**Institutional Logo**

**<BIOBANK – Name of Biobank>**

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

**Protocol**

**Version < date >**

**Principal Investigator <name>**

Template (v. September 27, 2024)



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**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 Research Ethics Board (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 (ISBER BP),
* Canadian Tissue Repository Network (CTRNet) Required Operational Practices (ROPs), and
* [Tri-Council Policy Statement - Panel on Research Ethics TCPS 2](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html)

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 REBs and other institutional/oversight bodies approving human health research.

It is important to note that the biobank protocol is just one piece of documentation required for REBs for 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 resources.

The researcher/biobanker should use inclusive language. Consider using gender neutral pronouns and language in all biobank documentation including participant facing materials such as the biobank informed consents.

The researcher/biobanker needs to be aware of specific considerations and consultations required when interacting with distinct communities and Indigenous Peoples. Refer to TCPS2 Chapter 9: Research Involving First Nations, Inuit, and Metis Peoples of Canada for guidance.

## 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, 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 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 (<https://www.isber.org/page/BPR>)
2. CTRNet Required Operational Practices (<https://www.ctrnet.ca/en/resources/national-standards/>)
3. Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans (<https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html>)
4. CTRNet SOPs and Policies (<https://www.ctrnet.ca/>)
5. Research staff training (<https://www.edx.org/course/biospecimen-research-methods-6>)
6. Quality assurance programs including the CTRNet certification program (<https://biobanking.org/webs/quality_programs>)
7. College of American Pathologists Biobank accreditation program (<https://www.cap.org/laboratory-improvement/accreditation/biorepository-accreditation-program>)
8. The International Organization for Standardization (ISO) 20387:2018 (<https://www.iso.org/standard/67888.html>)

Published guides

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
2. [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
3. Biospecimen User Fee Calculator, Biobank Resource Center (<https://biobanking.org/webs/biobankcosting> - available for members)
4. [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.
5. [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 will answer the following questions:

* What is the history and scientific rationale for the biobank?
* Where is the biobank located?
* How would the biobank user types be described?
* 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 most applicable to existing as opposed to new biobanks. The section will answer the following questions:

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

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

Attach the most recent annual report to the REB with details on enrollment and utilization in terms of studies supported during the 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.

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

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 biospecimens, data protection, and research with human participants. 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 infrastructure 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 of 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.

**Internal Governance**

The biobank has established the following governance structures/mechanisms:

<Insert organizational 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, 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 eligibility (inclusion and exclusion) criteria for the biobank participants?
* 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 biospecimens in the biobank?
* Does the biobank include any legacy collections\*? (\*definition of legacy collection - biospecimens collected for another biobank)

**Consent protocols**

* What consenting process(es) does the biobank use?
* 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-procedure or post-procedure consent approaches/protocols
* Details related to electronic consent (e-consent)
* For pediatric biobanks, details related to consent from legal representative, assent, re-consent at age of majority
	+ UBC CREB Addition:
		- a) Whether and how the capacity to consent will be assessed and documented.
		- b) The qualifications and role of the individual(s) responsible for making this assessment.
		- Ensure appropriate documentation (scripts, checklists) are attached to RISe Application Page 9

**Withdrawal in the future after providing consent**

This section will answer the following questions:

* What is the mechanism for a participant to withdraw after providing consent?
* What is the process, both for biospecimens already provided to a researcher and for biospecimens/data that are stored in the biobank?

## Biospecimen & Data

This section will answer the following questions:

Biospecimens

* What kind of biospecimens will be collected?
* What is the type and amount of biospecimen to be taken?
* Where are the biospecimens to be collected?
* What is the process by which the biospecimens are collected?
* How are biospecimens moved from collection site to the biobank?
* How are the biospecimens processed by the biobank?
* How are biospecimens stored in the biobank?
* What kind of storage units are the biospecimens stored in?
* What biobank software is used to track biospecimen location within storage units and the location of the storage units?

Data

* What kind of data will be collected? (Biospecimen, clinical, and personal data)
* What are the sources of data?
* Who collects the data?
* How is the data associated with the biospecimen, and how are the data coded and stored?

UBC CREB addition:

If samples/data will be from multiple sources, please add in Protocols Table with heading as follows (include where applicable):

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Site location name, Country | Sample to be collected | Volume of sample | Source of biospecimen (list Health authority and Dept) | Data to be collected | Source of data |

## Privacy, Confidentiality and Security

This section should answer the following questions:

* How are the privacy, confidentiality, and security of biospecimens maintained? (i.e., coding of participant initials)
* How is the data and the database secured? (i.e., what physical and information technology (IT) security features and role-based permissions are utilized?)
* What identifiers (labels or codes) are used on biospecimens and data?

# Access and Release

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

* 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 describe the requirements of the application process. Options could include Researcher’s CV, REB approval, scientific review etc.
* Are released biospecimens/data de-identified/anonymized for the receiving researcher?
* Are there relevant details of shipment of biospecimens/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 biospecimens 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?
* Are fees subject to change?

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.

Examples of different categories of users fees commonly applied are shown below:

* Academic internal user (x% of total costs\*)
* Academic external users (researchers outside of the biobanks institution) (x% of total costs\*)
* Industry user (100% of total costs\*)

\* all costs of enrolling participants, collection, storage, and release of biospecimens and data.

## Intellectual Property (IP)

This section will answer the following questions:

* What is the biobank’s approach to discussing IP with researchers, outside the biobank’s institution, receiving material from the biobank?
* When and for what kind of studies and users does the biobank involve the <insert contracts office name>?

The biobank will establish a contractual agreement known as a Material/Data Transfer Agreement (MTA/DTA) with the researcher prior to release of any biospecimens or data. The biobank will take direction from the institutional contracts’ office on this topic.

Note that the process of biobanking is a complex activity that can yield a range of quality biospecimens and data. There is no Intellectual Property (IP) in the biospecimens and associated data held by the biobank. The IP is generated by the analysis and data generated by the researcher.

## Final Biospecimen and Data Disposition

This section will answer the following questions:

* Where are the biospecimens stored?
* Where are the data stored?
* How long are the biospecimens and data stored?
* Where are biobank related documents stored?

Biospecimens are stored in facilities overseen by the institution under the supervision of the <PI, department x and name of institution>.

Biobank 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.

# Other Operational Issues

## Procedure for access to biobank materials for clinical purposes

How will the biobank deal with a participant’s request to access their own biospecimens/data for clinical purposes?

## Procedure for return of unexpected research results/Material Incidental Findings (MIFs)

What is the biobank’s procedure for return of actionable unexpected research results/Material Incidental Findings

## Process for providing information to participants about types of research supported by the biobank

The biobank may choose to provide participants with access to information within a reasonable timeframe via a website or newsletter.

# 7. 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?
* Are there foreseeable risks that may alter the sustainability of this biobank? What are the mitigation strategies that are in place?
* Is there an annual/periodic review of the sustainability plan?

## 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.

# Appendix

|  |  |
| --- | --- |
| Biobank Documents to submit to the REB | Biobank ProtocolBiobank Consent(s)/Assents (if applicable) All participant-facing documents List of SOPs highlighting those related to enrollment/consent of participants – (SOPs should be available upon request). Please follow your institutional policy.**UBC CREB addition:** * Certain SOPs are requested, please see UBC CREB Biobank Webpage
* Data collection forms/ data extraction form.
 |
| Requirements for CTRNet Biobank Certification  | Document review includes: REB documentation of Review/Approval of BiobankGovernance Structure/Organizational chartSOPs (2)– Biospecimen Collection and Processing, Biospecimen StorageAll biobank staff must complete the ‘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.