| CTRNet Standard Operating Procedure<br>Return of Biospecimens for Clinical Purposes | | | |
|---|---|---|---|
| SOP Number: | 09.005 | Version: | e1.0 |
| Supersedes: | | Category: | Material Request and Release |

| | | |
|---|---|---|
| Approved By: | CTRNet Management Group (CMG) | 26/09/2013 |
| | Per: Brent A. Schacter | 26/09/2013 |

## 1.0 PURPOSE

The purpose of this standard operating procedure is to describe how to respond to participant requests to access biobank samples for clinical purposes, and how requests will be reviewed and responded to. This protocol has been developed to ensure a thorough and universal process for considering participant requests to access biobank samples that will ensure that biobank samples are appropriately accessed and released for clinical purposes in accordance with the best standards that the biobank can deploy. It should be noted that CTRNet member biobanks are not accredited to operate as clinical care providers and cannot guarantee or warrant the quality, accuracy, or suitability of the sample(s) provided for clinical purposes.

## 2.0 SCOPE

These procedures pertain to the biobank Principal Investigators, Research Assistants and any other personnel who may receive participant requests to access biobank samples.

## 3.0 REFERENCE TO OTHER CTRNET SOPS OR POLICIES

*Note: When adopting this SOP for local use please reference CTRNet.*

***3.1*** *CTRNet Policy: POL 5 Records and Documentation*
***3.2*** *CTRNet Policy: POL 7 Material and Information Handling*
***3.3*** *CTRNet SOP: 08.03.011 Sample Retrieval*
***3.4*** *CTRNet SOP: 09.001: Sample Shipping and Transportation*

## 4.0 ROLES AND RESPONSIBILITIES

This SOP applies to biobanks and to biobank personnel involved in all aspects of the tissue biobank program. In particular, it applies to those personnel involved in the process of handling requests and releasing tumor biobank material.

| **Tumour Biobank Personnel** | **Responsibility/Role** |
|---|---|
| Biobank Principal Investigators | Are responsible for ensuring that all participant requests to access biobank samples are handled in accordance with this SOP. |
| All other biobank personnel | Are responsible for forwarding any participant requests to access biobank samples to the biobank Principal Investigators. |

| | |
|---|---|
| Biobank Management Committee | Responsible for general operations of the biobank study. |
| | |

## 5.0 MATERIALS, EQUIPMENT AND FORMS

The materials, equipment and forms listed in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the site-specific task or procedure.

| **Material and Equipment** | **Materials and Equipment (Site Specific)** |
|---|---|
| Form: Participant Request and Release of Materials | |
| Form: Participant Request for Specimen Release – Laboratory Worksheet | |

* See the Biobank Resource Centre (BRC) in the reference section for examples of forms.

## 6.0 DEFINITIONS

See the CTRNet Program Glossary: http://www.ctrnet.ca/glossary

## 7.0 PROCEDURES

Treat blood and all materials coming into contact with blood as biohazardous materials: wear personal protective equipment (PPE) throughout the procedure, including lab coat and disposable gloves.

**7.1** Process of response to participant request of materials access

7.1.1 **Responses involve two parts and requests may be accepted at any time.**

1. Part I comprises completion of the "Participant Request for Release of Materials" form. Biobank personnel must
    i. Provide "Participant Request for Release of Materials" form to participant or participant's legal representative or clinician liaison.
    ii. Instruct participant or participant's Legally Acceptable Representative or clinician liaison on how to complete the form and return.
    iii. Inform biobank PI and provide completed form upon its return for review by biobank access committee.

