

Alliance Indigenous Biobank Governance

Overarching Principles: The overarching principles of the collection and storage of Indigenous biospecimens is to acknowledge that the participants and their community are the ultimate owners of the samples. For the purposes of the Alliance study, clinical data, biospecimens and the participant's and community's information will not be used beyond what is proposed in the research protocol and consent (see Table 2 for specific details). Biospecimens will be used as stated in the participant consent forms, and in accordance with Local Community Advisory Board (LCAB) and National First Nations Working Group (NFWWG) agreements.

Clinical Research Laboratory and Biobank: The biospecimens collected as part of this study will be securely stored at an IQMH ISO15189 accredited central laboratory in Hamilton, the Clinical Research Laboratory and Biobank (CRLB). CRLB utilizes redundant 24-7 monitoring and maintains emergency capacity in the event of a freezer failure. Backup generators power the freezers in the event of a more widespread power failure. The vast majority of the biospecimens (~4 million) are stored long-term in nitrogen vapor for reasons of specimen stability at much colder temperatures and minimal dependence on external power. Normal operating controls and tolerances are governed by a global standard operating procedure (SOP). Refrigerator and freezer temperature-probes are connected to a security monitoring system. A call tree is defined for the biobank facility and is active 24-7. Activities related to freezer monitoring are governed by a global SOP. Sample storage conditions are monitored to ensure freezers and refrigerators are operating properly and to document the integrity of stored specimen and reagent/quality control materials. Proper preventive maintenance is required to ensure optimal performance of freezers and/or refrigerators and to correct potential problems before damage to specimens and materials can occur. CRLB performs maintenance and calibration procedures according to manufacturer's instructions. Instrument records are available for review on site.

Governance: The Alliance study will adhere to the CRLB Governance Document for Indigenous sample storage (Appendix 1). The Alliance National Aboriginal Working Group (NAWG) will oversee the storage and use of biospecimens and data. In order to ensure that the individual participant's values and interests are fully respected, the National Aboriginal Working Group includes at least one representative from their community.

Biospecimen Analysis and Data Storage: Any data generated from the Alliance samples will be stored on a secure server at the CRLB and Population Health Research Institute (PHRI), and will be stewarded by Dr. Sonia Anand. In the event that Dr. Anand is no longer affiliated with the Hamilton Health Sciences/McMaster University or is unable to perform her duties as steward of the Alliance samples, a designate will be identified and their appointment to this role will require majority agreement by the Alliance NFWWG.

Duration of Biospecimen Storage: The Alliance Consent states that biospecimens will be stored for 25 years (some variation between communities, see Table 1). After that time, each community can decide whether they would like the samples returned, continue to be stored, or destroyed in a ceremony at the Biobank informed by Indigenous elders.

Table 1: Community specific biospecimen storage duration

Community	Cholesterol and Diabetes Biospecimen	Genetic Biospecimen
Gitxsan	Destroy after testing	Approximately 50 years
Maskwacis	25 years	25 years
Oneida	25 years	25 years
Six Nations	25 years	25 years
Wendat	25 years	25 years
Pictou Landing	Destroy after testing	Approximately 50 years
La Ronge	25 years	25 years
Fort McKay	Need clarification	25 years
Thunder Bay	25 years	25 years

Table 2: Specific Points relevant to the Alliance Consent Forms (table to be updated quarterly if necessary):

	Last Updated June 2, 2016	Updates – January 3, 2017
Biospecimen Storage Lab Name	<ul style="list-style-type: none"> Clinical Research Laboratory and Biobank (CRLB) was formerly called the Clinical Research and Clinical Trials Laboratory 	
Biospecimen Storage Duration	<ul style="list-style-type: none"> Some consent forms indicate that samples will be destroyed after measurement of Apos and HbA1c (Gitxsan and Pictou) Most are 25 years - 	
Data Sharing	<ul style="list-style-type: none"> Data may be shared with Canadian Partnership for Tomorrow Project’s (CPTP) secure national health research database for better utilization. However, the sharing of this data will be done through the NAWG and with individual community’s input. 	
Confidentiality	<ul style="list-style-type: none"> Data will be stored in coded format with no identifying information Only identifier available to laboratory staff are barcode numbers on the biospecimen vials 	
Participant Withdrawal	<ul style="list-style-type: none"> Participants can request destruction of biospecimens at any time 	

