Tissue Collection			
Category:	**Materials Handling and Documentation**		
SOP number:	04.006	Version	1.0
Prepared By:	Mr. Meshal M. Al-Sharafa	Original Date:	Sep 2024
Approved by:	Dr. Alaa A. AlMasud	Effective Date:	

1.0 PURPOSE

The purpose of this SOP is to establish standardized procedures for the collection and transportation of tissue samples to Nourah's Tissue Biobank. These procedures ensure the integrity, viability, and traceability of tissue samples from the point of collection through to their arrival at the biobank.

2.0 SCOPE

This SOP applies to all personnel involved in the collection and transportation of tissue samples destined for Nourah's Tissue Biobank. It covers procedures for the safe and compliant handling of tissue samples from various collection sites, including hospitals, clinics, and research laboratories.

3.0 ROLES AND RESPONSIBILITIES

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

Biobank Personnel	Responsibility
Surgical and Clinical Staff	Responsible for collecting tissue samples according to this SOP, ensuring proper labeling, and initial handling before transportation.
Transportation Personnel	Responsible for ensuring that tissue samples are transported under the appropriate conditions to maintain their integrity and viability.
Biobank Personnel	Responsible for receiving, logging, and storing tissue samples upon arrival at the biobank.
Biobank Manager	Responsible for overseeing the tissue collection and transportation processes, ensuring compliance with this SOP, and addressing any issues that arise.
Quality Assurance (QA) Officer	Responsible for auditing the tissue collection and transportation processes to ensure adherence to protocols and regulatory requirements.

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.

Material to be used	Site
Sterile collection containers (e.g., cryovials, sterile bags)	
Labels and markers	
PPE (gloves, gowns, face masks)	
Ice packs or dry ice (depending on the sample requirements)	
Insulated transport containers (e.g., coolers, dry shippers)	
Transportation logs/forms	
Biohazard bags and containers	

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 steps involved in the collection, labeling, transportation, and receipt of tissue samples at Nourah's Tissue Biobank. These procedures are designed to maintain the integrity of the tissue samples throughout the process and ensure that they are properly documented and stored upon arrival.

6.1 ACCEPTANCE AND REJECTION CRITERIA OF TISSUE SAMPLES

1. Acceptance Criteria for Tissue Samples
    a. Tissue should be fresh, undamaged, and free from visible contamination.
    b. Samples should be well-preserved, either snap-frozen, embedded in OCT, or fixed in 10% formalin as per protocol requirements.
    c. The ischemic time (time between sample collection and preservation) should be minimized, ideally less than 30 minutes.
    d. Each tissue sample must be labeled with participant ID, sample type, collection date, and preservation details.
    e. Samples should be transported on ice or in dry ice to the biobank and processed within the required time frame.
2. Rejection Criteria for Tissue Samples
    a. Tissue samples that are damaged, degraded, or visibly contaminated.
    b. Tissue samples with prolonged ischemic time beyond the acceptable limit, which could affect sample integrity.

c. Samples not preserved using the appropriate method (e.g., not snap-frozen or improperly fixed in formalin).
d. Tissue samples that lack proper labeling, including participant identification or other required details.

6.2 RECEIPT AND STORAGE AT BIOBANK

1. Upon arrival at the biobank, immediately log the receipt of the tissue samples into the LIMS system, noting the time and condition of the samples.
2. Cross-check the sample labels and documentation to ensure accuracy.
3. Prepare the tissue samples for storage according to their specific requirements (e.g., cryopreservation, refrigeration).
4. Ensure that the samples are placed in their designated storage location within the biobank.
5. Update the inventory management system with the storage location and any relevant notes regarding the condition of the samples.
6. Ensure that all documentation, including the sample collection form, is completed and filed appropriately.

6.3 INCIDENT MANAGEMENT

1. In case of any deviations from the SOP (e.g., temperature excursions, delays), document the incident and notify the Biobank Manager immediately.
2. Implement corrective actions as necessary to mitigate any impact on sample integrity.
3. Complete an incident report detailing the deviation, corrective actions taken, and any follow-up measures required.
4. Submit the report to the QA Officer for review and documentation.

7.0 REFERENCES

1. ISO 20387:2018
2. CTRnet SOPs “08.03.001 Tissue Collection and Transportation”
3. Declaration of Helsinki. http://www.wma.net/en/30publications/10policies/b3/index.html
4. 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
5. 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
6. 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
7. US National Biospecimen Network Blueprint http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

8.0 REVISION HISTORY

SOP No.	Date Revised	Author	Summary

9.0 APPENDICES

Appendix A - Sample Collection Form

Appendix B – Tissue collection Acceptance and Rejection Criteria