**<Institution>**

**<BIOBANK – Name of Biobank>**

**A Collection of Biospecimens and Data for Research**

**Protocol**

**Version < date>**

**Principal Investigator <name>**

Template (v.1) created by



Table of Contents

[PREFACE 2](#_Toc8730258)

[Preface- Background 2](#_Toc8730259)

[Preface- How to Use This Template 2](#_Toc8730260)

[Preface - Resources 3](#_Toc8730261)

[1. Introduction 5](#_Toc8730262)

[2. Standards and Quality Assurance 7](#_Toc8730263)

[3. Governance and Management Plan 8](#_Toc8730264)

[4. Operations Overview 10](#_Toc8730265)

[Participant Enrollment 10](#_Toc8730266)

[Biospecimen & Data Accrual 11](#_Toc8730267)

[Biospecimen Processing 12](#_Toc8730268)

[Biospecimen and Clinical data 12](#_Toc8730269)

[Biospecimen and Data Storage 13](#_Toc8730270)

[Privacy, Confidentiality and Security 13](#_Toc8730271)

[5. Access and Release 15](#_Toc8730272)

[User Fees 16](#_Toc8730273)

[Intellectual Property 16](#_Toc8730274)

[Final biospecimen and data disposition 17](#_Toc8730275)

[6. Other operational issues 18](#_Toc8730276)

[Procedure for access to biobank materials for clinical purposes 18](#_Toc8730277)

[Procedure for return of unexpected research results 18](#_Toc8730278)

[7. Sustainability plan 19](#_Toc8730279)

[Legacy planning 19](#_Toc8730280)

[8. Appendix 20](#_Toc8730281)

[9. References 21](#_Toc8730282)

# PREFACE

Remove this PREFACE (including background, how to use, and resources sections) and all highlighted text before finalizing and distributing the biobank protocol.

## Preface - Background

This biobank protocol template is a suggested format for submitting to a Canadian REB but it can be used in any jurisdiction.

The goal of this template is to assist researchers/biobankers to write a comprehensive biobank protocol that meets the standards outlined in the International Society of Biological and Environmental Repositories Best Practices Version 4 (ISBER BP) and the Canadian Tissue Repository Network (CTRNet) Required Operational Practices (ROPs). Its use will also help researchers/biobankers think through the scientific assumptions, logistics and organizational structure of their new or updated biobank. The common protocol structure and organization will facilitate protocol review by oversight entities such as Research Ethics Boards and other institutional/oversight bodies approving human health research.

It is important to note that the biobank protocol template is just one piece of documentation required for a research ethics board or oversight review of a biobank. Other documents that may be required include an informed consent, privacy impact assessment, data management plan, or sustainability plan. For complete details on the requirements at your institution or for your project, please refer to the appropriate website.

## Preface - How to Use This Template

It is important to incorporate all sections of the template into your protocol and to do so in the same order. If a particular section is not applicable to your biobank include it, but indicate that it is not applicable.

This template contains two types of text: instruction/explanatory text and example text. Both appear in this template highlighted.

Instruction/explanatory text is highlighted in yellowand should be deleted when the protocol is finalized. This text provides information on the content that should be included.

Example text is highlighted in green and is intended to aid in protocol writing and should either be modified to suit the biobank design and activities of the planned biobank or replaced with new relevant text or deleted if the section is not applicable. Within example text, a need for insertion of specific information is notated by <angle brackets>.

The section headers include formatting to generate a table of contents.

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 study/biobanking activity. With each revision, the version number and date located in the footer of each page should be updated. When making changes to an approved and “final” protocol, the protocol amendment history should be maintained.

## Preface - Resources

Best practices, standards and SOPs, staff training, and quality assurance programs

1. International Society of Biological and Environmental Repository Best Practices Version 4 2018
2. CTRNet Required Operational Practices
3. Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans 2014
4. CTRNet SOPs and Policies (<https://www.ctrnet.ca/>)
5. Research staff training (https://www.edx.org/course/biospecimen-research-methods-1)
6. Quality assurance programs including the CTRNet certification program (<https://biobanking.org/webs/quality_programs>)

References that discuss background topics such as collection targets, plans for sustainability, and approaches to user fees

1. [A Model to Estimate Frozen Tissue Collection Targets in Biobanks to Support Cancer Research.](http://online.liebertpub.com/doi/pdfplus/10.1089/bio.2014.0081)

