**Note to Users**

The protocol should provide sufficient detail to enable:

1. Understanding of the background, rationale, objectives, study population, interventions, methods, statistical analyses;
2. Ethical considerations, dissemination plans, and administration of the project;
3. Replication of key aspects of project methods and conduct; and
4. Appraisal of the project’s scientific and ethical rigor from ethics approval to dissemination of results.

This protocol template is designed to be generic. Some subsections and suggestions will not be appropriate for your specific study. You should tailor the protocol contents to meet the needs of your study.

This document provides suggested content headings, and each section is explained underneath the relevant heading.

**You will need to input project specific information under each heading, and remove explanatory information which is written in blue.**

**Delete this page before submitting.**

*Acknowledgement: Grampians Health would like to acknowledge the work of the Clinical Research Development Office, Murdoch Children’s Research Institute in developing much of the guidance text within this protocol.*

|  |
| --- |
| protocol |
| [Insert Full Study Title] |
| Protocol Number (if applicable):  Version: #  Date: DD/MM/YYYY |
|  |
| **Author/s:**  <<List Author/s>>  **Sponsor/s:**  <<Insert Sponsor/s>> |
| [The sponsor is the company or institution that takes responsibility for the initiation, management and financing (or arranging the financing) of the study.]  **CONFIDENTIAL**  This document is confidential and the property of <<Insert Name of Institution>>. 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). |

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## **Glossary of Abbreviations & Terms**

|  |  |
| --- | --- |
| **Abbreviation/Term** | **Description (using lay language)** |
|  |  |
|  |  |
|  |  |

## **Study Sites**

### Study Location/s

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

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

## **Funding and Resources**

### Source/s of Funding

[This section should describe how the study will be financed, but should not contain specific dollar amounts. If you are not receiving financial support through a research grant for this study please state this and advise how the study will be resourced]

## **Introduction and Background**

### Lay Summary

[All information provided in this section must be in language that can be understood by an interested person without a scientific background. Do not use scientific jargon, abbreviations and do not include references. This summary should include information on the aims and importance of the study as well as briefly summarizing what is being asked of 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, how it will be conducted and its expected benefits.]

### Background and Rationale

[This section should provide background information on the field or topic of research, explain the research question being addressed and should convince the reader of why the study needs to be done. The following points may be used as a guide:

* Provide a short but comprehensive literature review (including references). The [Grampians Health Library](mailto:researchethics@bhs.org.au) can assist you in the undertaking of a literature review relative to your project.
* 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 how it will fill any gaps in the field.
* Discuss the importance of the topic to justify the research (e.g., public health, clinical importance, community, incidence, prevalence, mortality and morbidity)

## **Study hypothesis/research question/aim(s)**

[State the hypothesis to be tested if your study is a hypothesis testing method. If it is not hypothesis testing state the key research aim(s) or question(s) to be addressed.

This section states the overall aim of the study. In any study, you aim to do something. For example, you aim to verify, to investigate, to measure, to determine, to compare, to calculate, to explore, to understand or to describe.]

## **Study Objectives and Outcomes**

The following information guides the completion of sections 6.1, 6.2 and 6.3.

An **objective** is the purpose for performing the study (i.e. the scientific questions to be answered). Express each objective as a statement of purpose (e.g., to assess, to determine, to compare, to evaluate).

Your focused research question needs to be further refined into one or more study objectives. I.e. these are the specific research questions that will help you to answer the broader overarching aim of the research.

An **outcome** is a specific measurement or observation used to measure the objective. Outcomes should be prioritised and should correspond to the study objectives and hypotheses being tested. Give succinct, but precise definitions of the outcomes used to address the study’s primary and secondary objectives (e.g., specific laboratory tests, clinical assessments of the condition, assessments of psychological characteristics, participant-reported outcomes, behaviours, health outcomes, attitudes, views or experiences). Include the study visits or time points at which data will be recorded or samples will be obtained. Describe how outcomes(s) will be adjudicated, if applicable.

### Primary Objectives

[The primary objective is a single and quantifiable statement that will allow you to answer your research question or address your hypothesis. They are represented as clear statements that reflect the purpose of what you are trying to measure.]

### Secondary Objectives

[A study may or may not have secondary objectives. Secondary objectives consider outcomes of interest that may or may not be related to the primary objective. Secondary objectives may or may not be hypothesis-driven and may include more general non-experimental objectives, e.g. to develop a registry, to describe patients’ experiences.]

### Outcomes/Outcome Measures

Often outcomes and outcome measures are best represented in table format.

