National
Liver
Disease
Biobank

Standard Operating Procedure

DOCUMENT NAME: MATERIAL RELEASE

DOCUMENT NO. : ILBS#NLDB:J

Document Name : Sample Shipping and Transportation

Document No. : SOP: ILBS#NLDB: J.1

Version No. : 1.0

Effective Date : 01/01/2025

Address

National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Material Release

Sample Shipping and Transportation

Number	Effective date	Pages	Author	Authorized by
ILBS#NLDB:J.1	01/01/2025	8	Mr. Satish Kumar	Dr. Chhagan Bihari
Version	**Review period**	**No. of copies**	**Approved by**	**Date**
1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Sample Shipping and Transportation
Function	**Distribution**
To provide information on ensuring protection and maintaining sample integrity during the shipping process.	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

This SOP specifies the requirements to ensure proper packaging and safe shipping of samples.

RESPONSIBILITY:

This SOP applies to all NLDB biobank personnel involved in the shipping or receiving of samples. The Biobank HOD is responsible for reviewing requests, coordinating sample release, and ensuring proper shipment of samples.

1.0 PURPOSE

During the operation of the tissue biobank, samples will require shipping to different locations to meet the needs of users and for quality control purposes. Human Biological Materials (HBMs) are a precious resource. During the shipping process, care should be taken to protect and maintain sample integrity.

2.0 SCOPE

This SOP outlines processes for shipping samples within India and internationally. The SOP specifies considerations that should be followed to ensure appropriate packaging and shipping of the samples.

3.0 ROLES AND RESPONSIBILITIES

The SOP applies to all personnel from NLDB biobank who are involved in the shipping or receiving of samples.

HOD Biobank: Reviews request, coordinates sample release, ships sample

4.0 MATERIALS, EQUIPMENT AND FORMS

- Shipping waybill
- Performa invoice

5.0 PROCEDURES

The NLDB biobank manages the distribution of samples. Collection centres must only ship samples to qualified/approved researchers or to a designated third party laboratory for quality control analysis. The shipping process should only be initiated after obtaining written approval from the NLDB Biobank Manager. An established and tested shipping procedure is essential, as inadequate shipping procedures may lead to the loss of the samples and additional costs for repeat shipments.

The safe and legal transport of patient specimens is based on the following mandated activities:

a. Classification and naming of the material to be shipped,
b. Selection of packaging that will contain and protect the contents if the package is damaged,
c. Packing the shipment correctly,
d. Placing appropriate markings and labels onto the outer package,
e. Documenting relevant aspects of each package and its contents, and
f. Training individuals about the requirements for appropriate packaging and shipping of diagnostic specimens and infectious substances.

5.1 Appropriate Packaging and Shipping Conditions

5.1.1 Packaging must be appropriate for the transportation of perishable goods. Contents of the package may be categorized as being dangerous or biohazardous and so packaging must conform to transportation regulations.

5.1.2 The International Air Transport Association (IATA) has defined a "patient specimen" as material collected directly from human or animals for diagnostic, treatment, prevention, investigational or research purposes. Patient specimens have to be categorized as Category A, Category B or Exempt Specimens.

5.1.3 Biobank personnel who will be responsible for categorizing material to be shipped must be:

1. Trained in the transportation of dangerous goods; and

2. Knowledgeable regarding the material and its likelihood to contain infectious substances (e.g., if shipping Formalin-fixed paraffin-embedded tissue then infectious substances are inactivated). Once the material to be shipped is categorized, all packaging, labelling and documentation must reflect the same requirements – any differences in categorization between the waybill and commercial invoice may result in rejection or delay of the shipment.

5.1.4 A Category A substance is "an infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals".

5.1.5 A Category B substance is "an infectious substance which does not meet the criteria for inclusion in Category A". Typical clinical or patient specimens being shipped for routine culturing or other testing for a non-Category A infectious microorganism or suspected of containing a non-Category A infectious microorganism are examples of Category B substances.

5.1.6 Exempt human or animal specimens are those for which there is "minimal likelihood there are pathogens present".

5.1.7 Ship all frozen products in Cryovial and frozen sections in slide shippers. This can be done on dry ice or in dry-shippers on liquid nitrogen. Dry ice is classified as a dangerous substance and needs to be sent in a double insulated shipper (Styrofoam container in fitted cardboard box). Dry ice must NEVER be placed into a tightly sealed container (explosion hazard); the packaging must allow the release of CO2.

