This is a Biobank / Databank Protocol TEMPLATE

Please adjust to suit research project

Template Version October 2021

**PREFACE**

Remove this **Preface** before finalizing and distributing the Protocol.

The goal of this template is to assist investigators to write a comprehensive biobank protocol that meets requirements including the National Statement on Ethical Conduct in Human Research’ (National Statement) 2023

Researchers should refer to:

* **‘National Statement on Ethical Conduct in Human Research’ (National Statement) 2023**
* [**NHMRC Biobanks Information Paper 2010**](https://www.nhmrc.gov.au/about-us/publications/biobanks-information-paper#block-views-block-file-attachments-content-block-1)
* **Healt**h Records Act (2001)

The template will also help investigators think through the scientific assumptions, logistics and organisational structure of their new or updated biobank.

**INSTRUCTIONS ON HOW TO USE THIS TEMPLATE**

The template includes the framework for organising your protocol, as well as instructions and example text.

*Italics:* **Instruction / Explanatory Text** is indicated by in blue font*.* This text provides information on the content that should be included; these instructions should be deleted once you complete a section. Footnotes to instructional text should also be deleted. The instructions also note if a section should be left blank.

[Regular font]: **Example Text** is indicated in [regular font]. Within example text, the need to insert specific information is notated by <angle brackets>. Example text is included to further aid in protocol writing and should either be modified to suit the biobank design and activities of the planned biobank. If not applicable for your biobank, delete the example text.

***Do not delete any sections*** – You will find it helpful to consider all sections, however, depending on your biobank design, not all sections may be applicable. nat

If a sections is note required, retain heading and replace subtext with N/A. The section headers include formatting to generate a table of contents. Once the protocol is written, ensure the table of contents is updated (right click on the table of contents and select ‘Update Field’) to reflect any changes.

***Version control*** is important to track protocol development, revisions, and amendments. It is also necessary to ensure that the correct version of a protocol is used by all staff conducting the biobank. With each revision, the version date located in the Footer of each page should be updated.

Acknowledgement: Sections of this protocol have been adapted from The Hospital for Sick Children (SickKids) [SickKids BioBank Protocol Template](https://www.sickkids.ca/siteassets/research/reb/protocol-development-templates/sickkids-biobank-protocol-template-2020-2021.docx) -2020-2021 (Version 25)

|  |
| --- |
| BioBank / databank 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 2023 (National Statement), 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). |

**Revision History**

|  |  |  |
| --- | --- | --- |
| **Version Number** | **Issue Date** | **Summary of changes** |
|  |  |  |

# Signature Page

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

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

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

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

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# Biobank/Databank Synopsis

Provide brief information

|  |  |
| --- | --- |
| Title: |  |
| Short Title: |  |
| Design: |  |
| Biobank/Databank Centres: |  |
| Hospital: |  |
| Biobank/Databank Question: | *May be deleted if N/A* |
| Biobank/Databank Objectives: |  |
| Primary Objectives: | *May be deleted if N/A* |
| Secondary Objectives | *May be deleted if N/A* |
| Inclusion Criteria: |  |
| Exclusion Criteria:  |  |
| Number of Planned Participants: |  |
| Investigational product: | *May be deleted if N/A* |
| Safety considerations: |  |
| Statistical Methods: | *May be deleted if N/A* |
| 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 and reporting requirements:* Consultative
* Co-design
* Nil consumer involvement

Refer to section 6 for definitions and to provide details. |

# Glossary of Abbreviations & Terms

*Insert or delete information as required*

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

# Biobank/Databank Sites

### Biobank/Databank Location/s

[List all locations, their address & contact details]

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

# Introduction/Background Information

### Lay Summary

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

### Introduction

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

### Background information

This section should contain a background discussion for the Biobank/Databank. The following points may be used as a guide:

Provide clinical, epidemiological or public health information which will provide context for the disease entities being studied.

* Summary of findings from previous studies which are significant to the proposed Biobank/Databank.
* Literature review: discuss current literature and data relevant to the Biobank/Databank.
* If applicable, information regarding the broader (e.g. international) registry group or consortium of which this biobank/registry is a part of.

# Consumer Involvement

[This section of the protocol should confirm if there has been consumer involvement in the development of the Biobank/Databank concept or materials 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 Biobank/Databank.