[The **outcomes** (also known as endpoints) are the variables which are used to measure the objectives.

This section of the protocol must clearly state which variables are to be measured, at which study visits the outcomes will be obtained, the specific laboratory tests or other analytical measures to be used and the timeframe. Outcome measures should correspond to the study objectives and hypotheses being tested. A brief explanation (i.e. a justification) should be provided to explain why you have selected the outcomes listed in the protocol.

This section of the protocol must clearly state what the variables to be measured are and how they will be measured.

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 primary outcome is the basis for concluding whether or not the study has met its primary objective; the primary outcome measure should therefore be based on the primary objective of the study. It should reflect the specific key measurement or observation used to describe patterns of diseases or traits or associations with exposures, risk factors or treatment (e.g., systolic blood pressure, a specified validated questionnaire or clinical assessment scale). Sometimes there are multiple primary outcomes which fit with the primary objective.

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.

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 study design should enable the study objectives to be met.

Provide an overview of the study design and how and where the study will be conducted. Provide a rationale for the choices of methodology and method/s.

A thorough description of **ALL** study procedures and assessments in a logical and sequential format should be included.

1. Specific the type of study e.g., Cohort-study (retrospective or prospective), case-control study, cross-sectional study, qualitative study (e.g. phenomenology, ethnography, grounded theory, case study, action research, etc.)
2. Specify the basic design elements including the total number of participants to be enrolled (target number) or the actual number of participants that are enrolled in the clinical study, the population to be studied (e.g., Adults aged 18-35), staff working in a particular outpatient clinic, patients/consumers involved in a particular program) and any risk factors present. Where applicable, include a clear inclusion and exclusion criteria.
3. Describe the setting and location of the site/s
4. Specify how the design will achieve the aims and objective
5. Specify how you will recruit participants to this study (if applicable)
6. Please state what data will be collected e.g., blood tests, MRI’s, genetic testing, videos, photos, questionnaires, perspectives, experiences, behaviours, etc... For each item, specify how the data collected will be identified (previously known as identifiable, re-identifiable [code assigned] or non-identifiable [anonymized].
7. Describe how you will collect (e.g. survey, interview, focus group, observation, etc.), handle and store all types of data collected.
8. 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.
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/SCHEDULE OF ASSESSMENTS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Example procedures** | **Assessment/Procedure** | **Visit 1 Baseline/**  **Screening** | **Visit 2**  **(3 months)** | **Visit 3**  **(6 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 /Study Procedures

[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]

For each assessment:

* Specify how the test (e.g. diagnostics, physical or mental performance assessments) will be conducted, when it will be conducted, who will conduct it, how measurements will be obtained (specify units where applicable) and what information will be collected and documented. Reference to a separate manual/Standard Operating Procedure (SOP) may be necessary if tests are complicated.
* Specify if any particular member of the research team must conduct certain assessments and whether they will be required to undertake study-specific training or certification
* Specify whether the tests need to be timed in relation to other activities
* Detail efforts to standardise procedures and assessments (where applicable) such as the required equipment specifications for a radiology assessment, a consistent laboratory method throughout the study; use of single, central laboratory for multi-site studies).
* Specify whether there are any samples being collected and stored for future research

The procedures could include:

* **Medical Record Review**: Include a listing of the variables that will be collected from the medical record, e.g. date of birth, weight
* **Physical examination** (e.g., height and weight, organ systems, motor or vision assessment, or other functional abilities). If appropriate, discuss what constitutes a targeted physical examination.
* **Vital signs** (e.g., temperature, pulse, respirations, blood pressure). Carefully consider which vital signs (if any) should be measured to ensure that only essential data are collected. Include any specific instructions with respect to the collection and interpretation of vital signs. For example will blood pressure measurement be made sitting or lying down? Will more than one measurement be made and averaged?
* **Administration of questionnaires or other instruments by researchers** (such as gait assessment tools). Non-standard and non-validated instruments should be included in an Appendix.
* **Completion of participant-reported outcomes by parents/participants** (such as a daily diary, periodic quality of life questionnaires).
* **Biological specimen collection and laboratory evaluations.** Include specific test components and estimated volume and type of specimens needed for each test. Specify laboratory methods to provide for appropriate longitudinal and cross-sectional comparison (e.g., use of consistent laboratory method throughout the study, use of single, central laboratory for multi-site studies). If more than one laboratory will be used, specify which evaluations will be done by each laboratory.
* Special assays or procedures required (e.g., immunology assays, pharmacokinetic studies, flow cytometry assays, microarray, DNA sequencing). For research laboratory assays, include specific assays, estimated volume and type of specimen needed for each test.
* **Counselling procedures, including any dietary or activity considerations** that need to be adhered to during study participation.

