



Risk Assessment Policies			
Category:	QUALITY MANAGEMENT		
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Approved by:	Dr. Alaa Abdullah AlMasud	Effective Date:	

1.0 PURPOSE

The purpose of this SOP is to establish a standardized approach to risk assessment for Nourah's Tissue Biobank. This ensures that all risks associated with biobank operations, including biospecimen handling, data management, equipment, and personnel, are identified, assessed, and mitigated in compliance with ISO 20387:2018.

2.0 SCOPE

This SOP applies to all activities and processes within Nourah's Tissue Biobank that may pose a risk to sample integrity, data security, staff safety, and operational continuity. This includes sample collection, processing, storage, distribution, data management, and collaborations.

3.0 ROLES AND RESPONSIBILITIES

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

Biobank Personnel	Responsibility
Biobank Manager	Oversees the risk assessment process, ensures that all risks are documented, and that mitigation strategies are implemented.
Laboratory Staff	Participate in identifying potential risks within their operations and report issues that could impact biospecimen integrity, data security, or staff safety.
Quality Control Team	Conducts risk assessments, reviews identified risks, and develops appropriate mitigation plans.

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

This section outlines the standardized process for conducting risk assessments at Nourah's Tissue Biobank, including identifying risks, analyzing and evaluating them, implementing controls, and documenting results.

6.1 RISK IDENTIFICATION

1. Identify Areas to Assess:
 - a. Operational Risks (sample handling, storage, and transport)
 - b. Data Risks (data privacy, LIMS system integrity)
 - c. Safety Risks (staff health and biosafety)
 - d. Compliance Risks (regulatory and ethical standards)
2. Methods of Identification:
 - a. Regular team meetings and brainstorming sessions.
 - b. Incident reports and analysis of past non-conformities.
 - c. Feedback from internal and external audits.
3. Documentation:
 - a. All identified risks shall be recorded in the Risk Assessment Log (see Appendix A).

6.2 RISK ANALYSIS AND EVALUATION

1. Determine Impact and Likelihood:
 - a. Impact Rating: Assess the potential effect on the biobank's operations, sample integrity, data security, or personnel safety if the risk were to materialize (rated as Low, Medium, High).
 - b. Likelihood Rating: Assess the probability of the risk occurring (rated as Rare, Unlikely, Possible, Likely, Almost Certain).
2. Risk Matrix:
 - a. Use a risk matrix to classify each risk based on its impact and likelihood. Risks classified as High or Critical require immediate action, while Low or Moderate risks should be monitored.
3. Prioritization of Risks:
 - a. Rank risks according to their severity and prioritize those that require immediate mitigation.

6.3 RISK MITIGATION AND CONTROL

1. For each identified risk, create an action plan to reduce its impact or likelihood. Mitigation strategies may include implementing additional safety protocols, improving data security, or enhancing staff training.
2. Designate responsible personnel for implementing each mitigation strategy. Ensure timelines for completion and review are established.
3. Conduct regular follow-ups to ensure that mitigation strategies are effective and that any necessary adjustments are made.

6.4 REVIEW AND DOCUMENTATION



1. Conduct an annual review of all identified risks, mitigation strategies, and outcomes to assess overall effectiveness and make necessary adjustments.
2. Ensure that all risk assessment activities are documented and available for review during internal and external audits.
3. Maintain records of all risk assessments, mitigation actions, and reviews as per the biobank's documentation policies.

7.0 REFERENCES

1. ISO 20387:2018 – Biobanking Requirements for Biobank Management
2. King Abdullah Bin Abdulaziz University Hospital's Data Access Policy

8.0 REVISION HISTORY

SOP No.	Date Revised	Author	Summary

9.0 APPENDICES

Appendix A: Risk Assessment Log

Appendix B: Risk Assessment Template