**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]

<Insert Text>

# Scientific Rationale

This section should include the following information:

* Description of the Biobank and the selection of the participant population.
	+ What types of tissue specimens will be collected?
	+ From whom the tissue specimens will be collected?
* Justification for establishment of the Biobank.
* Benefits of establishing the Biobank. For example, provision of well-documented and properly preserved specimen for research use.

<Insert Text>

# Specific objectives of the Biobank

This section should include a detailed description of the objectives of the Biobank/Databank.

{Begin sample text}

The objectives of the <Name of Biobank> is the conservation of (list as appropriate biological material, DNA, and data such as clinical data and genetic data (“material/DNA/data”)) collected from (patients with XXXXX disorders, their family members as well as from control participants as required), in order to allow future research on XXXXX. The study of XXX (genetic factors, biomarkers, etc.) may lead to XXXXXXX (i.e., a better understanding of these diseases and better diagnostic tests or even the development of new treatments)

{End sample text}

<Insert Text>

# Governance and Accountability

This section should provide detailed information on the governance and management structures of the Biobank with the aim of protecting participants, operations within established legal and ethical laws as well as regulations and cultural standards to ensure transparency.

This information may be provided in this section or supporting documents referenced here.

Specific information to be included are as follows:

* Organizational structure; Identify persons or committees with responsibility for the following:
* Overall responsibility for the Biobank (e.g. the PI)
* Day-to-day operations (e.g. Operations Committee)
* Decision making for access to and use of data and samples stored in the biobank (e.g. Scientific Advisory Committee)
* List of duties and responsibilities of individuals in the Biobank
* Explanation of the two committees that are to be created as part of the Biobank Governance Structure:
	+ Operations committee: This committee will be responsible for the day-to-day operations of the biobank.
	+ Scientific Advisory/Oversight committee: This committee will be tasked with determining best uses of biospecimens and data, as well as monitor the compliance with the biobank’s mission and practices. This committee will also act as an 'access' committee and serve to evaluate the scientific merit of requests for tissues/data from external research groups. The committee will also ensure that appropriate HREC approval has been obtained by each study that is requesting access to biobank specimens.

{Begin sample text}

The biobank complies with both external and internal governance requirements.

**External Governance**

<Insert *name of biobank*> complies with external requirements from:

* Australian legislation and regulations governing human tissue, data protection, privacy, and research with human participants. This is monitored and compliance confirmed through regular review of policies.
* Australian professional codes of conduct where these overlap with stakeholders’ activities (e.g., Medical licensing bodies and societies.
* Human Research Ethics Committee (HREC): Research biobanks are considered research platform ‘projects’ and as such the biobank operates under <*name of HREC*> approval and undergoes annual ethics review by the HREC. The focus of the review is on the objectives for the biobank, its consent materials, recruitment protocols, enrollment and release statistics, and security measures.
* External biobank quality assurance program: The biobank is currently certified with the <xxx> biobank certification program. Research biobanks are recommended to be enrolled in one of several internationally recognized quality assurance programs to ensure that high quality biospecimens are used in research

**Internal Governance**

The biobank has established the following governance structures/mechanisms which have been approved by the governing Research Office of <insert organization name>:

<*Insert org chart and explain roles and reporting relationships*>.

Define the position or person with overall responsibility for the Bank

The biobank has a <\_#\_> tiered governance structure which provides a formalized governance and oversight. Committees include (as applicable):

* Management Committee
* Data Management Committee
* Scientific Advisory Committee
* Access Committee. The Access Committee may be separate to or part of the Scientific Advisory Committee.

State the function and composition of each committee.

{Begin sample text}

The Management Committee monitors accrual and personnel and operations of the < Insert *name of biobank* >. The committee is composed of the following individuals:

* Principal Investigator (PI)
* Leader
* Staff

{End sample text}

# Biobank/Databank Population

### Recruitment Procedure

[Define the group/s that the biobank/databank will include. Explain how participants will be identified and recruited. You should make a distinction between how you will recruit control participants compared to other groups.]

