CTRNet Standard Operating Procedure **Absorption of Legacy Materials**			
SOP Number:	01.008	Version:	e1.0
Supersedes:	Not applicable	Category:	Administration

Approved By:	CTRNet College of Advisors	14/08/2020
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1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the processes to be followed in the event that leadership personnel from a biobank approach a Canadian Tissue Repository Network (CTRNet) registered biobank to request that it absorb their collection. The various parameters to guide the decision-making processes around the absorption or destruction of biospecimens and associated data (e.g., ethical, legal, financial and governance) should be outlined in a legacy plan (refer to CTRNet SOP 01.007 Legacy Planning).

2.0 SCOPE

This SOP pertains to the CTRNet-registered biobank Director (i.e., the person appointed to the primary leadership role as determined by the biobank's governance structure), who will determine that it should be enacted, and all CTRNet-registered biobank personnel who are responsible for executing the processes laid out here.

3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

3.1 *CTRNet SOP 01.007 Legacy Planning*

3.2 *CTRNet SOP 08.01.003 Inventory Verification*

3.3 *CTRNet SOP 09.002 Completion of an MTA*

3.4 *CTRNet SOP 09.004 Material Request and Release*

4.0 ROLES AND RESPONSIBILITIES

Biobank Personnel	Responsibility/Role
Biobank Director or their delegate	Responsible for ensuring that all biobank personnel are aware of this SOP and that updated plans are in place to deal with a request to absorb legacy materials.
Biobank personnel	Receive direction from the biobank Director and takes follow-up action as outlined in this SOP.

5.0 MATERIALS, EQUIPMENT AND FORMS

None

6.0 DEFINITIONS

See the CTRNet Program Glossary: https://biobanking.org/webs/glossary

7.0 PROCEDURES

7.1 **Planning**: Upon receipt of a request to absorb a collection from the requesting party, the CTRNet-registered biobank will initiate the following planning phase.

7.1.1 Appoint a member of its personnel to coordinate the following activities.

7.1.2 Implement a detailed current state assessment of the collection (see for example Box 2 from Matzke et al., 2016). This will require provision of detailed information by the transferor and/or access to assess all the aspects below and will include:

a. Number of biospecimens
b. Format of biospecimens
c. How and where biospecimens are stored
d. Details on previous use of biospecimens (including but not limited to freeze-thaw events and remaining aliquots)
e. How and where data are stored and any relevant linkage to other data sources
f. Format for coding and level of data privacy (coding system, anonymization or de-identification details)
g. Consent status (informed consent details or basis for a waiver of consent)

7.1.3 Determine valuation of scope and scale of biospecimens and data (see Box 3 from Matzke et al., 2016) including:

a. Common versus rare disease types
b. Large or specialized population cohorts
c. Generalized or specialized SOP used and documentation
d. Collection format
e. Matched biospecimens formats (e.g., serum and matched formalin-fixed paraffin-embedded tissue)
f. Volume/weight of biospecimens
g. Age of biospecimens
h. Nature of therapeutic treatments associated with the cohort
i. Specialized therapy types
j. Amount and extent of available demographic and outcome data
k. Specialized data available (e.g., kinship)
l. Nature of consent (i.e., the specific commitments around research use and future storage, and including the type of consent in terms of broad versus specialized use allowed)

7.2 **Decision-making**: The CTRNet-registered biobank Director, in collaboration with the host institution and all other biobank leadership/governance roles/committees will oversee the following decision-making phase.

7.2.1 Use the current state assessment and the valuation of the scope and scale of biospecimens/data to consider:

a. The ethical, social and financial information along with any legal implications related to transferring a biobank (biospecimens and data)
b. The scientific merits, practical feasibility, and logistics of transferring biospecimens/data
c. The funding and resources needed to implement a transfer
d. Any external stakeholders that need to be included in formulating a decision (e.g., institutional department heads, Research Ethics Boards, funding bodies, financial entities, third party contractors)

7.2.2 Formulate a recommendation and supporting rationale to proceed to transfer/accept biospecimens and data, or to advise transfer to a different custodian, or to destroy biospecimens and data, or a combination of these options.

