



Quality Management System (QMS)			
Category:	Quality Management		
SOP number:	03.01.001	Version:	1.0
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Approved by:	Dr. Alaa Abdullah AlMasud	Effective Date:	

1.0 PURPOSE

The purpose of this SOP is to establish a comprehensive Quality Management System (QMS) at Nourah's Tissue Biobank. This QMS ensures that biobank operations, processes, and services consistently meet high standards of quality, reliability, and compliance, while prioritizing customer focus, personnel competency, safety, and operational efficiency.

2.0 SCOPE

This SOP applies to all quality-related activities at Nourah's Tissue Biobank, including customer focus, facilities and safety, personnel management, purchasing and inventory, equipment validation, document and record management, biological sample processing, safety reporting, proficiency testing, and internal audits.

3.0 ROLES AND RESPONSIBILITIES

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

Biobank Personnel	Responsibility
Biobank Manager	Oversees the QMS, ensures compliance with the quality assurance schedule, conducts internal audits, and reviews corrective actions.
Quality Control (QC) Personnel	Provides scientific oversight, reviewing research proposals for scientific merit and relevance to the biobank's mission.
Safety Officer	Implements safety protocols, oversees the safety reporting system, and ensures a safe environment.
All Personnel	Participate in quality and safety initiatives, proficiency testing, and internal audits as required.

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

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

6.1 ORGANIZATION

1. Nourah's Tissue Biobank is organized so that personnel can work together to carry out institutional and departmental objectives effectively and efficiently. (SOP 01.001 – Organizational Structure and Legal Administration).

6.2 CUSTOMER FOCUS

1. Collect feedback from researchers, participants and trainees to understand their requirements by conducting satisfaction surveys and evaluate feedback to improve biobank services. (SOP 02.007 - Handling Participant (Donor) Complaints) & (SOP 03.05.003 - Students Training and Evaluation) & (SOP 05.001- Process for Requesting Samples from Nourah's Tissue Biobank)
2. Ensure timely and accurate delivery of requested samples. (SOP 04.003 – Blood Collection) & (SOP 04.007 – Tissue Collection).

6.3 FACILITIES AND SAFETY

1. Regularly inspect and maintain biobank facilities to ensure a safe and clean working environment. (SOP 03.04.002 – Maintenance of Sample Storage Facility and Equipment).
2. Conduct facility reviews and implement necessary improvements. (SOP 03.04.003 - Emergency Procedure for Freezer and Refrigerator Failure).
3. Implement safety protocols and training to ensure a safe environment for personnel and visitors. (SOP 03.05.002 – Education and Training)
4. Monitor safety compliance through routine checks and maintain safety records. (SOP 03.03.001 – Safety Reporting System).



6.4 PERSONNEL

1. Implemented a comprehensive training program for all personnel on biobank SOPs, quality control, and safety procedures. (SOP 03.06.002 – Education and Training)
2. Conduct proficiency testing to evaluate and document staff competency. (SOP 03.06.001)
3. Conduct performance reviews for all personnel annually to ensure they meet job-specific competencies. (SOP 01.003 – Job Descriptions, Roles, and Responsibilities)

6.5 PURCHASING AND INVENTORY

1. Maintain an updated inventory of reagents, consumables, and equipment necessary for biobank operations. (SOP 04.001 Inventory Verification)
2. Conduct monthly inventory checks to ensure adequate stock and timely reordering.
3. Ensure that all purchasing decisions are made in alignment with the biobank's quality standards. (KAAUH purchasing policies)
4. Document and approve purchases to maintain transparency and accountability.

6.6 EQUIPMENT

1. Validate and calibrate all equipment used in sample handling and analysis. As well as conducting validation of new equipment upon installation and revalidation after maintenance or repair. (SOP 03.01.005 - Equipment's Validation & Calibration)
2. Perform scheduled maintenance on equipment to ensure functionality and reliability. Maintain a log of all maintenance and calibration activities. (SOP 03.04.002 - Maintenance of Sample Storage Facility and Equipment)

6.7 DOCUMENT AND RECORDS MANAGEMENT

1. Maintain an organized system for storing and managing all biobank documents, including SOPs, QA logs, and training records. Ensure documents are reviewed and updated annually to reflect current standards. (SOP 03.02.004 – Document Maintenance)
2. Retain records of QA checks, training, and corrective actions for a minimum of five years or as per regulatory requirements. (KAAUH Retention Policies)

6.8 BIOLOGICAL SAMPLE PROCESSING

1. Follow standardized protocols for collecting, processing, and storing biological samples. (SOP 04 - Biological Material Handling and Documentation)
2. Ensure samples are labeled accurately and tracked in the Laboratory Information Management System (LIMS). (SOP 04.002- Labeling and Tracking Materials)
3. Conduct routine QC checks on sample processing to confirm compliance with biobank standards. (SOP 03.01 – Quality Management (Quality)).

6.9 SAFETY REPORTING SYSTEM



1. All personnel must report any safety incidents or near-misses immediately to the Safety Officer. (SOP 03.03.001 – Safety Reporting System).
2. Investigate reported incidents, determine root causes, and implement corrective actions. Document and review all corrective actions to prevent recurrence. (SOP 03.03.002 - Risk Assessment Policies).

6.10 PROFICIENCY TESTING

1. Conduct annual proficiency testing for all personnel involved in sample processing, storage, and analysis. (SOP 03.05.001 - Competency Assessment)
2. Review proficiency test results and provide additional training if needed to improve skills and ensure competency. (SOP 03.05.002 – Education and Training)

6.11 INTERNAL AUDIT

1. Conduct internal audits annually to review compliance with SOPs, document control, and quality control processes. Include all aspects of the QMS in the audit, such as customer focus, personnel, safety, equipment, and inventory. (SOP 03.01.002 - Quality Management Audit Program).
2. Identify and document any non-conformities or improvement areas during audits. Implement corrective actions and follow-up to ensure that audit findings are addressed effectively. (SOP 03.01.003 – Internal Audit program for Nourah’s Tissue Biobank).

7.0 REFERENCES

1. ISO 20387:2018 – General requirements for biobanking.
2. Internal policies of Princess Nourah bint Abdulrahman University.

8.0 REVISION HISTORY



SOP No.	Date Revised	Author	Summary

9.0 APPENDICES

03.01.002 V1.0 - APPENDIX A - Audit Schedule.

03.01.002 V1.0 - APPENDIX B - Meeting Minutes.

03.01.002 V1.0 - APPENDIX C - Quality Management Review