<Insert Text>

###  Inclusion Criteria

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

<Insert Text>

Inclusion criteria are characteristics that define the population targeted, e.g., those criteria that every potential participant must satisfy, to qualify for Biobank/Databank entry. Provide a statement that individuals must meet all of the inclusion criteria in order to be eligible to participate in the Biobank/Databank and then list each criterion.

Create a numbered list of criteria that an individual must meet to be eligible to participate in the Biobank/Databank.

Some criteria to consider for inclusion are provision of appropriate consent and assent, willingness and ability to participate in procedures, age range, gender, health status, diagnosis or symptoms, background medical treatment, and laboratory ranges. Additional criteria should be included as appropriate for the design and risk.

{Begin sample text}

In order to be eligible to participate in this Biobank/Databank, an individual must meet all of the following criteria:

1. Consent provided
2. Waiver of consent as applicable (pending ethics review and approval)
3. Aged <specify range>
4. Disease or suspected disease entity
5. Patients who are seen at the institution for care
6. <Specify laboratory test> results between <specify range>]

{End sample text}

### Exclusion Criteria

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

Exclusion criteria are characteristics that make an individual ineligible for participation. Provide a statement that all individuals meeting any of the exclusion criteria at baseline will be excluded from participation and then list each criterion. Limited English proficiency cannot be an exclusion criterion.

Create a numbered list of criteria that would exclude an individual from enrollment. Some criteria to consider for exclusion are pre-existing conditions or concurrent diagnoses, concomitant use of medication(s) or devices, other factors that would cause harm or increased risk to the participant or close contacts. Additional criteria should be included as appropriate for the Biobank/Databank design and risk

{Begin sample text}

Participants are not eligible to take part in the Biobank/Databank if they are:

1. Unwilling or unable to give informed consent or for whom the informed consent requirement cannot be waived according to the ethics approval.
2. Present with a specific disease or suspected entity

{End sample text}

### Consent

[Describe form of consent to be obtained informed written consent (opt in), informed opt out consent or if a waiver of consent is required, or if no consent is required.

Informed consent - describe how informed consent will be administered. Describe who will obtain consent (using roles, note names) and how the process of informed consent will be structured to be conducive to rational and thoughtful decision making by the participant / participant’s legally authorized representative

Include information such as:

* Where the consent process will take place.
* How participant privacy will be assured.
* Whether participants will be permitted to provide consent at the time of the consent discussion or whether they will be required to come back to provide written informed consent.
* How the PI will ensure that participants comprehend the nature of the Biobank/Databank.
* Steps that will be taken to avoid coercion.

If the protocol involves multiple consenting sessions, or multiple informed consent forms, describe this information and the associated procedures in detail.

Describe any proposed waivers or alterations to informed consent. Describe any special circumstances regarding obtaining consent. Describe plans for obtaining consent from speakers of language other than English.

If not all participants will have the capacity to give informed consent, describe how capacity will be assessed. Describe the anticipated degree of impairment relative to their ability to consent to participate in research. Research with persons who have diminished capacity is allowed only for minimal risk or direct benefit studies. Clearly document that the PI has an adequate plan in place to assure an acceptable level of comprehension before consent is obtained. Include a specific plan to assess comprehension during assent (the participant’s agreement).

The consent plan should include information about re-consenting participants who attain capacity during the period for which consent has been sought. Assenting participants with parental/substitute decision maker consent should be consented into the biobank once they reach full decision-making capacity.

The PI is responsible for ensuring that valid consent is obtained and documented for all participants. Specifically describe how consent will be documented and how / where documentation will be stored. The PI is also responsible to ensure that all versions of the consent forms are maintained for the corresponding samples/data set.

The description in this section should be broad / general and the local specific consenting requirements would be detailed in the respective HREC application form.

When preparing the participant information and consent form the research team should ensure the participant is informed about:

* any potential benefits/risks associated with participation in the biobank,
* whether or not they can withdraw from the biobank,
* whether or not they may receive any results of testing undertaken using their stored samples,
* whether samples may be provided to overseas researchers
* whether or not samples can be requested to be returned for burial/cremation or other purpose

{Begin sample text FOR INFORMED CONSENT}

Informed consent is a process that is initiated prior to the individual’s agreeing to participate in the Biobank/Databank and continues throughout the individual’s participation.

Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be HREC approved and the potential participant will be asked to read and review the document.