Include in this section a discussion of the results of any study specific procedures that will be provided to participant (e.g., radiographic or other imaging or laboratory evaluations).]

## **Study Population**

### Recruitment Procedure

[Define the group of people who will be invited to take part in the research. Explain how participants will be identified, contacted and recruited (e.g., clinics, referring doctors, advertisements etc.) and retrospective data (e.g., medical records, registries, databases).

Include information on exactly **who** will recruit participants or collect data (e.g. Principal Investigator, Research Nurse, External university student).

Describe how controls will be identified and recruited if relevant (e.g., advertisements, letters from GPs, family members) and describe how they will be matched if the study is a matched control study. Provide a description and justification of the sampling population.]

### Inclusion Criteria

[Clearly describe the criteria or characteristics that are required for a participant to be included in the study. The inclusion criteria will be highly specific for each study and the following is general guidance only and not an exhaustive list. Consider criteria related to:

* Demographic characteristics (e.g. sex, gender, age range, profession, level of experience)
* The specific definition of the condition which will be used to assess patients for recruitment into the study and how it must be documented (e.g. diagnostic methods, criteria for classification etc)
* Clinical indicators of current status

### Exclusion Criteria

[Provide details of characteristics or criteria that would make a potential participant ineligible to participate and justify why they have been excluded. Consider criteria related to:

* Specific clinical contraindications (where appropriate, specify grades of signs and symptoms).
* Specify any clinical (e.g. life expectancy, co-existing disease, cognition), demographic (e.g. age, language) or other characteristic that precludes appropriate follow-up in the study.
* Inability or unwillingness of participant or legally acceptable representative to give written informed consent.

**Justification for exclusion of a specific population:** If a specific population is excluded (e.g. elderly or pediatric populations, women or minorities), provide a clear and compelling rationale and justification to establish that inclusion is inappropriate with respect to the health of the participants or the purpose of the research. Limited English proficiency should not be an exclusion criterion, but feasibility does need to be considered. Inclusive methods such as translation of questionnaires of the use of interpreters should be considered. Extra care is necessary to ensure validity of information is maintained when participants have limited English proficiency or other aspects of literacy, and ability to provide valid information in the format requested.]

### Consent

***Consent Overview***

*The National Statement on Ethical Conduct in Human Research states that if you want people to take part in your research project, you need to get their informed consent. This means that they:*

* *Understand what the study involves and*
* *Voluntarily agree to take part in the study*

*Methods of consent vary according to the nature, complexity and level of risk of the study and also the personal and cultural circumstances of the potential participant. Common methods for recording consent are:*

* *Written – for example, the potential participant signs a Participant Information and Consent Form.*
* *Verbal – for example, you ask the person whether they agree to take part in your study and record their response in writing or on an audio device.*
* *Implied – for example, the person gives consent by filling out and returning a survey.*

*An Opt out approach is another option; this is where the person is included in the research unless they give their express decision to be excluded. Note that their decision must be informed. Use of an Opt out approach requires justification to (and approval from) the Human Research Ethics Committee (HREC).*

*It may be appropriate to use different types of consent for different elements of a study. For example, you might seek explicit written consent for participation in clinical research. You might then use an Opt out approach if you are seeking to use participants’ information as part of a registry.*

*In the protocol, describe the consent procedures to be used in the study. State whether the following fundamental conditions for valid informed consent will be met for each participant:*

* *Disclosure of relevant information to prospective research participants and/or their legally acceptable representatives*
* *Comprehension of the information provided*
* *Voluntary agreement of the participant, free from coercion*

[Describe the method of obtaining consent e.g., individual consent, waiver of consent, no consent required.