Meredith Anna J., Slotty Alex, Matzke Lise, Babinszky Sindy, Watson Peter H. Biopreservation and Biobanking 2015 13:5, 356-362. PMID:26418967

1. [A Practical Tool for Modeling Biospecimen User Fees.](https://www.ncbi.nlm.nih.gov/pubmed/25162459)
Matzke L, Dee S, et al., Biopreservation and Biobanking. Biopreserv Biobank. 2014 Aug;12(4):234-9. PMID: 25162459
2. Biospecimen User Fee Calculator, Biobank Resource Center – <https://biobanking.org/webs/biobankcosting> (available for members)
3. [A Framework for Biobanking Sustainability.](https://www.ncbi.nlm.nih.gov/pubmed/24620771)
Watson PH, Nussbeck SY, et al. Biopreservation and Biobanking. Biopreserv Biobank. 2014; 12(1):60-68. PMID:24620771.
4. [Fundamental Considerations for Biobank Legacy Planning.](http://online.liebertpub.com/doi/pdfplus/10.1089/bio.2015.0073)
Matzke Lise Anne Marie, Fombonne Benjamin, Watson Peter Hamilton, Moore Helen Marie. Biopreservation and Biobanking 2016 14:2, 99-106.PMID:26890981

# Introduction

Biobanking is the activity whereby biospecimens and annotating data are collected to support health research. Biobanking provides critical fuel for research.

This section should answer the following questions:

What is the history and scientific rationale for biobank?

Where is the biobank located?

How would the user’s types be described?

Has the biobank completed any biobank certification/accreditation program?

Who is the custodian of the biobank?

Who is the sponsor of the biobank?

**Mission statement:**

What is the mission of the biobank?

**Vision:**

What is the biobank’s vision statement?

**Objectives:**

What are the objectives of the biobank?

**Utilization and Impact:**

This section is applicable to existing as opposed to new biobanks. The section should answer the following questions:

What is the (expected /actual) utilization and impact of the bank?

* How many new and ongoing projects were supported?
* How many publications arose from the supported projects?

Attach the most recent annual report to <name of REB> with details on enrollment and utilization in terms of studies supported in most recent reporting period.

**Future goals**

What are the future goals of the biobank?

The biobank aims to:

*

# Standards and Quality Assurance

This section will answer the following questions about the quality assurance processes and certification/accreditation standards that the biobank has in place.

What is the enrollment strategy?

Where are the enrollment sites?

What is the target and/or actual enrollment? Total and per year?

What is the number of participant cases and samples in the biobank?

Does the biobank include any legacy collections?

Is the biobank engaged with any biobank certification/accreditation program?

(See Preface resources # 7)

Options for certification/accreditation of biobanks

CTRNet certification – <https://biobanking.org/webs/certification>

CAP Biobank accreditation program <https://www.cap.org/laboratory-improvement/accreditation/biorepository-accreditation-program>

ISO 20387:2018 - <https://www.iso.org/standard/67888.html>

Ongoing quality management is an essential part of biobank operations and the creation of high quality biospecimen resources. Adhering to the standards of a national biobanking network is a way to reduce variability between individual biobank processes, resulting in cross biobank compatibility and more consistent support for health researchers. The biobank has <xxxx biobank certification/accreditation>.

# Governance and Management Plan

This section will answer the following questions:

How is the biobank governed?

How are decisions made?

How would you describe the management of the biobank?

The biobank complies with both external and internal governance requirements.

**External Governance**

<name of biobank> complies with external requirements from:

Canadian legislation and regulations governing human tissue, data protection, and research with human subjects. This is monitored and compliance confirmed through regular review of policies.

Canadian professional codes of conduct where these overlap with stakeholders’ activities (e.g., Medical licensing bodies and societies).

Research Ethics Board (REB): Research biobanks are considered research platform ‘projects’ and as such the biobank operates under <name of REB> approval and undergoes annual ethics review by the REB. 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: 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. The biobank is currently certified with the <x> biobank certification program.

CTRNet certification – <https://biobanking.org/webs/certification>

CAP Biobank accreditation program <https://www.cap.org/laboratory-improvement/accreditation/biorepository-accreditation-program>

ISO 20387:2018 - <https://www.iso.org/standard/67888.html>

**Internal Governance**

The biobank has established the following governance structures/mechanisms which have been approved by the governing Research Ethics Board (REB):

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

The biobank has a <x>-tiered governance structure which provides a formalized governance and oversight to the unit - a Management Committee and an Access Committee.

