**NOTE:**

This is a template.

Please adjust to suit research project.

**Template Version: August 25, 2020**

**Protocol Template: Biobank / Registry**

**PREFACE**

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

The goal of this template is to assist investigators / 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 investigators / biobankers think through the scientific assumptions, logistics and organizational structure of their new or updated biobank.

**INSTRUCTIONS ON HOW TO USE THIS TEMPLATE**

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

*Italics:* **Instruction / Explanatory Text** is indicated by *italics.* 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 study, delete the example text.

You will find it helpful to consider all sections, however, depending on your biobank design, not all sections will be applicable to your study and you should delete sections (including the section heading) that do not apply.

If sections are deleted, ensure that any text that refers to another section is updated as needed. 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 study. With each revision, the version date located in the header of each page should be updated.

**RESOURCES**

Remove **Resources** before finalizing and distributing the Biobank Protocol.

* SickKids Clinical Research Services
* SPRINT: Streamlined Pathway for Research Initiation
* Biobank Participant Consent Template (v.Mar 2020)
* Biobank Parent Consent Template (v.Mar 2020)
* CTRNet SOPs and Policies (https://www.ctrnet.ca/)
* References that discuss background topics such as collection targets, plans for sustainability, and approaches to user fees:
	+ Biospecimen User Fee Calculator, Biobank Resource Center – https://biobanking.org/webs/biobankcosting (available for members)
	+ Matzke, L. A. M., Fombonne, B., Watson, P. H., & Moore, H. M. (2016). Fundamental considerations for biobank legacy planning. *Biopreservation and Biobanking*, *14*(2), 99-106.
	+ Matzke, L., Dee, S., Bartlett, J., Damaraju, S., Graham, K., Johnston, R., ... & Watson, P. H. (2014). A practical tool for modeling biospecimen user fees. *Biopreservation and Biobanking*, *12*(4), 234-239.
	+ Meredith, A. J., Slotty, A., Matzke, L., Babinszky, S., & Watson, P. H. (2015). A model to estimate frozen tissue collection targets in biobanks to support cancer research. *Biopreservation and Biobanking*,*13*(5), 356-362.
	+ Watson, P. H., Nussbeck, S. Y., Carter, C., O'donoghue, S., Cheah, S., Matzke, L. A., ... & Johnston, R. N. (2014). A framework for biobank sustainability. *Biopreservation and biobanking*, *12*(1), 60-68.

**<tITLE OF THE PROTOCOL>**

|  |  |
| --- | --- |
| **Principal Investigator:** | *Insert the Name of the Investigator**Insert Department Name**Insert Address**Insert Email Address**Insert Phone Number* |
| **Additional Investigators:***[PI at additional sites, etc. as applicable]* | *Insert the Name of the Investigator**Insert Department Name**Insert Address**Insert Email Address**Insert Phone Number* |
| **Sponsor:** | *Insert Sponsor* |
| **Funding by:** *[If applicable]* | *Insert Funding Source (e.g., CIHR, Heart and Stroke Foundation, MOHLTC, etc.)* |
| **Version Date [Day, Month, Year]** | *All versions must have a date. Version date must be updated with each amendment. Use the international date format (day month year) and write out the month (e.g., 24 May 2020).* |

**Statement of Compliance**

The Principal Investigator (PI) will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the Research Ethics Board (REB) of Record, except where necessary to eliminate an immediate hazard(s) to the study participants. All personnel involved in the conduct of this study have completed the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the REB of Record for review and approval. Approval of both the protocol and the consent form(s) must be obtained before any participant is enrolled. Any amendment to the protocol or consent materials will require review and approval by the REB of Record before the changes are implemented to the study. All changes to the consent form will be REB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

*This page should be signed by the Principal Investigator at each site. If this is a single center study conducted only at SickKids, delete the site address below.*

Principal Investigator:

Name:

Signed: Date: 

<DD Month YYYY>

Site Address

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#  Introduction, Background Information and Scientific Rationale

### 1.1 Background

<Insert Text>

*This section should contain a background discussion for the study and the following information:*