The PI will explain the research biobank/databank to the potential participant and answer any questions that may arise. All potential participants will receive a verbal explanation in terms suited to their comprehension of the purposes, procedures, and potential risks of the biobank/databank and of their rights as research participants. Potential participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The potential participants should have the opportunity to discuss their participation with their surrogates or think about it prior to agreeing to participate. The potential participant will sign the informed consent document prior to any procedures being done specifically for the biobank/databank. The participant may choose specific, extended or unspecified consent for different components of the biobank/databank. The participants may withdraw consent at any time throughout the course of the biobank/databank. A copy of the signed informed consent document will be given to the participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this biobank/databank.

A copy of the signed informed consent document will be stored <enter storage location>. The consent process, including the name of the individual obtaining consent, will be thoroughly documented in the participant’s research record. Any alteration to the standard consent process (e.g. use of a translator, consent from a legally authorized representative, consent document presented orally, etc.) and the justification for such alteration will likewise be documented.

{End sample text}

### Strategies for Recruitment and Retention

[The following information should be included:

* Where the biobank/databank population will be recruited from / enrolled, i.e., in-patient services, out-patient clinics?
* Whether recruitment is single centre or multicentre?
* Who will identify potential participants?
* Initial Contact:
	+ Approach or initial contact with patients / legal representative for recruitment will need to comply with regulations and guidance documents protecting patient privacy – circle of care
	+ Circumstances where initial contact will occur, i.e., during clinic visit, prior to a procedure, etc.
	+ Methods of contact, i.e., in person, via a recruitment letter, etc.
	+ Recruitment procedures should provide a patient / legal representative with an opt-out to not be contacted further.

In addition, consider inclusion of the following information:

* Target sample size; what is the number of participant cases and samples in the biobank?
* Anticipated accrual rate
* How potential participants will be identified and approached?
* If participants will be compensated for their participation, describe amount and schedule of payments
* If the study requires long-term participation, describe procedures that will be used to enhance retention (e.g., multiple methods for contacting participants, visit reminders, incentives for visits and samples, etc.).
* Describe the plans to minimize loss to follow-up and missing data. The description should include when a participant will be considered lost to follow-up (e.g., if he or she fails to return for specified number of scheduled visits and is unable to be contacted by the site staff) and whether the biobank/databank design will accommodate replacing lost / withdrawn participants.]

<Insert Text>

### Participant withdrawal or termination

<Insert Text>

# Participant Withdrawals

### Risk Management and Safety

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

### Handling of Withdrawals

### Reasons for Withdrawal or Termination

[Participants may withdraw from the biobank/databank for the following reasons: participant has chosen to withdraw from the biobank/databank, protocol violation, or participant has experienced an adverse event. Describe the procedures to be followed when a participant is withdrawn from the biobank/databank. 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]

<Insert Text>

### Handling of Participant Withdrawals or Termination

[Describe efforts that will be made to continue follow-up of withdrawn of participant, if applicable.

This section should not include a discussion of how these participants will be handled in the data analysis procedures.]

<Insert Text>

# Biospecimen Acquisition, Processing, Storages, and Quality Assurance

[Describe what samples are collected/received, how long you will store each sample, where you will store the sample and state if any samples will be used for genetic testing.

Confirm if the biobank will include linked data]

## 12.1 Biospecimen Acquisition

Thefollowing information should be included in this section:

* Are the biospecimens already existing (retrospective) or to be obtained (prospective) or a combination of both?
* Will biospecimens be obtained from, or sent, interstate or overseas?
* Type(s) of biospecimens being collected.
* The process by which the biospecimens will be collected, i.e., location of biospecimen collection.
* For surplus tissue collection: who will determine whether surplus exists?
* Will collections from existing research projects be included? if so what assurance processes will be in place to ensure that samples/data are only included where the PI agrees, consents permit the sharing and conditions of consent can be upheld, the samples and data are of high quality
* How specimens will be identified and labeled?
* Procedures to ensure biospecimen/ data integrity
* Process for recording and documenting specimens received and released.

