



## Return of Biospecimen for Clinical Purposes

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Category:	Material Release		
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### 1.0 PURPOSE

The purpose of this SOP is to outline the standardized procedures for returning biospecimens from Nourah's Tissue Biobank to participants or healthcare providers for clinical purposes, ensuring compliance with regulatory, ethical, and institutional policies while maintaining sample integrity.

### 2.0 SCOPE

This SOP applies to all researchers requesting biological samples from Nourah's Tissue Biobank for research purposes, whether internal or external to the institution.

### 3.0 ROLES AND RESPONSIBILITIES

This SOP applies to all personnel of Nourah's Tissue Biobank members

Biobank Personnel	Responsibility
Biobank Manager	Reviews and approves all biospecimen return requests and oversees the process, ensuring compliance with biobank policies.
Clinical Coordinators	Coordinate the return of biospecimens to healthcare providers or participants and ensure all documentation is completed.
Participants or Medical Providers	Must request the return of biospecimens through proper channels, providing necessary clinical documentation.

### 4.0 MATERIALS, EQUIPMENT, AND FORMS

Listing of the materials, equipment, and forms being used to achieve the goals of the SOP, this list will mainly contain necessary materials and, or recommendations that may be substituted by alternative or equivalent materials more suitable at the time of testing.



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Material to be used	Site
LabVantage LIMS system for tracking requests and releases	
Shipping and packaging materials	
Documentation (e.g., physician's request, clinical documentation)	

### 5.0 POTENTIAL HAZARDS

In this part of the SOP, we explain the potential hazards from chemicals and methodologies used in this procedure. It will also contain information on how to handle these chemicals and the level of biosafety

Material	Safety and handling

### 6.0 PROCEDURES

This section outlines the standardized process for receiving, reviewing, and processing requests for the return of biospecimens from Nourah's Tissue Biobank. It ensures that biospecimens are returned efficiently and securely while meeting all clinical and regulatory requirements.

#### 6.1 REQUESTING THE RETURN OF BIOSPECIMENS

1. The participant or medical provider submits a formal request for the return of biospecimens through the biobank's email (HSRC-BB@pnu.edu.sa)
2. The request must include the reason for the biospecimen return and the intended clinical use (e.g., diagnostic or therapeutic purposes).
3. Clinical documentation, such as a physician's order or diagnostic report, must accompany the request.
4. The Biobank Manager reviews the request to ensure that it complies with the biobank's return policy and regulatory requirements.
5. The manager verifies the availability of the requested biospecimen and checks for any legal or ethical concerns.
6. If the request is approved, the Biobank Manager notifies the clinical coordinators to initiate the return process.
7. If the request is rejected, reasons for the decision will be communicated to the requester, and an opportunity to revise the request may be provided.

#### 6.2 PREPARATION OF BIOSPECIMENS FOR RETURN

1. Once approved, the requested biospecimens are retrieved from storage by the logistics personnel, ensuring that the correct samples are selected.
2. The condition and integrity of the samples must be verified before packaging.
3. The biospecimens are prepared for transport following clinical standards, ensuring that they are placed in appropriate packaging materials (e.g., insulated containers, biohazard bags, and absorbent materials).
4. Each package must be clearly labeled with the necessary information, including:
  - a. Type of biospecimen



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- b. Storage conditions (e.g., dry ice or cold pack requirements)
  - c. Recipient details (medical provider or participant)
5. All necessary permits or medical forms required for the transport and return of the biospecimens are attached.

### 6.3 SHIPPING AND TRANSPORT

1. For biospecimens being returned to a medical provider within Saudi Arabia, samples may either be collected in person or shipped via SMSA courier, following the biobank's shipping protocols.
2. For international transport, DHL or Aramex is the preferred courier. The packaging must comply with IATA/DGCA regulations for the transportation of biological materials.
3. Ensure that all required customs forms, permits, and health declarations are included with the shipment.
4. The shipping details, including tracking numbers, are logged in the LabVantage LIMS system for monitoring purposes.
5. The recipient (medical provider or participant) is notified of the shipment details and provided with tracking information.

### 6.4 RECEIPT AND CONFIRMATION

1. The recipient must confirm receipt of the biospecimens upon delivery, verifying that the samples have arrived in proper condition.
2. Any issues with the shipment, such as delays, damage, or compromised sample integrity, must be reported to the Biobank Manager immediately.
3. In the event of any issues with the return process (e.g., lost or damaged samples), a formal investigation is initiated by the Biobank Manager, and corrective actions are taken to prevent future occurrences.
4. A full report is generated and logged in the LabVantage LIMS system.

### 6.5 STORAGE AND HANDLING UPON RECEIPT

1. Once received, the biospecimens must be handled and stored according to the recipient institution's clinical protocols. This includes appropriate storage conditions to maintain the integrity of the samples until they are used for diagnostic or therapeutic purposes.
2. The recipient institution is responsible for documenting the clinical use of the biospecimens and providing feedback to the biobank, if necessary, on how the samples were used and the outcomes achieved.

## 7.0 REFERENCES

1. CTRnet SOPs "09.005 Return of Biospecimen for Clinical Purposes"
2. LabVantage LIMS System Manual
3. King Abdullah Bin Abdulaziz University Hospital's send out Policy



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### 8.0 REVISION HISTORY

SOP No.	Date Revised	Author	Summary

### 9.0 APPENDICES