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

* Principal Investigator (PI)
* Leader
* Staff

# Operations Overview

## Participant Enrollment

**Enrollment strategy**

What is the enrollment strategy of the biobank?

**Consent protocols**

What consenting process(es) does the biobank use?

Consent information could include

* Type of collection - retrospective or prospective collection
* How participants are referred to the biobank – from primary health care provider, self-referral other)
* Justification for timing of consent where applicable
* Pre-op or post op consent approaches/protocols

**Withdrawal in the future after providing consent**

This section will answer the following questions:

Can participants withdraw after providing consent?

If yes, what is the process?

## Biospecimen & Data Accrual

This section will answer the following questions:

* What kind of biospecimens will be collected?
* Where are the samples collected?
* What is the process by which the biospecimens are collected?
* What is the eligibility (inclusion and exclusion) criteria for the biobank participants?
* How are samples are moved from collection site to biobank?
* How tissues are stored in the biobank?
* Where are storage facilities located?
* How are the participant’s privacy maintained?

## Biospecimen Processing

How are the biospecimen processed?

## Biospecimen and Clinical data

 What tissue, clinical and personal information will be collected?

## Biospecimen and Data Storage

This section will answer the following questions:

How are tissues stored?

What kind of storage units are specimens stored in?

How does the biobank keep track of sample location within the storage unit and the location of the storage unit?

What biobank software/ data base is used?

How is privacy in the database secured?

How long is tissue and information stored?

Does the biobank share specimens and data? If yes, how do other researchers access samples from the biobank?

If no, add explanation re why the samples are not shared?

## Privacy, Confidentiality and Security

How are the privacy, confidentiality and security of biospecimens and data are maintained?

# Access and Release

This section will answer the following questions about the biobank’s access and release processes (if the bank plans to share specimens):

* What kind of research does the biobank support?
* What kind of researchers can access the biobank? – 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? Options could include Research Leader CV, REB approval, scientific review
* 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?

## User Fees

This section will answer the following questions:

Are user fees charged to researchers?

If yes, how are these user fees determined?

If no, why?

Are there discounts for academic vs industry researchers?

(See Preface Resources # 8 and 9)

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)

## Intellectual Property

This section will answer the following questions:

What is the biobank’s approach to discussing potential IP with researchers receiving material from the biobank?

When does the <insert contracts office name> need to get involved? Industry studies, other?

Are there any specific details of the biobank’s Material transfer agreements or data sharing agreements that researchers need to be aware of?

There is no significant Intellectual Property (IP) in the samples and associated data collected by the biobank. The IP is generated by the data and analysis of this data generated by the researcher working on the biospecimens

## Final biospecimen and data disposition

This section will answer the following questions:

Where are the samples stored?

Where is the data stored?

How long are the samples stored?

Where are study/biobank related documents stored?

Biospecimens are stored at <x address>

Study documents and electronically stored data is stored at <x>

Data are stored in <x> server behind <x> firewall and backed-up in the <x> server network

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# Other operational issues

## Procedure for access to biobank materials for clinical purposes

How will the biobank deal with a participant’s request to access samples for clinical purposes?

## Procedure for return of unexpected research results

1. What is the biobank’s procedure for return of actionable unexpected research results?

# Sustainability plan

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?

(See Preface Resources # 10)

## Legacy planning

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

(See Preface Resources # 11)

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.

# Appendix

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| --- | --- |
| Biobank Documents to submit to the REB | Biobank ProtocolBiobank Consent(s)/Assents (if applicable) All communication documents, pamphlets, correspondence templates to biobank participantsList of SOPs highlighting those related to enrollment/consent of participants – (actual SOPs should be filed so that they are all readily available upon request) |
| Requirements for CTRNet Biobank Certification  | Document review includes REB documentation of Review/Approval of BiobankGovernance Structure/Org chartSOPs (2)– Biospecimen Collection and Processing, Biospecimen StorageAll biobank staff must complete ‘overview of research biobanking’ module and at least one member of the staff will complete each of the 8 specialty education modules. Declaration of Compliance – all must sign a statement saying they will strive to follow best practices  |

# References

Add all references used in a standardized reference format.