<Insert Text>

### Biospecimen Processing

The following information should be included in this section:

* How sample preparation and handling prior to storage will be performed?
* What are the procedures for transporting biospecimen- i.e., moving samples from the collection site to the biobank?
* How tissues will be stored in the biobank?
* Where are storage facilities located?
* How are the participant’s privacy maintained?
* If specimens are to be discarded, provide information on how these will be done securely.
* If samples are found to be unacceptable, is there a process for repeat sample collection and if so, how will this be operationalized? If no option for repeat sample collection, what will be done with the data collected with the specimen?

<Insert Text>

### Biospecimen Storage

The following information should be included in this section:

* How will the specimens be stored?
* What kind of storage units are specimens stored in?
* Location of storage?
* Duration of specimen storage? If indefinite, please specify that specimens will be stored until they are used up for all HREC-approved research studies.
* How does the biobank keep track of sample location within the storage unit and the location of the storage unit?
* What biobank software / database will be used?
* Quality control processes to ensure integrity and viability of samples stored in the Biobank
* Maintenance of storage conditions to ensure sample preservation. For frozen specimens, include information on freezer temperature monitoring and recording, alerts and plans for deviations of temperature including presence of a back-up freezer if available.
* How does the biobank keep track of sample location within the storage unit and the location of the storage unit?
* What biobank software/ database is being used?
* How is privacy in the database secured?

<Insert Text>

### Biospecimen Quality Assurance

The following information should be included in this section:

* Will the biobank include any legacy collections?
* Is the biobank enrolled in a biobank certification/accreditation program?
* How will the quality of the samples be ensured/maintained? Will internationally recognized processing and storage procedures be used (documentation must reflect this)?
* What systems are in place to ensure integrity of tissue samples (if applicable) is maintained e.g. temperature alarms on storage units?
* Process for maintaining and complying with any restriction on the use of samples /data (as per the consent **or** HREC approval)

<Insert Text>

### Biobank Data

This section should include a description of the data that will be collected along with the samples (if relevant).

* Will data be obtained from, or sent, interstate or overseas?
* If the biobank is not disease-specific, but more general (example: collecting specimens for neuromuscular diseases of which there are many), is there a minimum core data element set for inclusion in the biobank?
* Specify data (medical records review) other forms of data especially if child is already participating in other related studies: collection of images, validated questionnaires that are specific to the disease or to related diseases
* Data Collection Tools need to be submitted to the HREC for review and approval.

<Insert Text>

# Data Handling and Record Keeping

The following subsections should include a description of the data handling and record keeping for the conduct of the Biobank/Databank.

###  Data Collection and Management Responsibilities

This section should include a description of the data that will be collected along with the samples.

* If the biobank is not disease-specific, but more general (example: collecting specimens for neuromuscular diseases of which there are many), is there a minimum core data element set for inclusion in the biobank?
* Specify data (medical records review) other forms of data especially if child is already participating in other related studies: collection of images, validated questionnaires that are specific to the disease or to related diseases
* Data Collection Tools need to be submitted to the HREC for review and approval.

Provide details regarding the type(s) of data captured.

Specify whether it will be paper or electronic, distributed or central, batched or ongoing processing, and any related requirements.

Briefly describe steps to be taken to ensure that the data collected are accurate, consistent, complete, and reliable.

Describe responsibilities for data handling and record keeping.

Information should include the role in data collection, review of data, materials, and reports, as well as retention of source documents, files, and records. Describe coding dictionaries to be used and reconciliation processes, if applicable. If data are to be generated in one location and transferred to another group, describe the responsibilities of each party.

Describe the process for maintaining and complying with any restriction on the use of samples /data (as per the consent **or** HREC approval)

<Insert Text>

### Biobank/Databank Records Retention

Specify the length of time all records pertaining to this Biobank/Databank will be maintained.

The PI should use the most conservative rule for document retention- i.e., retention should follow the rule that has the longest period

<Insert Text>

### Quality Control

Describe quality control processes and responsibilities including training of personnel, data dictionaries, database entry controls and reviews, Data management or other committee oversight, reporting and auditing.

