



## Organizational Structure and Legal Administration

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Category:	ADMINISTRATION		
SOP number:	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 define the legal organization and management structure of Nourah's Tissue Biobank to ensure transparency, accountability, and compliance with ISO 20387:2018 standards. This SOP provides a clear overview of the biobank's place within the broader organizational framework of Princess Nourah bint Abdulrahman University and outlines the roles of the governing and advisory bodies that oversee biobank operations.

### 2.0 SCOPE

This SOP applies to all departments, staff members, and committees involved in the administration, management, and governance of Nourah's Tissue Biobank. It outlines the biobank's organizational structure, legal administration, and the functions of its oversight committees.

### 3.0 ROLES AND RESPONSIBILITIES

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

Biobank Personnel	Responsibility
Biobank Oversight Committee	Oversees the governance and strategic direction of Nourah's Tissue Biobank, ensuring compliance with university policies and regulatory standards.
Scientific Committee	Provides scientific oversight, reviewing research proposals for scientific merit and relevance to the biobank's mission.
Institutional Review Board (IRB)	Ensures that all research conducted through the biobank complies with ethical and regulatory requirements.
Biobank Manager	Manages the day-to-day operations of the biobank and ensures alignment with the biobank's mission and legal framework.

### 4.0 MATERIALS, EQUIPMENT, AND FORMS



## Organizational Structure and Legal Administration

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

#### 6.1 LEGAL ORGANIZATION OF THE BIOBANK

1. Nourah's Tissue Biobank operates as a legally recognized entity under the General Administration of Health Affairs (GAHA) at Princess Nourah bint Abdulrahman University (PNU).
2. The biobank's activities are regulated by university policies and adhere to national and international standards, including ISO 20387:2018, to ensure compliance with ethical, scientific, and operational guidelines.
3. The General Administration of Health Affairs (GAHA) at PNU provides administrative oversight, resource allocation, and policy alignment for the biobank.
4. GAHA ensures that the biobank operates within the legal and ethical framework established by the university, enabling the biobank to fulfill its role in supporting clinical and translational research.

#### 6.2 BIOBANK MANAGEMENT STRUCTURE

The biobank's management structure consists of a hierarchical chain that defines oversight and operational responsibility from university leadership down to biobank-specific roles and committees.

1. University Leadership:
  - a. Princess Nourah bint Abdulrahman is the ultimate authority over the biobank, establishing its mission, policies, and alignment with the university's objectives in advancing research and public health.
2. General Administration of Health Affairs (GAHA):



## Organizational Structure and Legal Administration

- a. GAHA serves as the administrative bridge between university leadership and the biobank. It ensures that the biobank has the support, resources, and policies required to function effectively within the university's healthcare research framework.
3. Oversight Committee:
  - a. The oversight committee is the primary governing body responsible for the strategic oversight of the biobank. It monitors compliance, evaluates performance, and provides guidance to ensure that the biobank meets its objectives.
  - b. The Biobank oversight committee reports to GAHA and is accountable for implementing university policies, approving budgetary requirements, and addressing any operational challenges.
4. Scientific Committee:
  - a. The Scientific Committee operates under the GAHA supervision and is responsible for evaluating the scientific validity of research proposals involving biobank resources.
  - b. It reviews project feasibility, relevance, and scientific integrity, ensuring that research aligns with the biobank's mission and objectives.
5. Institutional Review Board (IRB):
  - a. The IRB is responsible for ensuring ethical compliance in all biobank-related research involving human participants.
  - b. It reviews informed consent processes, participant rights, and data protection measures, ensuring that all research activities adhere to ethical standards and regulatory requirements.
6. Biobank Manager:
  - a. The Biobank Manager is responsible for managing the biobank's daily operations, ensuring that processes are aligned with ISO 20387:2018 standards and internal policies.
  - b. The manager oversees staff, budget, inventory, quality control, and compliance with operational protocols.
7. Operational Staff:
  - a. Includes laboratory technicians, data managers, administrative personnel, and quality control specialists, all working under the Biobank Manager's guidance to maintain biobank functions.
8. Operational Support Committee:
  - a. Includes members from the Princess Nourah bint Abdulrahman University different departments and sections that guide the processes for biobank.

### 6.3 ROLES AND RESPONSIBILITIES OF COMMITTEES AND STAFF

1. Biobank oversight committee :
  - a. Establishes and approves the strategic goals and long-term vision of Nourah's Tissue Biobank, ensuring alignment with national and PNU's objectives, such as Saudi Arabia's Vision 2030.
  - b. Develops and oversees policies that govern Nourah's Tissue Biobank's operations, ensuring that all practices meet ethical, legal, and operational standards.
  - c. Ensures adherence to international biobanking standards, such as ISO 20387, CAP, and the Canadian Tissue Repository Network.
  - d. Reviews and approves budgets, funding proposals, and financial strategies to maintain Nourah's Tissue Biobank's financial health and long-term sustainability.
  - e. Oversees cost-control measures and revenue-generating activities, such as service offerings, to support Nourah's Tissue Biobank's financial viability.



## Organizational Structure and Legal Administration

- f. Supporting the biobank with necessary resources—whether funding, personnel, or technology to ensure it meets demand and remains sustainable.
2. Scientific Committee:
  - a. Review and approve research proposals for scientific soundness and alignment with biobank objectives.
  - b. Advise on potential collaborations that could enhance the biobank’s resources and research impact.
3. Institutional Review Board (IRB):
  - a. Ensure that all research involving biobank samples complies with ethical standards.
  - b. Review informed consent documents, data protection measures, and research protocols for regulatory compliance.
4. Biobank Manager:
  - a. Implement policies and procedures in alignment with the biobank’s goals and ISO standards.
  - b. Supervise biobank operations, including sample collection, processing, storage, and distribution.
  - c. Coordinate with the Biobank and all committees to facilitate seamless operations.
5. Operational Staff:
  - a. Conduct daily tasks related to sample handling, data management, and quality control.
  - b. Report any operational issues, incidents, or non-compliance to the Biobank Manager.
  - c. Follow approved SOPs and protocols for safe and ethical handling of biobank resources.
6. Operational Support Committee:
  - a. **Operational Oversight:** Reviewing and ensuring adherence to protocols for sample collection, storage, and data handling, and regularly evaluating standard operating procedures (SOPs) to maintain high-quality standards.
  - b. **Compliance and Regulatory Guidance:** Ensuring that all biobank operations comply with ethical, legal, and regulatory requirements, including participant consent, data privacy, and biospecimen handling.
  - c. **Risk and Quality Management:** Identify potential risks and oversee quality assurance programs to address issues proactively. This might include overseeing certifications, safety protocols, and contingency plans.
  - d. **Continuous Improvement:** Promoting best practices by implementing improvements based on feedback from audits, research staff, and user experiences, fostering an environment of innovation and efficiency.
  - e. **Ethical and Participant Support:** Overseeing participant engagement strategies, including transparent consent processes, and withdrawal protocols, and maintaining participant confidentiality to build and retain public trust.



## Organizational Structure and Legal Administration

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