| **CTRNet Standard Operating Procedure**<br>**Legacy Planning** | | | |
|---|---|---|---|
| SOP Number: | 01.007 | Version: | e1.0 |
| Supersedes: | Not applicable | Category: | Administration |

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| Approved By: | CTRNet College of Advisors | 14/08/2020 |
| |  <br>Per Peter Watson and Anne-Marie Mes-Masson | 14/08/2020 |

## 1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the processes to be followed in the event that the biobank must consider undergoing a significant alteration to its operations, such as transferring its biospecimens/data to another appropriate entity or destruction of its biospecimens/data. This situation may occur for example due to loss of funding, change in leadership, or completion of the collection. These processes should be documented in a Legacy Plan.

## 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 01.008 Absorption of Legacy Materials*

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 legacy event. |
| 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 **Preparing**: Upon a triggering event (e.g., loss of biobank funding, change in leadership), the CTRNet-registered biobank will initiate the following legacy 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 prospective 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 (Matzke, Box 3, 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, biomarker, research data)
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 **Developing the Legacy Plan**: The CTRNet-registered biobank Director, in collaboration with the host institution and its other biobank leadership/governance roles/committees will oversee the following steps to develop the Legacy Plan.

7.2.1 Using the current state assessment (7.1.2), assemble a list of biobanks/research groups that may be interested in acquiring the materials. Consider:

a. Feasibility and logistics of transferring biospecimens/data.
b. Current ethical, social and financial information along with any legal implications related to transferring the materials.
c. Funding and resource requirements to transfer the materials.

7.2.2 Formulate a rationale and recommended decision to destroy biospecimens and data, or to keep/transfer biospecimens and data (the decision may include a combination of both options).

7.2.3 Consider any stakeholders that need to be included in the planning and/or implementing phases of a legacy plan (e.g., participants, institutional department heads, Research Ethics Boards, funding bodies, third party contractors) and develop an appropriate Communications strategy. In particular, consider if there is a duty to ensure that participants maintain the ability to withdraw their biospecimens and data from future research use and if they need to be notified of the decision.

7.2.4 The biobank Director and the host institution's leadership will make the decision to destroy or keep/transfer biospecimens and data on basis of the information obtained from the above assessment including consultations with appropriate stakeholders. Detail the rationale, formal decision and Communications strategy in a Legacy Plan document.

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 all tasks (from 7.2).
7.3.2 Implement communication plan to relevant stakeholders (from 7.2.3).
7.3.3 If biospecimens and data are to be destroyed, maintain accurate records of the process and store in final location when completed.
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<br>Pulling biospecimens from storage (freezer, shelf, box) | Biobank administrative manager<br>Biobank technician | Random selection of subset biospecimens<br>Apply QA/QC methodology | Biobank technician<br>Data analyst/ manager | Recoding/labeling biospecimens<br>Packaging and shipping of Biospecimens preparing and executing required documentation (e.g., Material Transfer Agreement, general agreements, shipping logs) | Biobank technician<br>Administrative manager |
| Data | Identifying specimens in LIMS<br>Identifying which data belongs to the bank and the relations between data<br>(a) fully understanding the data sources<br>(b) understand the history, structure, meaning of source data<br>Identifying required systems/software<br>(a) what software is needed to process that data (e.g., format of the database<br>(b) hardware<br>Planning the migration of the data<br>(a) which parts can/should be migrated/where manual input is easier<br>(b) specifications for mapping the data | Data manager | Record QA/QC biospecimen results<br>Identify quality issues in data | Biobank technician<br>Data manager | Migrating the data using defined migration rules<br>(a) Start with a small sample to test<br>Validate/test the data<br>Follow-up and maintenance | Data manager |

## 10.0 REVISION HISTORY

| SOP Number | Date revised | Author | Summary of Revisions |
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