5.1.8 Ship all refrigerated products on frozen gel packs in insulated shippers.

5.1.9 Ship paraffin blocks and slides with paraffin sections at room temperature. In summer weather or if high temperatures are anticipated, consideration should be given to including a cooling pack in the shipment.

5.1.10 To prevent damage during shipping and ensure leak-proof conditions, cryovials must be inserted in cardboard or plastic vial shippers. Glass slides must be inserted in slide shipping cassettes to prevent breakage and damage.

5.1.11 The quantity of samples to be shipped will affect the size of the packaging. Add sufficient refrigerant to maintain desired temperature throughout the shipping cycle. Use sufficient dry ice to ensure that the sample will remain frozen even if delayed in transit for 48-72 hours.

5.1.12 Tape and seal the packaging securely to prevent condensation of refrigerant and provide additional security for the contents.

5.1.13 Affix appropriate labels required to comply with shipping regulations and to ensure timely and proper shipping protocol. (e.g., dry ice declaration sticker, "Keep Frozen" sticker etc).

5.1.14 Before use, validate packaging to make sure it is able to maintain appropriate conditions of temperature, humidity, light sensitivity, structural quality and spill containment if relevant.

5.2 Appropriate Supporting Documentation

5.2.1 Contact the courier to establish what supporting documentation is needed to ship the sample to the specified destination. For international shipments, research any new regulations that may have been adopted or special permits that are needed for that destination.

5.2.2 Complete shippers Waybill and Performa invoice (to provide contact information and to declare nature of contents to customs and regulatory agencies).

5.2.3 Submits an undertaking that they are following and will follow all the applicable rules, regulations & procedures for safe transfer and disposal of the biological samples being imported/ exported as per the related norms/regulations set by WHO*/DGFT

5.2.4 Dry ice is a Class 9 dangerous good, and requires a dry ice checklist

5.3 Appropriate Courier

5.3.1 Identify and build a relationship with a courier that can consistently deliver frozen shipments within 24 hours.

5.3.2 To insure package is traceable use established couriers such as FedEx, Purolator or World Courier.

5.3.3 Assess and choose couriers for following characteristics:

- Reliability
- Experience with and ability to routinely ship biologics and HBMs to national and international destinations.
- Ability to provide online tracking of shipments.
- Knowledge about relevant transportation regulations and permits.
- Existence of established, standardized paperwork accompanying shipments.
- Efficient customer service ensuring that unforeseen delays and deviations are tracked and communicated to relevant personnel.
- Customer service agents capable of troubleshooting and expediting shipments in accordance with temperature and time sensitivity of the samples.
- Willingness to "top-up" dry ice in the package in the event of a delay in transit.

5.4 Shipping Log

5.4.1 Maintain a shipping log to record receipt and dissemination of shipments.

5.4.2 Track the following items:

a. Invoice number
b. Waybill number for tracking package
c. Recipient / source
d. Date received or shipped
e. Courier name and contact information
f. Sample description
g. Quantity shipped
h. Researchers name
i. Study name
j. Confirmation of delivery

5.5 Shipping Procedure

5.5.1 The day before the shipment is to go out, verify that there is an adequate stock of dry ice available.

5.5.2 Before scheduling a pick-up, assemble packaging material, refrigerants, samples to be shipped, accompanying documentation, shipping documentation and permits.

5.5.3 Contact shipper to schedule package pick-up.

5.5.4 Verify that all shipping information, contacts and required documents are accurate and complete.

5.5.5 It is optimal to specify to whose attention the shipment is being delivered. This measure should prevent the shipment from arriving and being held in the receiving department for too long.

5.5.6 Retrieve samples from storage and keep frozen on dry ice until packaged.

5.5.7 Use appropriate safety procedures when handling dry ice or when retrieving samples from liquid nitrogen containers.

5.5.8 Document sample retrieval in biobank database and complete shipping log according to established procedure.

5.5.9 Verify that samples match researcher's request.

5.5.10 Package samples as is appropriate.

5.5.11 Contact (call or e-mail) consignee to provide them with Waybill number and inform them that package has been shipped. Give them an estimated delivery time so that they can anticipate arrival of the sample.