7.2.3 Determine timelines to operationalize the retrieval, Quality Assessment, and transfer of materials.

7.2.4 Consider what if any communications activities are needed (e.g., messaging to participants, institutions, funders or other research partners). Consider if there is a duty to ensure that participants maintain the ability to withdraw their biospecimens and data from future research use.

7.2.5 Determine documentation requirements including any Material Transfer Agreements (MTAs) and Research Ethics Board approvals (required).

7.2.6 Determine the final location and term (years) of storage of documents.

7.3 **Execution**: Identify all tasks required for the execution phase (see Appendix A) and assign to appropriate biobank personnel to complete.

7.3.1 Confirm timelines for tasks (from 7.2.3).
7.3.2 Implement communication plan to relevant stakeholders (from 7.2.4).
7.3.3 If biospecimens and data are to be destroyed, maintain accurate records of the process and store in final location when completed.
   a. Legacy Material may be discarded, in part or entirely, if found to be unusable or damaged.
   b. Legacy Material may be discarded in part or entirely, if found to be of lower perceived value than other materials competing for storage space and operational resources.
   c. Data related to the unusable, damaged or lower perceived value Legacy Material: Confirm current database is updated or deleted in its entirety; ensure all archive and back-up data are deleted.
   d. The original custodian of the collection (biobank Director or equivalent and the host institution) will be notified if decisions are made to dispose of Legacy Material.
7.3.4 If biospecimens and data are to be transferred, maintain accurate biospecimen and data transfer records and store in final location when completed. Include (if applicable):
   a. Material Transfer Agreements
   b. Other identified agreements
   c. Who the materials were sent to
   d. Where the materials were sent
   e. Where the data were transferred (i.e., existing biobank data system, archived data in network drives, or database servers)
   f. Shipping details
   g. Signatures at time of receipt of collection (from the receiving member of the biobank's personnel)
   h. Ethical approvals at time of transfer

8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

8.1 Tri-Council Policy Statement 2: Ethical conduct for Research Involving Humans. 2018. https://ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf

8.2 International Society for Biological and Environmental Repositories (ISBER) Best Practices 4th edition 2018. https://www.isber.org/page/BPR

8.3 Matzke et al. Fundamental Considerations for Biobank Legacy Planning. Biobanking and Biopreservation. 2016; 14(2): 99–106. PMID: 26890981.

9.0 APPENDICES

9.1 Appendix A – Example list of tasks required for Execution phase

TABLE 2. RETRIEVAL, QUALITY ASSESSMENT, AND TRANSFER OF MATERIALS

	Retrieval		*Quality Assessment*		*Transfer*	
Components	*Process*	*Personnel*	*Process*	*Personnel*	*Process*	*Personnel*
Biospecimens	Locating biospecimens Pulling biospecimens from storage (freezer, shelf, box)	Biobank administrative manager Biobank technician	Random selection of subset biospecimens Apply QA/QC methodology	Biobank technician Data analyst/ manager	Recoding/labeling biospecimens Packaging and shipping of Biospecimens preparing and executing required documentation (e.g., Material Transfer Agreement, general agreements, shipping logs)	Biobank technician Administrative manager
Data	Identifying specimens in LIMS Identifying which data belongs to the bank and the relations between data (a) fully understanding the data sources (b) understand the history, structure, meaning of source data Identifying required systems/software (a) what software is needed to process that data (e.g., format of the database (b) hardware Planning the migration of the data (a) which parts can/should be migrated/where manual input is easier (b) specifications for mapping the data	Data manager	Record QA/QC biospecimen results Identify quality issues in data	Biobank technician Data manager	Migrating the data using defined migration rules (a) Start with a small sample to test Validate/test the data Follow-up and maintenance	Data manager

10.0 REVISION HISTORY

SOP Number	Date revised	Author	Summary of Revisions