* *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 study.*
* *Literature review: discuss current literature and data relevant to the study.*
* *If applicable, information regarding the broader (e.g. international) registry group or consortium of which this biobank/registry is a part of.*

## Scientific Rationale and Scope

<Insert Text>

*This section should include the following information:*

* *Description of the Biobank and the selection of study population*
	1. *What types of tissue specimens will be collected?*
	2. *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*

## 1.3 Specific Objectives of the Biobank

<Insert Text>

*This section should include a detailed description of the objectives of the study.*

*{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}*

# Governance and Accountability

<Insert Text>

*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.*

*Specific information to be included are as follows:*

* *Organizational structure; Identify persons or committees with responsibility for the following:*
1. *Biobank (e.g. the PI)*
2. *Day-to-day operations (e.g. Operations Committee)*
3. *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:*
	1. *Operations committee: This committee will be responsible for the day-to-day operations of the biobank.*
	2. *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.*

*{Begin sample text}*

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.

**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 <\_\_\_> 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

*{End sample text}*

# Study Enrollment and Withdrawal

## 3.1 Participant Inclusion Criteria

<Insert Text>

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

*Create a numbered list of criteria that an individual must meet to be eligible to participate in the study.*

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

*{Begin sample text}*

In order to be eligible to participate in this study, 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}*

## 3.2 Participant Exclusion Criteria

<Insert Text>

Exclusion criteria are characteristics that make an individual ineligible for study participation. Provide a statement that all individuals meeting any of the exclusion criteria at baseline will be excluded from study 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 study 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 study design and risk*

*{Begin sample text}*

Participants are not eligible to take part in the study 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}*

## 3.3. Strategies for Recruitment and Retention

<Insert Text>

*The following information should be included:*

* *Where the study population will be recruited from / enrolled, i.e., in-patient services, out-patient clinics?*
* *Whether recruitment is single centre or multicentre?*

***NOTE:*** *For multicentre studies, Research Ethics Review and Approval at each centre will be required.*

* *Who will identify potential participants?*
* *Initial Contact:*
	1. *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*
	2. *Circumstances where initial contact will occur, i.e., during clinic visit, prior to a procedure, etc.*
	3. *Methods of contact, i.e., in person, via a recruitment letter, etc.*
	4. *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 study 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 study site staff) and whether the study design will accommodate replacing lost / withdrawn participants.*

## Participant Withdrawal or Termination

### Reasons for Withdrawal or Termination

<Insert Text>

*Provide a list of reasons for the termination or withdrawal of a participant (e.g. safety reasons, failure of participant to adhere to protocol requirements, participant consent withdrawal, disease progression, etc.). It may be appropriate to provide distinct discontinuation criteria for participants and cohorts. If so, both sets of criteria should be listed separately and the distinction between the two must be stated clearly. Also note that participants may withdraw voluntarily from the study at any time.*

*{Begin sample text}*

Participants are free to withdraw from taking part in the study at any time upon request. An investigator may terminate participation in the study if:

* Any clinical adverse event (AE), laboratory abnormality, or other medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant.
* The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

*{End sample text}*

### Handling of Participant Withdrawals or Termination

<Insert Text>

*Describe efforts that will be made to continue follow-up of withdrawn or terminated participants, if applicable. If a participant withdraws consent to participate in the study, describe whether attempts will be made to obtain permission to record at least survival data up to the protocol-described end of participant follow-up period. Also specify the methods that should be used before a participant is considered lost to follow-up (e.g. number of phone calls to participant, phone calls to next-of-kin if possible, certified letters, etc.).*

*This section should include a discussion of replacement of participants who withdraw or discontinue early, if replacement is allowed. This section should not include a discussion of how these participants will be handled in the data analysis procedures.*

# 4 Biospecimen Acquisition, Processing, Storages, and Quality Assurance

## 4.1 Biospecimen Acquisition

<Insert Text>

*The**following information should be included in this section:*

* *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?*
* *How specimens will be identified and labeled?*
* *Procedures to ensure biospecimen/ data integrity*
* *Process for recording and documenting specimens received and released.*

