



Safety Reporting System			
Category:	QUALITY MANAGEMENT		
SOP number:	03.03.001	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 standardized process for reporting, documenting, and addressing safety incidents, near-misses, and potential hazards within Nourah's Tissue Biobank. This system promotes a safe working environment and ensures compliance with regulatory and institutional safety standards.

## 2.0 SCOPE

This SOP applies to all personnel, including staff, volunteers, and contractors, involved in the operations of Nourah's Tissue Biobank. It covers the procedures for reporting safety incidents, investigating root causes, implementing corrective actions, and maintaining safety records.

## 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 safety reporting system, ensuring that all reports are addressed and corrective actions are implemented.
Safety Officer	Investigates reported incidents, recommends corrective actions, and monitors the effectiveness of safety measures.
All Personnel	Responsible for promptly reporting any safety incidents, near-misses, or hazardous conditions.

## 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

These following procedures outline the steps for reporting safety incidents, conducting investigations, implementing corrective actions, and maintaining records. The goal is to reduce risks, prevent recurrences, and promote a culture of safety.

### 6.1 REPORTING SAFETY INCIDENTS AND HAZARDS

1. All personnel must report any safety incident, near-miss, or hazardous condition to the Safety Officer or Biobank Manager as soon as possible.
2. In the event of a serious injury or emergency, contact the emergency response team immediately before reporting the incident.
3. Complete a Safety Incident Report Form (see Appendix A) within 24 hours of the incident.
4. Include detailed information about the nature of the incident, location, individuals involved, and any immediate actions taken.
5. In situations where written reporting is delayed, verbally inform the Safety Officer or Biobank Manager to ensure prompt attention.

### 6.2 INVESTIGATION AND ROOT CAUSE ANALYSIS

1. The Safety Officer will initiate an investigation within 48 hours of receiving the incident report.
2. The investigation will involve gathering information from involved personnel, witnesses, and reviewing any relevant documentation.
3. Conduct a root cause analysis to determine the underlying cause(s) of the incident or hazard.
4. Identify any contributing factors (e.g., equipment failure, procedural lapse, environmental conditions).
5. Document all findings from the investigation, including photos, witness statements, and any relevant supporting evidence.

### 6.3 IMPLEMENTING CORRECTIVE ACTIONS

1. Based on the investigation findings, the Safety Officer will recommend corrective actions to eliminate the root cause of the incident and prevent recurrence.
2. Corrective actions are reviewed and approved by the Biobank Manager.
3. Assign responsible personnel for implementing each corrective action, including a target completion date.
4. The Safety Officer will monitor the implementation of corrective actions and assess their effectiveness.
5. Any additional corrective actions, if necessary, will be documented and implemented.

### 6.4 RECORD KEEPING AND DOCUMENTATION



1. All safety reports, investigation records, corrective actions, and follow-up documentation will be maintained in a secure, centralized system managed by HR.
2. Information regarding incidents and personnel involved will be treated confidentially and only accessible to authorized personnel.
3. Retain safety records for a minimum of five years or as per institutional policy.

## 6.5 TRAINING AND AWARENESS

1. All new personnel, including volunteers, will receive training on the safety reporting system and procedures during orientation.(SOP 07.001 & SOP 07.002)
2. Conduct annual refresher training on safety protocols, including incident reporting, hazard identification, and corrective action processes.
3. Regularly communicate the importance of safety to all personnel and encourage proactive identification and reporting of hazards.

## 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

Appendix A: Safety Incident Report Form

Appendix B: Safety Incident Report Log