Detail the approach to provision of information to participants and/or consent (as required in addition to that outlined in the HREA). Provide details of the degree of participant commitment, project duration and any requirements for participant follow-up. Describe when and how re-consent will be sought]

# **Participant Safety and Withdrawal**

### Risk Management and Safety

*Major risks in undertaking research can be broadly categorised into:*

1. *Risks to the safety and rights of the study participants*

*Although observational studies are generally expected to involve lower risk for study participants than studies involving an intervention, observational studies still involve a level of risk.*

*Consideration needs to be given to psychological events such as anxiety or depression that may result from participation. Even a survey that asks questions about a participant’s mood or feelings can evoke psychological stress or embarrassment. Safety events may also result from a procedure in the study such as blood sampling.*

*Safety concerns for participants in observational studies may also relate to disclosure of risk of harm to self or another including, for example, mental health concerns, concerns regarding family violence and so on. Where observational studies are studying sensitive areas (e.g. childhood trauma or maltreatment) there can be risk of triggering safety concerns.*

1. *Risks to the successful conduct of the study (e.g. inadequate funding, poor recruitment, poor quality data/samples, risks to the staff when undertaking home visits etc).*

*Any unexpected, significant issues arising during the study should be reported to the approving HREC and to the authorising Research Governance Offices. The Coordinating PI is also responsible for providing any updated safety information to all Site PIs.*

[Identify all areas where participant safety may be compromised, 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.]

### Adverse Event Reporting

[If applicable, provide a description of how adverse events will be defined for your study. Include how adverse events occurring in the study subjects are to be identified and reported. Details should include the definition of a serious adverse event (SAE) and reporting timeframes.

### 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, interview transcripts 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]

# **Data analysis**

### analysis of quantitative data

[Describe the statistical methods that will be undertaken for this study. It is recommended this section is written in collaboration with a statistician. Statistical analyses should directly relate to the aims/hypotheses outlined above. Include details about:

* Power calculations.
* The estimated sample size and justify how this will ensure that your study numbers will reach statistical significance.
* The statistical analyses that will be employed for each analysis undertaken.
* Outcome measures.]

***Please note that the study design should be considered in context with the planned statistical analyses to address the primary objectives. If the design is not robust to begin with, it is often impossible to rescue robust findings at the analysis stage.***

### analysis of qualitative data

Describe how qualitative data (interviews, focus groups, free text surveys, audio recordings, photographs etc.) will be analyzed and by whom. Include justification of and theoretical framework and provide details of any software to be used. The theoretical/philosophical framework should be with the study design and the approach to data analysis should be aligned with the methodology.]

# **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 Management**

Consider having a separate Research Data Management Plan as part of your study documentation

### Data Generation (source data)

*What is the source of the data you will capture? Will you collect existing data, will you generate new data or will you use both?*

*Source data are all information, original records of clinical findings, observations, or other activities in a study necessary for the reconstruction and evaluation of the study. Electronic source data are data initially recorded in electronic form.*

*Source data are contained in source documents (paper or electronic). Examples of paper or electronic source documents are: medical records; participant diaries; researcher diaries; memos; recorded data from automated instruments (e.g. blood pressure measurement); participant- or researcher-completed questionnaires or rating scales; videos; photographs; laboratory results; ECGs and reports; and imaging scans and reports.*

### Data Capture Methods and Data Use, Storage, Access & Disclosure

**Data collection**

[In this section of the protocol, provide a brief outline of the following:

* Whether data capture and entry will be paper and/or electronic.
* Whether any relevant data standards (e.g. ICD10 for disease coding, CTCAE for coding adverse events, CDASH for standardising data collection formats and structures across studies and sponsors) that are being utilised as a part of the study.
* Data capture processes - who will process the collected data, how, when and where

Note: You should develop a Data Dictionary to provide a detailed description for each data variable (i.e. the source of the variable, coding information if used [for example, MedDRA, SNOMED CT], and expected ranges [if relevant]) or can be exported from the project's database(s) – for example, REDCap).]

**Data storage and access**

[State how and where hardcopy data will be stored and how access will be restricted.

State how and where electronic data will be stored, how it will be backed up and how access will be restricted (e.g. setting user permissions).]

**Access to data**

[Describe in this section who will have access to the data and study documents, noting that for the purposes of quality assurance reviews, audits, and evaluation of study safety, progress, and data validity, each site must permit authorised representatives of the sponsor, HREC, Research Governance Office and regulatory agencies to examine source records for participants.]

**Disclosure of data**

[Describe whether there are any situations in which personally identifiable information or data will be released to third parties.]

### Data Confidentiality

[Detail how personal information and data about potential and enrolled participants will be collected and maintained in order to protect confidentiality before, during, and after the study. Include procedures for maintaining participant confidentiality, privacy protections, and any special data security requirements. (Refer to section 3.1.40 of the National Statement for discussion about research where removal or separation of identifiers may not be required).]