<Insert Text>

# Security & Confidentiality

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

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

This section should include the following:

* List of the types of data that will be stored i.e. consent conditions, source of samples, medical results, videos, photographs and images etc.
* List of location/s where records will be held. If there are multiple locations, list the exact data to be held at each location.
* Procedures for maintaining participant confidentiality (e.g. specimens will be coded, bar-coded, de-linked).
* Procedures for data security e.g. password protected, backing up of all data and where the back-up data will be kept?
* How often will back up occur and how often will recoverability testing of back up data occur?
* Security - information must be secure against unauthorized access; systems that can access the biobank data should also be secure. There should be rigorous standards around passwords (e.g. number and type of characters, passwords should be changed at regular intervals). Who will issue passwords and ensure removal of access once a project is finished or a researcher moves on, etc. Criteria for databank permissions should be set according to the principle of least access.
* Will access to the biobank be logged/monitored and by whom?
* Will access be able to be audited?
* Who (position or person) will be responsible for the maintenance and integrity of the biobank? NB: If a specific person is nominated the protocol must include a contingency should that person no longer be available.
* Who has access to the database, to identifiable information, the key or to coded information?
* How the data will be linked to the participants.
* How is privacy in the database secured?
* Confirm that the database will include information on the type of consent provided to cross check use is permitted (Specific, Extended or Unspecified)
* Confirm there is a process for participants to change or withdraw consent? How will this be documented?
* Length of time records will be stored and maintained. Specify if the data will be stored indefinitely or until the related biospecimans are used up.
* NHMRC guidelines require that all records for non drug trials should be kept for a minimum of 5 years post Biobank/Databank closure, if your Biobank/Databank contains a CTN drug/device, then records must be kept for a minimum of 15 years.

However, storage of data in Biobanks is usually ongoing (indefinitely), The protocol and participant information should make this clear.

* Explain what will happen to data upon completion of the Biobank/Databank or if the biobank is no longer sustainable.
	+ 1. will be retained specify for how long and by whom.
		2. will be destroyed, specify how and when.

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

<Insert Text>

# Access and Release

This section should include the following information pertaining to the biobank’s access and release processes (if the bank plans to share specimens):

* Does the biobank share specimens and data?
	+ If yes, how do other researchers access samples from the biobank?
	+ If no, add explanation regarding why the samples are not shared?
* What samples/data will be available?
* What kind of research does the biobank support?
* What kind of researchers can access the biobank? For example, academic internal to institution, academic external to institution, and / or industry.
	+ Are there any differences between access processes for different types of researchers?
* What is the access process?
	+ Is there an access form?
	+ Where does the researcher access the form?
	+ Briefly, what are the requirements of the application process? This should include Research Leader name and CV, HREC approval, scientific review, HREC approved ethically defensible plan.
* Who at the biobank will review the application?
* Are released tissues / data de-identified / anonymized to the receiving researcher?
* Are there relevant details of shipment of tissue / data to researchers to include in this section? Options could include test shipment, batch shipments, how transfer of data will occur etc.
* What factors affect timelines between request and receipt of material and data from biobank?

<Insert Text>

# Communication with Donor Participants

Describe the process for communication with participants (if applicable):

* Will there be a website
* Will there be on-going direct contact (with consent) –emails, newsletters

<Insert Text>

# Ethically Defensible Plan (EDP)

An Ethically Defensible Plan (EDP) is required when research conducted with human biospecimens may identify information that may be clinically relevant. An EDP describes the management of disclosure to participants of any incidental findings that have been discovered during this research.

EDPs should be prepared in accordance with Chapter 3 of the National Statement on Ethical Conduct in Human Research, 2023.

Refer to RMH Ethically Defensible Plan Guideline for instructions on preparing an EDP for the biobank.

Note, requests to access biobank samples/data must include an HREC approved EDP.

The EDP should include a process to ensure that only findings that meet each of the following criteria will be returned:

* Significant: The finding indicates a life threatening health condition.
* Clinically actionable: There are specific established therapeutic interventions or other available actions.
* Confirmed: The finding has been checked and confirmed as accurate and/or valid, as far as reasonably possible in a research context.

The committee overseeing data/sample access should check that the HREC approval for each external study has an EDP consistent with the biobank EDP.

<Insert Text>

# Complaints Procedure

Describe the procedure for managing complaints from various stakeholders.

<Insert Text>

# Protocol Deviations

Plans for detecting, reviewing, and reporting deviations from the protocol should be described. A statement should be included to indicate that deviations are not allowed unless a statement is included in the investigator agreement. Provisions for approval of deviations can be described.

