



Administration of Standard Operating Procedures

Category:	ADMINISTRATION		
SOP number:	01.005	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 provide guidelines for the creation, implementation, revision, and management of Standard Operating Procedures (SOPs) at Nourah's Tissue Biobank. This ensures that all processes are documented, accessible, and updated regularly to maintain compliance with institutional, regulatory, and ethical standards.

2.0 SCOPE

This SOP applies to all personnel involved in drafting, reviewing, approving, and implementing SOPs at Nourah's Tissue Biobank. It outlines the lifecycle of an SOP, from creation to archiving, ensuring consistency and compliance in all biobank operations.

3.0 ROLES AND RESPONSIBILITIES

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

Biobank Personnel	Responsibility
Biobank Manger	Oversees the entire SOP administration process, ensuring that all SOPs are up-to-date, approved, and accessible to staff.
Biobank Team	Individuals or teams responsible for drafting SOPs, including revising and updating existing SOPs when necessary.
Participant (Donor)	Participants are encouraged to voice any concerns or complaints they may have during or after their involvement with the biobank.

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
SOP templates approved by the biobank	
SOP review checklist	



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Training materials for SOP implementation	
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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 full lifecycle of Standard Operating Procedures, from drafting to archiving. It ensures that all SOPs are regularly reviewed, updated, and easily accessible to staff to maintain high standards in biobank operations.

6.1 CREATION OF SOPS

1. New SOPs are required whenever a new process, method, or regulation is introduced that affects biobank operations.
2. The SOP should follow the standard format (see SOP template, Appendix A); the word “draft” should be added to the header. For major revisions to previous SOPs, the major SOP version number must be incremented by one (e.g., 1.0 becomes 2.0). For minor revisions to previous SOPs, the minor version number must be incremented by 1 (e.g. 1.0 becomes 1.1). The first version of an SOP is always 1.0.
3. The Biobank Manager or any staff member may propose the creation of an SOP by submitting a request to the SOP Administrator.
4. The SOP Author or designated team drafts the SOP using the approved template.
5. The draft must include sections such as Purpose, Scope, Responsibilities, Procedures, and References.
6. SOPs should be clear, concise, and include step-by-step instructions for performing the relevant task.
7. The draft SOP is reviewed by the Biobank Manager and relevant department heads to ensure accuracy, completeness, and alignment with biobank policies.
8. Any required revisions are made before moving forward to legal and regulatory review.

6.2 APPROVAL AND IMPLEMENTATION OF SOPS

1. All SOPs must undergo review by the biobank manger and institutional review board to ensure they comply with applicable laws, guidelines, and ethical standards.
2. The SOP is then submitted to the Biobank manger for final approval. The approved version is assigned an SOP number, version number, and effective date.
3. Once approved, the SOP is distributed to relevant staff and uploaded to Nourah’s Tissue Biobank sharefolder.
4. Ensure that all staff are notified of the new or revised SOP and that it is easily accessible for reference.
5. All relevant staff must receive training on new or revised SOPs. Training may include in-person sessions, online modules, or documentation reviews.
6. Staff must sign an acknowledgment of training completion, which is kept on file. (Appendix B)

6.3 SOP REVIEW AND REVISION



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1. SOPs must be reviewed at least annually to ensure they remain current and applicable. The SOP Administrator is responsible for scheduling and coordinating reviews. (Appendix C)
2. A review checklist is used to ensure that each SOP is evaluated for relevance, accuracy, and compliance. (Appendix D)
3. If a change in regulations, procedures, or technology necessitates an update to an SOP, an ad hoc review may be initiated by the Biobank Manager or relevant department head.
4. If updates are needed, the SOP is revised by the original author or a designated team. Revised SOPs are submitted for the same review and approval process as new SOPs.
5. Updated SOPs must be assigned a new version number and effective date, and the previous version must be archived.

6.4 ARCHIVING SOPS

1. When an SOP is replaced or deemed no longer relevant, it is archived in the LabVantage LIMS system or another secure document storage system.
2. Archived SOPs must be retained for at least [Insert retention period, e.g., 5 years] in accordance with institutional policies and legal requirements.
3. Ensure that only the most current version of the SOP is available to staff. Archived SOPs must be clearly marked as obsolete and stored in a separate folder to avoid confusion.

6.5 MONITORING AND COMPLIANCE

1. Periodic audits are conducted to ensure that all staff are following the current SOPs. The SOP Administrator and Quality Assurance team are responsible for performing these audits.
2. If an audit reveals non-compliance, corrective actions are taken, including retraining staff or updating procedures to align with the SOP.

7.0 REFERENCES

1. CTRnet SOPs "01.001 Administration of Standard Operating Procedures"
2. LabVantage LIMS System Manual
3. King Abdullah Bin Abdulaziz University Hospital's send out Policy



8.0 REVISION HISTORY

SOP No.	Date Revised	Author	Summary

9.0 APPENDICES

Appendix A – Standard Operating Procedure Template

Appendix B - Standard Operating Procedure Distribution Record

Appendix C – Standard Operating Procedure Review Record

Appendix D - Standard Operating Procedures Index