/s? *If yes, please explain:*	☐	☐

Vulnerable groups (Chapter 4 of the National Statement)

Does your research involve targeted participation by…s47F ?	YES	NO
Women who are pregnant or the human foetus or foetal tissue? Or does the research relate to issues pertaining to parenting, fertility or termination of pregnancy? *If yes, please explain:*	☐	☐
Children and young people? *If yes, please explain:*	☐	☐

s47E(a), s47E(d)

Does your research involve targeted participation by…s47F ?	YES	NO
People in a dependent/unequal relationship with researchers, or with those involved in facilitating or implementing the research? s47F *If yes, please explain:*	☐	☐
People highly dependent on medical care who may be unable to give consent? *If yes, please explain:*	☐	☐
People with a cognitive impairment, intellectual disability, or a mental illness (e.g. depression, anxiety, eating disorders etc.)? *If yes, please explain:*	☐	☐
People who may be involved in illegal activities? s47F *If yes, please explain:*	☐	☐
Aboriginal and Torres Strait Islander Peoples? *If yes, please explain:*	☐	☐
People overseas where regulations, rules, ethical standards or review processes may be in tension with the National Statement? *If yes, please explain:*	☐	☐
Is there another vulnerability that your research may be targeting? E.g: • People with language barriers • Members of a socially identifiable group with special cultural or religious beliefs or political vulnerabilities or participants specifically belonging to a cultural/minority group? • People who may be unable to give consent (e.g. in dependent or unequal relationships)? • Residents of a custodial institution? *If yes, please explain:*	☐	☐

s47E(a), s47E(d)

Sensitive topics

Will the research involve…	YES	NO
Issues pertaining to parenting, fertility or termination of pregnancy? *If yes, please explain:*	☐	☐
Disclosure of information or findings that may harm the wellbeing of participants? *If yes, please explain:*	☐	☐
Sensitive topics related to cultural, political or religious issues? *If yes, please explain:*	☐	☐
Sensitive topics related to traumatic events such as serious trauma or death? *If yes, please explain:*	☐	☐
Sensitive topics related to addictive behaviour (e.g. gambling)? *If yes, please explain:*	☐	☐
Sensitive topics related to illicit drug taking or substance abuse? *If yes, please explain:*	☐	☐
Sensitive topics related to sexuality, gender identity or race/ethnic identity? *If yes, please explain:*	☐	☐

Step 1 result:

- If all your answers are 'No', move on to step 2.
- If your answer is 'Yes' to one or more of the boxes above, there is a potential risk of harm and the risk assessment is 'More than low'. Skip the remaining Part 1 steps (steps 2–4) and proceed directly to Parts 3 and 4 of this form.

s47E(a), s47E(d)

Step 2: For other harms, what is the impact on participants? Complete the table below.

	Impact on participants		
Are any of the following foreseeable (even if unlikely)?	**No discomfort**	**Discomfort only**	**More than discomfort**
Side-effects from medication *If yes, please explain:*	☐	☐	☐
Measurement of blood pressure *If yes, please explain:*	☐	☐	☐
Anxiety induced by interview *If yes, please explain:*	☐	☐	☐
Anxiety induced by being asked to speak in front of their peers *If yes, please explain:*	☐	☐	☐
Anxiety induced by a survey *If yes, please explain:*	☐	☐	☐
Other discomfort/s (please specify)	☐	☐	☐

Step 2 result:

- If all your answers are 'No discomfort', move on to step 3.
- If your answer is 'discomfort only' as the biggest impact for participants, the risk assessment is 'Low'. Proceed directly to Parts 3 and 4 of this form.
- If your answer is 'more than discomfort' as the biggest impact for participants, they should be viewed as harms and the risk becomes 'More than low risk'. Proceed direcly to Parts 3 and 4 of this form.

Step 3: Does the research involve inconvenience to participants? Complete the table below.