5.5.12 Track delivery (using the online tracking capability of the courier) to monitor shipment and expedite sample if delayed by Customs or regulatory agencies.

5.5.13 Timing of shipping (to prevent delays in-transit):

a. Schedule pick-up early in the day so that the package goes out on the earliest flight available.

b. Schedule pick-up for early in the week (Monday or Tuesday) to prevent delays in shipment or delivery due to the weekend schedules.

c. Do not ship just before a holiday long weekend as it usually translates into delays in transit.

d. Be aware of public holidays in the province or country of destination to plan for optimal shipping dates.

5.6 Test Shipment

In some situations, especially for extremely precious samples or when shipping to a new destination, biobanks may choose to send a test shipment with approximate characteristics of the actual shipment. This process may identify potential obstacles that could arise. It allows for corrective actions to be implemented, thus ensuring more successful shipment.

National
Liver
Disease
Biobank

Standard Operating Procedure

DOCUMENT NAME: MATERIAL RELEASE

DOCUMENT NO. : ILBS#NLDB:J

Document Name : Completion of an MTA (Material Transfer Agreement)

Document No. : SOP: ILBS#NLDB: J.2

Version No. : 1.0

Effective Date : 01/01/2025

Address

National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Material Release

Completion of an MTA (Material Transfer Agreement)

Number	Effective date	Pages	Author	Authorized by
ILBS#NLDB:J.2	01/01/2025	5	Mr. Satish Kumar	Dr. Chhagan Bihari
Version	**Review period**	**No. of copies**	**Approved by**	**Date**
1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Completion of an MTA (Material Transfer Agreement**)**
Function	**Distribution**
To give information about MTA once the transfer of the sample has been approved by a Research Ethics Board (REB)	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

This SOP covers the procedures for completing a Material Transfer Agreement (MTA) after approval by the Research Ethics Board (REB) and the relevant authority for specimen release, using appropriate MTAs as per the recipient.

RESPONSIBILITY:

This SOP applies to all NLDB biobank personnel involved in sample transfer, where the Biobank HOD ensures required approvals and the Pathology Coordinator/Technical Executive completes and documents the MTA.

1.0 PURPOSE

During the operation of NLDB biobank human biological material (HBM) and clinical information may be transferred to researchers at academic or commercial research institutions. The purpose of the Material Transfer Agreement (MTA) is to ensure that before the tissue or data is shared with approved parties outside the biobank, an agreement is signed to outline the terms of the transfer, which include details regarding maintaining donor privacy, intellectual property rights (if relevant), terms for data sharing and other similar ethical and legal requirements. The purpose of this document is to outline procedures that should be followed when completing an MTA.

2.0 SCOPE

This Standard Operating Procedure (SOP) covers the procedures for completing an MTA once the transfer of the sample has been approved by a Research Ethics Board (REB) and the body that adjudicates specimen release. Depending on the individual or organization the material is being transferred to, specific MTAs may be used.

3.0 ROLES AND RESPONSIBILITIES

The SOP applies to all personnel from NLDB biobank who are involved in the shipping or receiving of samples.

Bio Bank Personnel	**Responsibility / Role**
HOD Biobank	Determine that the Biospecimen release committee has approved the study. Determine that REB approval has been obtained for Material Release. -Complete MTA -Document Completion of MTA
Pathology Coordinator/Technical Executive	Complete MTA -Document Completion of MTA

4.0 MATERIALS, EQUIPMENT AND FORMS

The SOP applies to all qualified NLDB biobank personnel that are responsible for completing MTAs before releasing samples from the NLDB biobank. This may include the following personnel:

Materials and Equipment	
Inventory Database	
REB approval for reference	
Appropriate MTA	

5.0 PROCEDURES

Samples are received following an informed consent process. NLDB biobank essentially have "custodianship" of the samples. Release of the sample to a third party requires that we ensure that ethical, legal and privacy issues of the donor will be upheld. Proper completion of a

contractual agreement (the MTA) is an important step in the material release process. The sequence of the steps outlined below may vary slightly at member biobanks to accommodate diversity in the practice of when the MTA is completed (before or after REB approval).

5.1 Completion of the MTA

5.1.1 Once an application for tissue has been received and approval for the release of samples has been given, an MTA should be drafted between the researcher and / or their host institution receiving the samples and the biobank that is releasing them. An REB approval should be on file indicating that the researcher has obtained appropriate REB approval before the material is released.