If a protocol deviation or an unanticipated problem occurs, it is the responsibility of the PI to submit the necessary application to update HREC*.*

<Insert Text>

# Sustainability and Destruction of Biosamples/Data

Biobanks are resource intense and planning for their longevity should begin at the outset.

### Sustainability and Legacy Planning

This section will answer the following questions:

* What is the current and future source of funds for the biobank?
* What strategies will be implemented to ensure secure long-term funding for the intended life of the biobank?
* Does the biobank have a business plan and or a sustainability plan? If not, will one be created?

<Insert Text>

### Destruction of Biosamples/Data

This section will answer the following questions:

* Under what circumstances e.g. participant request, condition of consent (timeframe) or discontinuation of Bank?
* How will this be managed and by whom?
* What documentation will be maintained for auditing and quality purposes
* Consider possible extent of deletion of information – i.e. what will happen to information backed up on servers; that has been shared with external researchers? Determine what is feasible and ensure that information provided to participants reflects what can/will be done.
* Are there any cultural or religious requirements regarding the destruction of samples e.g. tissue samples?

<Insert Text>

Legacy planning

What is the (legacy) plan to deal with an expected or unexpected biobank closure or significant change at the operational level?

Legacy planning involves preparing for the phase that follows either biobank closure or a signiﬁcant change at an operational level. In the case of a mono-user type research biobank collection, this may be brought about by the completion of the initial scientiﬁc goals of a project, a loss of funding, or loss of or change in leadership. In the case of a poly-user type research biobank, this may be brought about by an overall change in research infrastructure needs, a loss of funding, or loss of or change in leadership.

Ultimately, legacy planning may require making a decision about when and where to transfer materials or whether to destroy them. Because biobanking in its entirety is a complex endeavour, legacy planning touches on biobank operations as well as ethical, legal, ﬁnancial, and governance parameters.

<Insert Text>

# Intellectual Property

This section should include the following:

* Include IP information relevant to your institution.
* Reference to institutional policies and/or agreements (e.g. material transfer agreements, data transfer agreements) where the IP details are outlined to the researchers using the biospecimens.
* An explanation of the biobank’s approach to discussing potential IP with researchers receiving material from the biobank.
* Specific details of the biobank’s Material transfer agreements or data sharing agreements that researchers need to be aware of.

<Insert Text>

# Publication and Data Sharing Policy

The publication and authorship policies should be established and clearly outlined in this section. For example, for a study with multiple investigators, this section might state that an Executive Committee will be responsible for developing publication procedures and resolving authorship issues. Refer to your specific contract grant and / or Study Agreements.

This should include a statement which explains how authorship will be negotiated and/or the biobank acknowledged in publications by researchers who have accessed biobank samples/data.

<Insert Text>

# User fees

This section will answer the following questions:

Are user fees charged to researchers to cost recover preparation of requested samples?

* If yes, how are these user fees determined?
* If no, why?

Are there discounts for academic vs industry researchers?

{Begin sample text}

The biobank determines fees using <xxxx method> to calculate costs and determine user fees to charge to researchers for services involved in accessing the biobank.

Academic internal user (x% of total costs)

Academic external user (x% of total costs)

*Industry user (100% of total costs)*

*{End sample text}*

<Insert Text>

# References

<Insert Text>

# Appendix 1

**Appendix 1.** STANDARD OPERATING PROCEDURES (SOPs)

This section should provide information on standard operating procedures including:

{Begin sample text}

1. Development of a manual of procedures providing SOPs on:
	1. Biospecimen/data acquisition procedures
	2. Consent process
	3. Procedures for testing the biospecimen for suitability for use and storage
	4. Procedures to ensure biospecimen/ data integrity
	5. Procedures to identify and label samples
	6. Procedures for proper tissue and/or data storage environments
	7. Procedures for transporting biospecimens
	8. Procedures for secure transfer data
	9. Procedures for maintaining participant confidentiality
	10. Procedures for access to specimens and data: screening eligibility of potential researchers and projects prior to access
	11. Quality control processes to ensure integrity and viability of samples stored in the Biobank
	12. Policies for destruction data and samples

*{End sample text}*

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)