Potential inconvenience	YES	NO
Being unaware of their involvement in research *If yes, please explain:*	☐	☐
Filling in a form that is minimal and non-sensitive *If yes, please explain:*	☐	☐
Participating in survey that is minimal and non-sensitive *If yes, please explain:*	☐	☐
Giving up time to participate in research *If yes, please explain:*	☐	☐
Being involved anonymously in research *Please explain:*	☐	☐
Acceptable and approved secondary use of data s47E *If yes, please explain:*	☐	☐
Other inconvenience/s (please specify)	☐	☐

Step 3 result:

- If your answer is 'Yes' to one or more of the boxes above, there is a risk of 'inconvenience' to participants and the risk assessment is 'Negligible'. Move on to step 4 to see whether data considerations could change this risk assessment.

s47E(a), s47E(d)

Step 4 Important data considerations: If your research involves any of the factors below, consider whether it increases your initial risk assessment in steps 2 and 3.

Data collection and privacy	**YES**	**NO**
a. Does your research ***only*** involve the collection or use of data that i. already exists, and/or ii. would have been collected regardless of whether this project occurred or not? *Please explain:*	☐	☐

Step 4 result:

- If your answer is 'Yes', the risk rating is "Negligible". Proceed directly to Parts 3 and 4 of this form.
- If your answer is 'No', the risk rating is "Low". Proceed directly to Parts 3 and 4 of this form.

Part 3: Identification of ethical review required

Resulting ethical review required	Yes	No
More than low risk: Ethical review by HREC s47E(a),	☐	☐
Low risk: Ethical review by BETA Ethics Committee of Peers s47E(a),	☐	☐
Negligible risk (with existing, non-identifiable data): Exempt from ethical review (can be internally reviewed if desired)	☐	☐

See Attachment A for a flowchart to illustrate the risk assessment process.