Participant Withdrawal, continued	<ul style="list-style-type: none"> • If records linking participants name to their study ID number have been destroyed, biospecimens cannot be destroyed • If biospecimens have already been analyzed those results do not need to be destroyed 	
Future tests	<ul style="list-style-type: none"> • Must be approved by NAWG • Results will not be given back to participants 	<ul style="list-style-type: none"> • Lac La Ronge Indian Band asks for written requests to LCAB for future use of biospecimens and either written approval from the LCAB or approval by their community representative at the NAWG. • Removal of Sandy Bay as they are no longer participating in the study
Ownership	<ul style="list-style-type: none"> • Participants are the owners of their blood/DNA biospecimens, and it is considered to be “on loan” to us for the purpose of this research. 	
Governance	<ul style="list-style-type: none"> • Follow OCAP principles and TCPS 2 statement 	

Appendix 1: CRLB Governance Document for Indigenous sample storage

CRLB Governance Document for Indigenous Biospecimen Storage:

Background: The storage and governance of Indigenous biospecimens (including, but not limited to, blood, saliva, DNA, urine, placenta, microbiome) recognizes the ownership, control, access, and possession (OCAP®) principles established in 1998. OCAP® ensures that Indigenous peoples own their information including biospecimens. It also reflects First Nation commitments to use and share information in a way that maximizes the benefit to a community, while minimizing harm. We recognize that Indigenous people own their DNA and have consented in research to provide the gift of DNA to be held in trust by researchers for specific purposes.

Purpose:

1. To ensure biospecimens provided by Indigenous participants are stored and utilized in full adherence to the informed consent of the participants.
2. To ensure communities that biospecimens will only be utilized as per the Governance of the particular study and as indicated in the informed consent.
3. To prevent researchers accessing biospecimens of Indigenous participants without the consent of the community.
4. To return or destroy biospecimens stored in the biobank in a manner acceptable to Indigenous people when requested by an individual study participant, or when the biospecimens have passed the storage date indicated in the consent.

Governance of Biologic samples collected from Indigenous communities:

- Each study which utilizes the Biobank must have a Governance policy in place with respect to the storage, access and processing of biospecimens.
- This Governance document should acknowledge the Tri Council Policy Statement (TCPS) Article 9.19 - regarding the collection of Human Biological Material involving Aboriginal Peoples. Specifically this states that “As part of community engagement, researchers shall address and specify in the research agreement the rights and proprietary interests of individuals and communities, to the extent such exist, in human biological materials and associated data to be collected, stored and used in the course of the research”. This agreement must include: the objectives for collection, use and storage of human biological materials;
- The roles and responsibilities regarding stewardship of the data and the human biological materials; and
- Any future use of these human biological materials and associated data, including material transfer agreements to third parties, and any subsequent requirements for community engagement.
- Furthermore as per **Article 9.20 in the TCPS 2** secondary use of data and human biological material identifiable as originating from an Aboriginal community or peoples is subject to REB review and or agreement by the study-specific Governing authority. Researchers shall engage the study leadership or community from which the data or human biological materials and associated identifiable information originate, prior to initiating secondary use where:

- Each study must outline how annual storage and final disposition costs will be covered,
- Consent forms must outline the duration of time biospecimens will be stored and what should happen to the biospecimens after this time passes.

Decision making regarding biospecimen use:

The decision making body of each study will inform the Biobank how long the biospecimens will be stored, when they should be pulled for analysis, and when they should be destroyed or returned to a constituent community(ies). A Principal Investigator based at Hamilton Health Sciences/McMaster University will be identified as the lead of the Indigenous Biospecimens Subcommittee.

What happens after time outlined in the consent to collect and store biospecimens has passed?

- a. The Biobank will work with the study team to destroy or return biospecimens as outlined in the consent form and Governance document developed for each study.
- b. If the study would like to continue to store the biospecimens they must seek appropriate REB approval and any community or other approvals required in the study Governance document.

Leadership: The biospecimens from Indigenous communities stored in the CRLB will be overseen by an Indigenous Biospecimens Subcommittee. This committee will be Chaired by a local scientist who is actively involved in Indigenous research and includes individuals nominated from each study team.

Communication with local investigators and communities:

All communication related to biospecimens from the CRLB will go through the Indigenous Biospecimens subcommittee, and the lead of the subcommittee will communicate to the Investigative Teams. The Investigative Teams will correspond with their constituent researchers and Indigenous communities.

References:

1. <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/#toc09-1>