5.1.2 The researcher and the appropriate representative from the NLDB biobank must sign the MTA. In some situations, institutional signatures from the Office of Research Services (or equivalent institutional office) may be required.

5.1.3 The MTA might contain the following elements. It should be adapted to fit the laboratory's practice:

a. Clarification about custodianship of the samples.
b. Outline of the research objectives.
c. Tissue being supplied 'as is' with no representations or warranties unless otherwise specified by the MTA.
d. Potential for tissue to have unknown characteristics or carry infectious agents.
e. Restrictions on the use of the tissue/clinical data if any.
f. Privacy and Confidentiality principles that must be adhered to.
g. Instructions about return, retention or disposal of unused tissue if applicable.
h. Specific conditions for publication of research results if any.
i. Specific conditions for sharing data if any.
j. Specific conditions for managing intellectual property if any.
k. Specific conditions about compensation for material transfer if relevant.
l. If possible, a list of samples (identification codes) to be released to researcher (if the list is not finalized at the time of signing of the MTA, a complete list should be appended to the form before sample release).
m. Specify if annotating data is being included.

5.1.4 Do not supply tissue to a third party without the approval of the recipient and/or biobank REB (or equivalent) and the signing of an MTA.

5.1.5 Release of tissue to academic or commercial researchers may warrant the use of tailored or specific MTAs.

5.1.6 The signed MTAs are valuable documents for tracking material utilization. MTAs should be documented and signed copies filed.

5.1.7 Retain signed copies of MTAs securely for audit purposes or to handle complaints.

National
Liver
Disease
Biobank

Standard Operating Procedure

DOCUMENT NAME: MATERIAL RELEASE

DOCUMENT NO. : ILBS#NLDB:J

Document Name : **Material Request and Release**

Document No. : **SOP: ILBS#NLDB: J.3**

Version No. : **1.0**

Effective Date : **01/01/2025**

Address

National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Material Release

Material Request and Release

Number	Effective date	Pages	Author	Authorized by
ILBS#NLDB:J.3	01/01/2025	6	Mr. Satish Kumar	Dr. Chhagan Bihari
Version	**Review period**	**No. of copies**	**Approved by**	**Date**
1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Material Request and Release
Function	**Distribution**
To give information about MTAs prior to the release of samples from the biobank.	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

This SOP covers the processes for handling material requests from researchers and establishing appropriate contractual agreements between the biobank and researchers.

RESPONSIBILITY:

This SOP applies to all authorized biobank personnel responsible for the preparation, review, and execution of Material Transfer Agreements (MTAs) prior to the release of biospecimens.

1.0 PURPOSE

A goal of the NLDB is to standardize mechanisms for release/use of tissues and products to research collaborators. Release mechanisms should be designed to promote the goals of the biobank as well as safeguarding the interests of the participants.

2.0 SCOPE

The SOP applies to ethical, legal and practical considerations that arise in the process of releasing tissue samples from the 'custodian' (NLDB biobank) to the researchers requesting samples from the biobank. The SOP covers the processes of handling material requests from researchers and completing appropriate contractual agreements between biobank and researchers.

3.0 ROLES AND RESPONSIBILITIES

The SOP applies to all qualified ILBS Tissue bank personnel that are responsible for completing MTAs before releasing samples from the bank

4.0 MATERIALS, EQUIPMENT AND FORMS

- Material Request Form
- MTA

5.0 PROCEDURES

A consistent standard of scientific and ethical review for tissue requests will ensure that all requests meet consistent ethical standards and a high level of scientific merit. The procedure is also geared to ensure efficient handling of requests and adequate completion of contractual agreements.

5.1 Material Request and Release Process Overview

Material Request Form

Use the Material Request Form to obtain the following information from the requesting researcher:

a. Applicant's name and contact information.
b. Title and description of research project (including objectives and hypothesis).
c. Duration and proposed start date.
d. Methodology of research project.
e. Funding source.
f. Types and quantity of samples required.
g. Ethics review and approval for research project.
h. Curriculum vitae of the applicant.
i. Fee schedule

Material Request from Researchers

a. Access should be granted only after review by a documented review process, scaled as appropriate to the nature of the request.
b. Applications for biobank access should be evaluated by an Access Committee
c. Evaluation should be made on aspects such as the basis of the researchers' qualifications, scientific merit, feasibility including statistical justification, and evidence of adequate funding.
d. Review of applications should be documented, such as through the use of a standardized reviewer form.
e. The biobank should provide feedback on rejected applications if requested by the researcher-applicant.
f. Reviews should be completed in a timely manner.