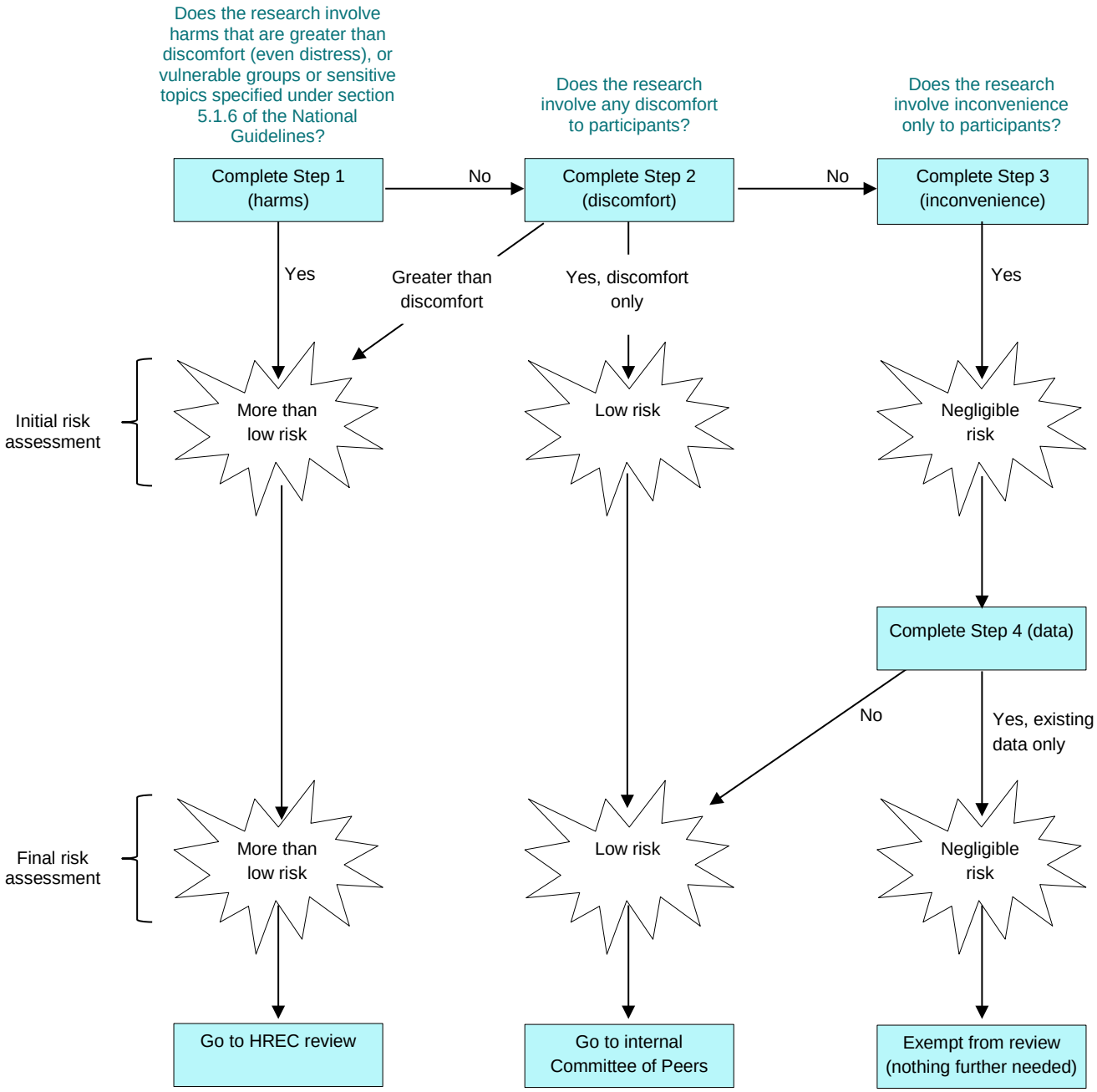
Part 4: Risk assessment form sign-off

Sign-off	
Risk assessment by (insert project lead):	
Risk assessment approved by (insert relevant Project Team EL2):	
Risk assessment reviewed and approved by s47F	

s47E(a), s47E(d)

ATTACHMENT A

BETA Ethical Risk Assessment Flowchart



Legend:

Action to complete

Australian Government
Department of the Prime Minister and Cabinet

BEHAVIOURAL ECONOMICS TEAM OF THE AUSTRALIAN GOVERNMENT

BETA ETHICAL COMMITTEE OF PEERS APPLICATION FORM

1. Project title and contact details

Project Title	
Partner Agency	
BETA Project Manager	Name: Email: Phone number: Relevant qualifications, expertise and/or experience in working on similar research areas:
Partner Agency Contact Officer	Name: Email: Phone number: Relevant qualifications, expertise and/or experience in working on similar research areas:
Other Project Officers (the names and contact details of any other people who will work on this project)	
Person 1	Name: Email: Phone number:

	Relevant qualifications, expertise and/or experience in working on similar research areas:
Person 2	Name: Email: Phone number: Relevant qualifications, expertise and/or experience in working on similar research areas:
Date of form submission	

2. Summary of research and methodology

Briefly describe the proposed research: *[Outline key research questions, hypotheses or objectives of the research, as well as a brief overview of the rationale or background to the research.]*
Outline the design of the project: *[Briefly describe the research design, including the different research methods to be utilised as part of the research. Specify which components of the research are the subject of the present ethics application and, where applicable, which will be the subject of a future application.]*
Outline the size and profile of the sample to be recruited, and the recruitment method: *[Provide a justification that the size and profile of the sample to be recruited is adequate to answer the research question. In addition, provide a rationale for the selection of participants and a fair recruitment method.]*
Provide reference to the research being based on a thorough study of current and previous literature: *[Briefly acknowledge the evidence base for conducting the proposed research. Include and refer to relevant attachments such as research proposals.]*
Outline risks to research participants and/or others (if any): *[Briefly outline any identified risks to research participants, the likelihood and severity of the risks, whom the risks may affect (participants and/or others)*
Outline the reasons which lead you to be satisfied that the possible benefit to be gained from the proposed research justifies the discomforts and risks involved (if any):

[Draw upon the potential findings and policy implications in the project outline to demonstrate the potential value and benefit from the project. Include a statement reiterating what steps have been, or will be, taken to minimise the potential risks to participants, and how the benefits outweigh the risks. Identify to whom the benefits are likely to accrue. Specify what monitoring processes are in place to manage any potential risks. Specify whether there is any relevant body (e.g. Steering Committee or Working Group) providing oversight and/or support to the research.]