***Note that the 2018 update of the National Statement no longer uses the terms ‘identifiable’, ‘potentially identifiable’, ‘re-identifiable’, ‘non-identifiable’ or ‘de-identified’ as descriptive categories for data or information due to ambiguities in their meanings. Rather, the identifiability of information is a characteristic that exists on a continuum.***

***The risks related to identifiability of data and information in research are greatest where the identity of a specific individual can reasonably be ascertained by reference to an identifier or a combination of identifiers (examples of identifiers include the individual’s name, image, date of birth or address, attribute or group affiliation). Risk may also arise where identifiers have been removed from the data or information and replaced by a code, but where it remains possible to re-identify a specific individual (by, for example, unlocking the code or linking to other data sets that contain identifiers). Due to technological advances, risks may arise in relation to data and/or information that has never been labelled with individual identifiers or from which identifiers have been permanently removed.***

*As outlined in the updated National Statement (2018):*

* *Researchers and reviewers must consider the identifiability of data and information in order to assess the risk of harm or discomfort to research participants or others who may be at risk.*
* *Researchers should adopt methods to reduce the risk of identification during collection, analysis and storage of data and information. Methods to reduce identifiability and the consequent risks may include:*
  1. *minimising the number of variables collected for each individual;*
  2. *separation and separate storage of identifiers and content information; and*
  3. *separating the roles of those responsible for management of identifiers and those responsible for analysing content.” (NS 3.1.41)*
* *Where research involves linkage of data sets with the consent of participants, researchers should advise participants that use of data or information that could be used to identify them may be required to ensure that the linkage is accurate. They should also be given information about the security measures that will be adopted, for example the removal of identifiers once linkage is completed.*

*Additional comments:*

* *If data are to be generated in one location and transferred to another group, describe the responsibilities of each party, including the expectations regarding time to transfer.*
* *Discuss any additional features to protect confidentiality and privacy.*

*The security arrangements should be proportional to the risks of the research project and the sensitivity of the information (NS 3.1.46).*

### Archiving – Data and Document Retention

***Archiving***

[How will the data be stored post-study? What is the minimum, mandatory retention period for the data for this study?]

*The time period for which study data, information and documents must be retained (the archive period) is determined by the type of research and relevant legislation, code and guidelines. Where more than one legislation/code/guideline is relevant, the one with the longest retention period applies.*

*Below is some guidance on current minimum retention requirements for research in Australia - contact the* [*Research Ethics and Governance Unit*](mailto:researchethics@bhs.org.au) *to further discuss the requirements for your particular study.*

* *All research – in general at least 5 years from publication (The Australian Code for the Responsible Conduct of Research 2007)\**
* *All research – retention of any new health data for at least 7 years for adults or until age 25 for children [VIC HRA]*
* *Clinical trials - must archive for at least 15 year post-trial completion (TGA)*
* *Gene therapy research data - must retain permanently (The Australian Code for the Responsible Conduct of Research 2007)\**
* *Research that has community or heritage value - must retain permanently, preferably within a national collection (The Australian Code for the Responsible Conduct of Research 2007)\**

*\* The revamped Code (2018) does not include guidance on required data retention periods - we are awaiting the release of the supporting guide “Management of Data and Information in Research”.*

[Describe how long and where all research data, information and documents will be kept following the end of the study. During the archive period, data should be stored in a way that allows re-identification in case this is needed (e.g. for regulatory audits). Outline how the data will be secured and how confidentiality of stored data will be ensured.

State who (i.e. person’s position) will be the custodian during the archive period, who will have access to the stored data and outline any procedures that may be followed to dispose of the data at the end of the archival period.

Specify that records should not be destroyed without the written consent of the Coordinating Principal Investigator / Site Principal Investigator. In multi-site studies, the Coordinating Principal Investigator should inform Site Principal Investigators when these documents no longer need to be retained.]

**Destruction**

[If the plan is to destroy data and documents after the required archive period, state this here and describe the planned method of destruction. Secure destruction of research data involves using irreversible methods to ensure that the data is no longer usable. It is particularly critical that confidential or sensitive data is made unreadable.

Hardcopies should be disposed of via a confidential shredding process.

For electronic data, note that deleting files does not destroy the information completely; it may be necessary to utilise software which permanently erases data\* (Seek guidance from Grampians Health IT). Consider also other data devices.

\* It may not actually be possible to completely expunge data from institutional backups [i.e. those back-up tapes held off-site].

# **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, flyers, photographs of devices etc….]

**List of Attachments included:**

|  |  |  |
| --- | --- | --- |
| **Document Name** | **Version Number** | **Date**  (e.g. 18 January 2021) |
|  |  |  |
|  |  |  |
|  |  |  |

# **References**

[Researchers must include up-to-date references to evidence the study background and rationale for their study.]