The biobank should require, at a minimum that the researcher provide the following documentation prior to release of any biospecimens or data:

a. Proof of approval for their project

The biobank would establish a contractual agreement with the researcher prior to release of any biospecimens or data

a. MTA
b. MTA Information should include
    i. Clarification about custodianship of the samples.
    ii. Privacy and Confidentiality principles that must be adhered to.
    iii. Statement that the recipient agrees to absolve the biobank for liability from any claims, costs, damages or expenses resulting from usage of the biospecimens provided.
    iv. Restrictions on the use of the tissue, if any.
    v. Statement on the bio hazardous nature of human biospecimens.
    vi. Instructions about return, retention or disposal of unused tissue if applicable.
    vii. Specific conditions for publication of research results, if any (e.g., that the biobank should be acknowledged appropriately in all resulting publications, and that copies of the publications should be returned to the biobank).
    viii. Specific conditions for sharing data, if any.
    ix. Specific conditions for managing intellectual property, if any.
    x. Specific conditions about compensation for material transfer if relevant.
    xi. That tissue cannot be provided to a third party without the written consent of the biobank (that would require a new, revised MTA).

5.2 Turnaround Times for Handling Requests

- Fifteen days or less

6.0 APPLICABLE REFERENCES, REGULATIONS AND GUIDELINES

- Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER).

http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositories

- International Air Transport Association (IATA)
  http://www.iata.org/Pages/default.aspx
- Qualman, SJ. et al. Establishing a tumor bank: banking, informatics and ethics. Br. J. Cancer (2004). 90-1115-1119.

- L.D. Gray and J.W. Snyder, (2006) Practical guidance to facilitate compliance with current international regulations that govern the packing and shipping of dangerous goods. Chapter 21 in Biological Safety, Principles and Practice, 4th edition, ed. D.O. Fleming and D.L. Hunt.

National
Liver
Disease
Biobank

Standard Operating Procedure

DOCUMENT NAME: MATERIAL RELEASE

DOCUMENT NO. : ILBS#NLDB:J

Material Release

Return of Biospecimens for Clinical Purposes

Document Name	**:**	**Return of Biospecimens for Clinical Purposes**
Document No.	**:**	**SOP: ILBS#NLDB: J.4**
Version No.	**:**	**1.0**
Effective Date	**:**	**01/01/2025**

Address

National Liver Disease Biobank,
Institute of Liver & Biliary Sciences,
D-1, Vasant Kunj, New Delhi-110070

Phone no

Telephone: +91-11-46300000; extension: 24816, 24813.
Email: ilbsbiobank2024@gmail.com
Website: www.nldb.in, www.ilbs.in,

Material Release

Return of Biospecimens for Clinical Purposes

Number	Effective date	Pages	Author	Authorized by
ILBS#NLDB:J.4	01/01/2025	6	Mr. Satish Kumar	Dr. Chhagan Bihari
Version	**Review period**	**No. of copies**	**Approved by**	**Date**
1.0	2yrs	3	Dr. Chhagan Bihari	30/12/2024

Location	Subject
Biobank Reception area Almira	Return of Biospecimens for Clinical Purposes
Function	**Distribution**
To give information about Research Assistants and any other personnel who may receive participant requests to access biobank samples	➢ HOD ➢ Biobank Reception area ➢ Master files

SCOPE AND APPLICATION:

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

RESPONSIBILITY:

This SOP applies to all NLDB biobank personnel involved in the tissue biobank program and handling of sample access requests. The Biobank HOD ensures compliance with this SOP, while all other personnel forward participant requests to the Principal Investigators. The Biobank Management Committee oversees overall biobank operations.

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 NLDB biobank is 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 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 NLDB biobank material.

Bio Bank Personnel	**Responsibility / Role**
HOD Biobank	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

4.0 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.

Materials and Equipment	
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.

5.0 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.

5.1 Process of response to participant request of materials access

5.1.1 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 release 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 release 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°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.