What is the anticipated project commencement date?	
What is the anticipated project completion date (public release or other agreed dissemination of the findings)?	

3. Collection of data materials and procedures

If you are collecting prospective data, how will it be collected?	
☐ Questionnaire(s) or survey(s)	☐ Fully identifiable (including names) ☐ Potentially identifiable (coded) ☐ Anonymous (can never be identified)
☐ Interviews	☐ In-depth ☐ Semi-structured ☐ Unstructured ☐ Audio recorded ☐ Video recorded
☐ Focus groups	Specify data collection procedure:
☐ System data	Specify data collection procedure:
☐ Other	Specify data collection procedure:
Describe the research procedures as they affect the research participants and any other parties involved: *[Describe the step by step process through which participants will be identified and selected, and how the data will be collected, stored and analysed. Include and refer to relevant attachments (e.g. interview schedules, survey questions, plain language statements or*	

consent forms, and/or contracts or memorandum of understandings between research partners and data providers, should data be held by another party).]

4. Maintaining privacy and confidentiality

The *Privacy Act 1988* sets out thirteen Australian Privacy Principles (APPs) that govern Commonwealth agencies in their collection, management and use of data containing personal information. Information on the APPs can be found on the Office of the Australian Information Commissioner website.

To ensure that the research is conducted in accordance with the *Privacy Act 1988*, please address the following points.

Are you collecting, using or disclosing personal information? (please tick the relevant box)	☐ No ☐ Yes
In what form will personal information be collected?	☐Identifiable ☐Re-identifiable ☐De-identified
In what form will personal information be stored?	☐Identifiable ☐Re-identifiable ☐De-identified
If YES, give details of the measures which will be adopted to protect confidential information about participants. *[Outline the strategies that will be in place to ensure the confidentiality of participants and the information they provide will be maintained. This includes confidentiality in reporting results, as well as in the collection and management of data. Guidelines under Section 95 of the Privacy Act 1988 include a number of information privacy principles which set the current standard for the protection of privacy in the conduct of research involving human participants. They provide a framework in which research involving personal information should be conducted, to ensure that such information is protected against unauthorised collection or disclosure. If participants can be identified from the research, you should explain the reasons why. Procedures with respect to informing participants of provisions relating to anonymity and confidentiality should be described.]*	
Provide an overview of data storage procedures for the research. *[Include security measures and duration of storage.]*	

5. Details about the participants of the proposed research

Additional ethical consideration must be given when conducting research relating to some target groups. See Section 4 of the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* (National Statement) for requirements.

When answering the following questions, note that a distinction should be made between 'targeting' certain groups and the possible inclusion of individuals in these groups through random selection. Participants included through random selection are not considered to be 'targeted'. For example, research investigating long-term unemployment of job seekers may include people with a cognitive impairment, an intellectual disability or a mental illness, however, selection is based on their length of employment, and therefore the research wouldn't be specifically targeting this cohort.

Specify whether your research will target participants listed in Section 4 of the National Statement, and whether payment will be made to any subjects? *[If YES, describe the steps that have been taken to ensure that the research complies with the standards outlined in Section 4 of the National Statement for research involving these groups. Where payment will be made, researchers should specify the nature and purpose of this payment.]*	☐ No ☐ Yes
Does your research relate primarily to Aboriginal and Torres Strait Islander Peoples? *[If YES, please provide details about how the research will include assessment by or advice from:* • *Aboriginal and Torres Strait Islander Peoples networks and/or knowledge of research with Aboriginal and Torres Strait Islander Peoples; or* • *People familiar with the culture and practices of the Aboriginal and Torres Strait Islander peoples who will be asked to participate in the research* *If no assessment or advice has been sought, please explain why.]*	☐ No ☐ Yes
Describe the procedures you will follow to obtain the informed consent of participants: *[If you are seeking permission from the Committee of Peers to provide limited disclosure to participants of the aims and/or methods of research, please provide justification for this*	

approach against the criteria under Section 2.3.1 (and Section 2.3.2 where the limited disclosure involves active concealment or explicit deception) of the National Statement. Criteria for various approaches to limited disclosure are outlined in the National Statement under sections:

- *2.3.6 (for opt-out); and*
- *2.3.10 to 2.3.12 (for waiver).]*

Comment on any cultural or social issues pertaining to the research participants which have affected the design of the research or which may affect its conduct:

[This is particularly important for research involving Aboriginal and Torres Strait Islander Peoples or culturally and linguistically diverse communities.]

6. Dissemination of results

See Section 1 of the National Statement and Section 4 of the Australian Code for the Responsible Conduct of Research for requirements.

Outline how and to whom the research findings will be disseminated:

[Outline the main channel you will use to disseminate the research findings, and the main target audience you expect to have access to the research findings. Specify if there are any restrictions by third parties or government agencies on the dissemination of research findings.]

Will participants be debriefed at the completion of the research?

[Provide details and include agencies to whom participants may be referred if they have been distressed by the procedures.]

7. Other

Note if this research will be reviewed by another ethics review body:

[Name any other ethics review body that will review this research.]

Note to users

- **This protocol template is designed to be generic. Some subsections and suggestions will not be relevant for your specific study.**
- **You should edit the protocol contents to meet the needs of your study.**
- **Only include sections pertinent to the study, omit irrelevant sections, reorder and add sections as needed.**
- **Once you have finished your template, don't forget to highlight and right hand click on the contents page and select "update all", this will automatically update the page and section numbers that have change.**
- **Please also ensure you delete any edits and comments, and that you submit a clean, final version.**
- **A protocol should be a standalone document. Any additional application form used (including for example the HREA) should be in addition to the protocol. Please note we do not require any other application forms other than the completion of the on-line eProtocol form.**
- **The protocol should be a detailed description of every aspect of your project.**
- **Protocol Title: Descriptive title identifying the study design, population, interventions, and, if applicable, study acronym.**
- **Please include a footer to the Protocol that contains title, date, version and page number.**

Protocol

[insert full study title]

Protocol number (if applicable):
Version:
Date: dd/mm/yyyy

Author/s:
<<list author/s>>

Sponsor/s:
<<insert sponsor/s>> (if applicable)

Trial registration:
<<Insert Trial Identifier (i.e. ANZCTR)/s>> (if applicable)

Confidential

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) and the TGA note for guidance on good clinical practice (CPMPICH-135/95).

Signature _____ Date:_____

Name of Principle Investigator (please print) _____

Table of contents

Contents

Study synopsis (please provide brief information)

Title:	
Short title:	
Design:	
Study centres:	Where is the study being managed? E.g. BETA office location, partner agency office location.
Hospital/Site/Campus:	Where are study participants going to take part in the study?
Study question:	
Study objectives:	
Primary objectives:	
Secondary objectives	
Inclusion criteria:	
Exclusion criteria:	
Number of planned subjects:	What is the total sample size?
Investigational product:	e.g. final report
Safety considerations:	e.g. physical safety considerations (if applicable)
Statistical methods:	
Subgroups:	What subgroup analysis will be undertaken?

1. Site location

1.1 Study location/s

[list all locations, their address & contact details where this study or parts of the study will be conducted. e.g. details for PM&C contacts and partner agency contacts

Site	Address	Contact person	Qualifications	Phone	Email

1.2 Governance Arrangements

High level roles and responsibilities of partners and implementing bodies, steering committee arrangements, data management team, and other individuals or groups overseeing the trial, if applicable] E.g. details for PM&C contacts and partner agency contacts. See also section 6.1 Monitoring

2. Background information

2.1 Purpose of study

[A brief statement as to why the study is being undertaken, e.g. policy aims/ "to assess the impacts of intervention x on outcome y". (No more than ten lines).]

