Blood Collection			
Category:	**Materials Handling and Documentation**		
SOP number:	04.002	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 outline the procedures for the safe and standardized collection of blood samples for storage and research within Nourah's Tissue Biobank. These procedures ensure the safety of both the donor and the personnel, as well as the integrity of the collected samples.

2.0 SCOPE

This SOP applies to all personnel involved in the collection of blood samples within Nourah's Tissue Biobank, including phlebotomists, nurses, and laboratory technicians. It covers the entire blood collection process, from donor preparation to sample labeling and storage.

3.0 ROLES AND RESPONSIBILITIES

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

Biobank Personnel	Responsibility
Laboratory Technicians	Responsible for receiving, processing, and storing the blood samples as per the established guidelines.
Biobank Manager	Responsible for overseeing the blood collection process, ensuring compliance with this SOP, and addressing any issues or incidents.
Quality Assurance (QA) Officer	Responsible for auditing the blood collection process, ensuring adherence to protocols, and managing incident reports.

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
Blood collection tubes (e.g., EDTA, citrate, serum separator tubes)	
Needles and needle holders	
Alcohol swabs and gauze	
Tourniquets	
Adhesive bandages	
Labels and markers	
PPE (gloves, lab coat, face shield)	
Biohazard waste containers	
Sharps disposal containers	
Sample transport 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 procedure is intended to ensure that blood samples will be obtained from consented participants in a safe and efficient manner while eliminating the risks of contamination.

6.1 ACCEPTANCE AND REJECTION CRITERIA

1. Acceptance Criteria for Blood Samples
    a. Blood samples should be free from hemolysis. Any visible signs of hemolysis, such as a pink or red tinge in serum/plasma, are grounds for rejection.
    b. Samples should not contain clots if the sample is intended for plasma separation.
    c. Samples must meet the minimum required volume as per the biobank's specifications (e.g., 4-10 ml).
    d. Blood should be collected in the appropriate tube type, such as EDTA for plasma or serum separator tubes for serum.
    e. Each tube must be labeled with the MRN of patient, collection date. And accompanied with the blood collection form
    f. Samples must be transported to the biobank under controlled temperature conditions and processed within the specified time (e.g., within 2 hours of collection if plasma or serum separation is required).
2. Rejection Criteria for Blood Samples

a. Blood samples that exhibit signs of hemolysis or clotting in plasma or serum samples intended for further processing.
b. Samples that do not meet the minimum volume requirement for the planned analyses or storage.
c. Tubes lacking proper identification or labels with incorrect or incomplete information.
d. Blood collected in the wrong tube type for the intended analysis, which can impact the quality and utility of the sample.

6.2 SAMPLE HANDLING AND PROCESSING

1. Verify that all tubes are correctly labeled with the donor's unique identifier, date, and sample type.
2. Centrifuge the blood samples at 2500RPM at 10 minutes or as per the specified conditions of the project.
3. Separate and aliquot the serum or plasma into appropriately labeled secondary tubes.
4. Store the blood samples or derivatives at the required temperature, depending on the intended use (e.g., refrigeration, freezing).
5. Ensure that samples are logged into the inventory management system immediately after processing.

6.3 WASTE DISPOSAL

1. Dispose of needles and other sharps in designated sharps containers immediately after use.
2. Dispose of any blood-contaminated materials (e.g., gauze, gloves) in biohazard waste containers.
3. Clean the area with an appropriate disinfectant to ensure a safe environment for subsequent collections.

6.4 INCIDENT MANAGEMENT

1. If a donor experiences an adverse reaction (e.g., fainting, excessive bleeding), provide immediate care and document the incident.
2. Report the incident to the Biobank Manager and QA Officer for further investigation and follow-up.
3. In the event of a needlestick injury, follow the established protocol for post-exposure prophylaxis and report the incident immediately.

7.0 REFERENCES

1. ISO 20387:2018
2. CTRnet SOPs "08.02.001 Blood Collection"
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 - Blood Collection Form

Appendix B - Blood Acceptance and Rejection Criteria