Quality Management Audit Program

Category:	**Quality Management**		
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Approved by:	Dr. Alaa Abdullah AlMasud	Effective Date:	

1.0 PURPOSE

This SOP establishes a structured process for conducting Quality Management System (QMS) audits at Nourah's Tissue Biobank. The aim is to ensure continuous improvement, compliance with policies, and alignment with objectives related to the collection, storage, and management of biological materials and data.

2.0 SCOPE

This SOP applies to all departments, activities, and processes within Nourah's Tissue Biobank that are involved in quality management. It also covers interactions with external bodies for quality assessments.

3.0 ROLES AND RESPONSIBILITIES

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

Biobank Personnel	Responsibility
Audit Manager	Responsible for planning, implementing, and maintaining the audit program.
Biobank team	Provide information and data during audits and implement corrective actions within the biobank.
External Auditor (if applicable)	Assess compliance with external standards and provide recommendations.
Biobank management	Oversee the implementation of the quality management audit program.

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
Audit Schedule Template	Appendix A
Meeting Minutes Template	Appendix B

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 Auditing Nourah's Tissue Biobank.

6.1 PLANNING THE AUDIT PROGRAM

1. Quality management audits shall be conducted bi-annually (every six months).
2. Additional audits may be scheduled based on significant operational changes or external feedback.
3. Internal QMS requirements of Nourah's Tissue Biobank.
4. Compliance with the biobank's policies and objectives.
5. Alignment with relevant external standards and guidelines.
6. Assess the suitability, adequacy, and effectiveness of policies, procedures, and operations.
7. Review compliance with corrective actions from previous audits.
8. Quality management representatives will assemble the audit team, which may include external auditors where necessary.

6.2 CONDUCTING THE AUDIT

1. The audit team will review records, interview staff, and assess procedures to evaluate compliance with QMS requirements.
2. Areas of focus will include, but are not limited to:
    a. Fulfillment of operational and quality objectives.
    b. Suitability of policies and procedures.
    c. Corrective actions and improvements.
    d. Results of internal and external assessments.
    e. User feedback, complaints, and effectiveness of monitoring activities.
3. Review audit records, risk management outcomes, and corrective actions.
4. Assess the adequacy of biological materials and data to ensure alignment with objectives.
5. Identify operational risks and assess the effectiveness of mitigation strategies.

6.3 REPORTING AND FOLLOW-UP

1. The audit report shall summarize findings, including non-conformities, corrective actions, and opportunities for improvement.
2. It will be submitted to top management for review.
3. Top management will review the audit results to ensure the QMS's effectiveness and recommend improvements.
4. The review will address:
    a. Corrective action implementation.
    b. Changes in activities or operations.
    c. User feedback, complaints, and improvements.
    d. Outcomes of internal and external assessments.
5. Biobank units must implement corrective actions without undue delay.
6. The Quality Management team will monitor the status of these actions.

6.4 RECORD KEEPING

1. Records of audit schedules, reports, and corrective actions will be maintained as evidence.
2. Documentation will include:
    a. Audit criteria and scope.
    b. Findings and action plans.
    c. Meeting minutes from management reviews.
    d. External audit results (if applicable).
3. All records will be stored in the biobank's document management system for a minimum of five years.

6.5 KEY PERFORMANCE INDICATORS (KPIS)

1. Percentage of completed audits as per the planned schedule.
2. Timely implementation of corrective actions.
3. Reduction in non-conformities from previous audits.
4. Feedback from external assessments or CERTIFICATIONS.

7.0 REFERENCES

1. ISO 19011: Guidelines for auditing management systems.
2. ISO 20387:2018: General requirements for biobanking.

8.0 REVISION HISTORY

SOP No.	Date Revised	Author	Summary

9.0 APPENDICES

Appendix A - Audit Schedule

Appendix B - Meeting Minutes

Appendix C - Quality Mangement Review form