2.2 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]

2.3 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)

3. Hypothesis / Aims and Objectives

3.1 Hypothesis

[Include theory of change if relevant]

3.2 Study aims

[E.g. how will the study contribute to the evidence base/how will it benefit the target population?]

3.3 Outcome measures

[This section of the protocol must clearly state the variables to be measured. The primary outcome measure should reflect the 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.]

4. Methodology

4.1 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., administrative data, self-reported data from surveys, qualitative data from interviews, etc.) and include a description of study instruments (e.g. how will existing administrative datasets be obtained and used, if new administrative data is being collected, what is the mechanism?, surveys, interviews etc) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol. 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. Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (e.g., duplicate measurements, training of assessors).

7. Specify date of commencement as well as 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.

8. Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols.

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

Include in this section justification for consent procedures around administrative data collection if relevant. See standard paras s47E(a), s47E(d) :

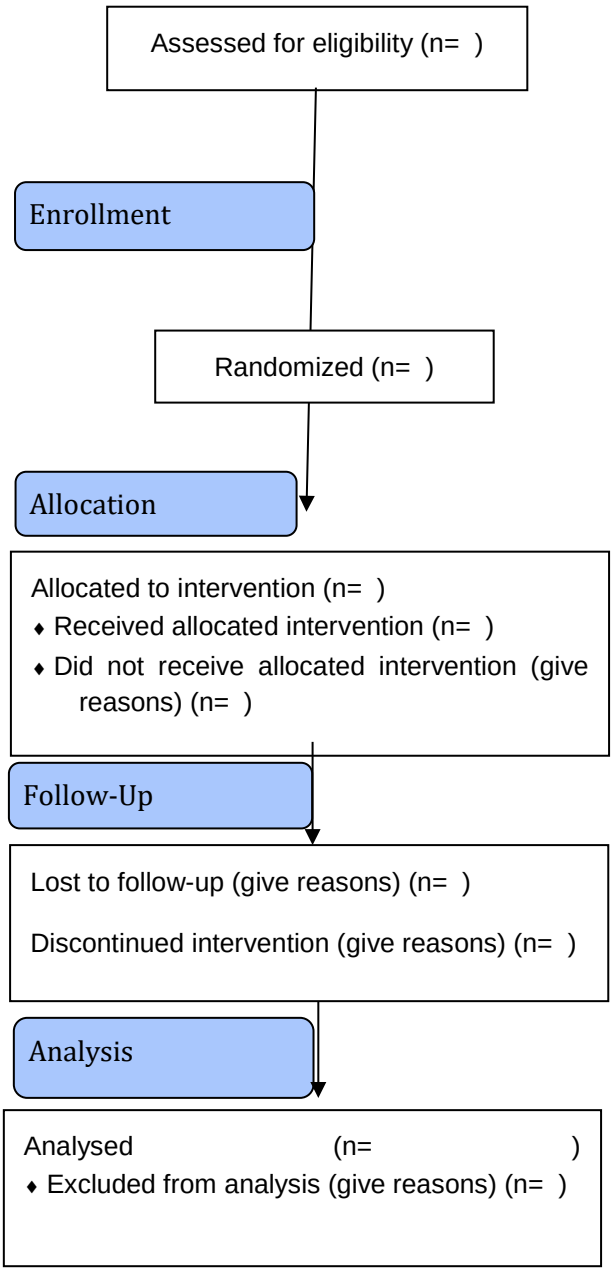
Standard para:

The use, handling and disclosure of personal information by government departments is governed by the Privacy Act and its Australian Privacy Principles (APP). According to the APP 6.1, as well as the National Statement on Ethical Conduct in Human Research (2018) 'Secondary use of data or information' (3.1.5), the use of personal information for a purpose other than that for which it was collected is permissible where an individual would reasonably expect the department to use the information for the secondary purpose, which is related to the primary purpose of collection'.

s42, s47E(a), s47E(d)


s42, s47E(a), s47E(d)

Protocol Flow Diagram



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			

4.2 Randomisation

[Include method of generating the allocation sequence (e.g., computer-generated random numbers), ratio of assignment to group and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (e.g., blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions.