##  Biospecimen Processing

<Insert Text>

*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?*

##  Biospecimen Storage

<Insert Text>

*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 REB-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?*

## 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?*

## Study Data

<Insert Text>

*This section should include a description of off the study 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 REB for review and approval.*

# Access and Release

<Insert Text>

*This section should include the following information pertaining to 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? 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? Options could include Research Leader CV, REB approval, scientific review.*
* *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?*
* *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?*

# Ethics / Protection of Human Participants

## 6.1 Informed Consent Process and Documentation

<Insert Text>

*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 study.*
* *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 study. 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 REB application form.*

*{Begin sample text}*

Informed consent is a process that is initiated prior to the individual’s agreeing to participate in the study and continues throughout the individual’s study participation. Extensive discussion of risks and possible benefits of participation will be provided to the participants and their families. Consent forms will be REB approved and the potential participant will be asked to read and review the document. The PI will explain the research study 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 study 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 the study 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 study. The participants may withdraw consent at any time throughout the course of the study. 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 study.

A copy of the signed informed consent document will be stored in the participant’s research record. 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}*

*The* ***consent forms*** *should also contain the following information:*

* *Procedures should clearly distinguish standard clinical care procedures from research procedures*
* *Collection of Specimens:*
	1. *What specimens will be collected, i.e., residual diseased tissue, surplus tissue, normal tissue, blood samples, saliva samples, CSF*
	2. *How specimens will be collected, i.e., via planned procedures (diagnostic, curative, palliative) which are part of clinical care or research-related procedures*
	3. *Follow-up specimen collection*
* *Collection of information from the individual’s health care records that is relevant to their disease (e.g., pathological report, disease outcome).*

*Please refer to the SickKids Biobank consent template for more information.*

## Research findings

*This section discuss how incidental findings will be disclosed to participants.*

* *Are there any anticipated incidental findings from analysis that will be done as part of the primary objective of the biobank?*
* *How will incidental findings be handled from research done on biobanked samples*

## 6.3 Confidentiality

<Insert Text>

*This section should include the following:*

* *Procedures for maintaining participant confidentiality (e.g. specimens will be coded, bar-coded, de-linked).*
* *Procedures for data security.*
* *Length of time records will be stored and maintained. Specify if the biospecimens and data will be stored indefinitely or until they are used up.*
* *How the data will be linked to the participants during the study.*
* *How is privacy in the database secured?*
* *Explain what will happen to the biospecimens and data upon completion of the study.*
	+ 1. *If the data will be retained specify for how long and by whom.*
		2. *If the data will be destroyed, specify the time.*

# Data Handling and Record Keeping

*The following subsections should include a description of the data handling and record keeping for the conduct of the study.*

##  Data Collection and Management Responsibilities

<Insert Text>

*Provide details regarding the type(s) of data captured that will be used for the study. 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, study 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.*

*Indicate the roles of each party with regards to interpretation of data, plans for analysis, review of tables and listings, and plans for reporting.*

##  Study Records Retention

<Insert Text>

*Specify the length of time for the PI to maintain all records pertaining to this study. The PI should use the most conservative rule for document retention- i.e., retention should follow the rule that has the longest period.*

# Protocol Deviations

<Insert Text>

*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 REB.*

# Intellectual Property

<Insert Text>

*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.*

# Other Operational Issues

<Insert Text>

*This section should include the following information pertaining to procedures to access biobank materials for clinical purposes and return of unexpected research results:*

* *How will the biobank deal with a participant’s request to access samples for clinical purposes?*
* *What is the biobank’s procedure for return of actionable unexpected research results?*

# Sustainability Plan

<Insert Text>

*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?*

# Publication and Data Sharing Policy

<Insert Text>

*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.*

# User Fees

<Insert Text>

*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?*

*{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}*

# References

*This is the bibliography section for any information cited in the protocol. It should be organized as any standard bibliography.*

1. Author, Title of work, periodical and associated information.
2. Author, Title of work, periodical and associated information.

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

This section should provide information on standard operating procedures including:

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