2. Part II comprises the release of materials:
    i. Biobank PI and or designate arrange for a review to be conducted by an appropriately qualified person or committee (e.g., the biobank's access committee). The purpose of this review is to determine whether the biospecimen(s) under consideration for release are suitable for the clinical intention.
    ii. Complete release and shipment of materials requested using the Participant Request for Specimen Release of Materials Laboratory Worksheet:

a. Amount of aliquot to be release and decision on any remaining sample(s) to be made by biobank PI.
b. The biobank project Research Intern and Biospecimen Technician or designate independently query the biobank database to determine the corresponding biobank ID to match the identified patient:
    - Match first and last names
    - Match Date of Birth
    - Match Provincial Health Number (PHN)
c. The biobank project Research Intern, using the selected biobank ID and the study database, review the original blood processing worksheet:
    - Match biobank consent date
    - Match biobank ID
    - Match ID
    - Match first and last names
    - Match storage location
d. The biobank project Research Intern removes the patient specimen from freezer and places in holding box at -80$^{o}$C and asks Biospecimen Technician or designate to verify that the biobank ID desired does match the actual vial removed.
e. The biobank project Research Intern will prepare a new label with the identifiers below to add to the vial:
    - Patient first and last names
    - Date of Birth
    - ID
f. The biobank ID will be removed and placed on the Participant Request for Specimen Release of Materials Laboratory Worksheet.
g. The biobank Research Intern will package the specimen as required by the diagnostic lab or, if no special packaging instructions given prepare as described in the files below. Signature required by receiver.
    - Create a shipping label
    - Create a packing slip
    - Package shipment and arrange carrier pick up via courier
h. All forms must be filled in biobank file cabinet.

**7.2** Reporting

7.2.1 **Biobank PI to report request and release of materials to the biobank Management Committee at a monthly meeting.**

7.2.2 **Biobank Management Committee to report annually to Research Ethics Board.**

## 8.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

**8.1** Declaration of Helsinki
http://www.wma.net/en/30publications/10policies/b3/index.html

**8.2** Tri-Council Policy Statement 2; Ethical Conduct for Research Involving Humans; Medical Research Council of Canada; Natural Sciences and Engineering Council of Canada; Social Sciences and Humanities Research Council of Canada, December 2010.
http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

**8.3** Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics
http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420

**8.4** National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999.
http://bioethics.georgetown.edu/nbac/hbm.pdf

**8.5** Canadian Biobank Resource Centre. http://biobanking.org

## 9.0 APPENDICES

**9.1** Appendix A – Participant Request and Release of Materials Form

## 10.0 REVISION HISTORY

| SOP Number | Date revised | Author | Summary of Revisions |
|---|---|---|---|
| 09.005 | 26-Sept-2013 | CMC | Initial document approved |
| | | | |
| | | | |

**PARTICIPANT REQUEST FOR RELEASE OF MATERIALS FORM**

**To:** **Biobank Access Committee**
**Attention:** **Chair**

I am writing to request the release of the sample(s) specified below, previously donated to your biobank.

Sample(s) (specific type of sample and quantity requested if known):

_____

_____

Sample(s) should be released to Dr: _____

Organization: _____

Justification for the clinical request *[eg, the sample is required for a specific investigation xyz which can only be conducted from my sample held by biobank and withholding the sample could have a negative impact for myself or family member(s)]:*

_____

_____

_____

_____

_____ _____ _____
Participant's Signature Printed name Date

Date of Birth: _____

Provincial Health Care Number (PHN): _____

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If the above signature is not from the participant please sign below and attach copy of Power of Attorney.

_____ _____ _____
Power of Attorney's Signature Printed name Date

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I support the request and agree to receive or direct the distribution of sample(s) to an appropriate recipient or organization as noted in the shipping contact table below.

_____ _____ _____
Physician's Signature Printed name Date

_____ _____ _____
Biobank PI Signature Printed name Date

Please provide contact and organization information of recipient:

**Laboratory Contact Person** *(e.g., lab manager who will receive the materials):*

_____

**Laboratory Shipping Address** *(including institution, department, building, room number):*

_____

_____

**Telephone:** _____

**Fax:** _____

**Special Instructions:**

_____

_____

_____

**DISCLAIMER**

_____ (Participant Initials) I understand that the requested sample was collected for research purposes and handled according to the best standards that the research program can deploy. However the research program is not accredited to operate as a clinical care provider and cannot guarantee or warrant the quality, accuracy, or suitability of the sample(s) provided. We expressly disclaim all warranties, representations and conditions regarding use of the sample(s).

_____ (Participant Initials) I understand that there will be no charge for any typical processes related to release of the sample(s). Shipping costs related to the sample(s) will be the responsibility of the requestor.