Mechanism of implementing the allocation sequence (e.g., sequentially numbered, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned.

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]

4.3 Study methodology

[Describe each procedure / activity 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 tests please attach a copy of each of these tests to the appendix of the protocol]

5. Selection of Volunteers / Participants:

5.1 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.

Description of study settings (e.g., community clinic, academic campus, place of employment) and list of sites where data will be collected. Reference to where list of study sites can be obtained

Cohort studies: describe sources and methods that will be employed in the identification and recruitment of potential participants e.g. existing datasets, organisations/locations for personal recruitment, advertisements, etc. and provide a justification for how bias has been accounted for

Cross-sectional studies: describe the sources and methods that will be employed in the identification and recruitment of prospective participants (e.g. existing datasets, organisations/locations for personal recruitment, advertisements etc.…) and retrospective data (e.g., medical records, membership lists, registries, databases etc…) and provide a justification for how bias has been excluded

5.2 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…]

5.3 Exclusion criteria

[Provide details of participants who 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].

5.4 Consent

[Describe if individual consent will be obtained, whether an opt-out approach to consent or a waiver of consent is required; or if no consent is required – see sections 2.2.1 through 2.3.12 of the National Statement]

[Explain whether any parts of the research will be of limited disclosure and provide justification for this approach against section 2.3.1 of the National Statement].

[If an opt-out approach is being taken, provide explanation of the approach and how it addresses the guidelines in National Statement 2.3.6.]

[If a waiver of consent is needed, provide a justification for this and show how it addresses the guidelines in National Statement 2.3.10. In addition, if the study involves the collection, use or disclosure of health, sensitive or personal information without consent from the individual(s) to whom the information relates, clarification of how this complies with s95 or s95A of the federal Privacy Act is also required]

5.5 Handling of withdrawals

[Participants may withdraw from the study for the following reasons: participant has chosen to withdraw from the study (e.g. opt outs), 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., administrative data, survey responses, interview recordings and transcripts, meta-data, 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]

5.6 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]

6. Participant safety

6.1 Monitoring

[Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct.

Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor.

Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial.

If applicable, Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed.]

6.2 Risk management and safety

[Identify all areas where participant safety may be compromised, such examples may include, but are not limited to, exposure to radiation, physical danger/s from or to participants (e.g. research involving prisoners or refugees); and invoking psychological or physical distress.

Safety considerations are not just physical, they can also be psychological, and therefore, you must ensure for psychological distress you have arranged an appropriate contingency plan.]

7. Data Analysis and Reporting of Results

7.1 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. Outline how the sample relates to study objectives. Please also specify how participants will be recruited]

7.2 Power calculations

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

7.3 Statistical methods to be undertaken

[Describe the statistical methods that will be undertaken for this study. Include what procedures are in place to account for missing, unused and spurious data. What procedures are there for reporting any deviation(s) from the original statistical plan? It is recommended this section be written in collaboration with a statistician.]

7.4 Publication policy

8. Data security & handling

8.1 Details of where records will be kept & how long they will 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 15 years post study closure (in regard to the interview recordings, the protocol should make it clear whether the recordings are to be retained or destroyed after being transcribed. The transcriptions and recordings if not destroyed would need to be retained for 15 years. A useful outline of how to develop an effective data management policy is included in section 3.1.45 of the National Statement.]

8.2 Confidentiality and security

[Describe how confidentiality of all study data will be ensured via security mechanisms in place - see 3.1.40 - 3.1.43 in the National Statement]

8.3 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]

8.4 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]

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

9. Appendix

[Attach any participant information sheets, consent forms, questionnaires, functional and/or cognitive tests, surveys, telephone scripts, advertisements, photographs of devices etc.].

List of attachments included:

Document name	**Version number**	**Date** **(e.g., 18/01/2015)**

10. References