Process for Requesting Samples			
Category:	**Material Release**		
SOP number:	05.001	Version	1.0
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1.0 PURPOSE

The purpose of this SOP is to establish a standardized procedure for researchers to request samples from Nourah's Tissue Biobank. It outlines the requirements for a request submission, the review and approval process, and the final evaluation of services provided. This SOP ensures efficient and compliant handling of sample requests in alignment with biobank policies and ethical standards.

2.0 SCOPE

This SOP applies to all external researchers and collaborators who wish to request samples from Nourah's Tissue Biobank. It also applies to biobank personnel involved in the review, approval, and release of samples.

3.0 ROLES AND RESPONSIBILITIES

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

Biobank Personnel	Responsibility
Requester (Researcher)	Submits a complete request for samples, including all required documentation.
Biobank Manager	Conducts an initial review of the request to confirm sample eligibility and availability.
Scientific Committee	Reviews the scientific validity and relevance of the research request.
Institutional Review Board (IRB)	Ensures the research request complies with ethical standards.

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

6.1 SUBMITTING A SAMPLE REQUEST

1. The researcher must submit a request to the biobank through the designated biobank email with the following information attached:
    a. Completion of research application form (APPENDIX A)
    b. Research statement: outline of the research objectives and justification for sample use.
    c. Updated CV: current curriculum vitae highlighting relevant experience.
    d. Pubmed or ORCID ID: a link to the researcher's publication profile to verify contributions to scientific research.
2. The request must include the following affiliation information:
    a. Institute details: name and address of the affiliated institution.
    b. Contact details: email address and phone number for direct communication.
    c. Position title: official title or role at the institution.
3. The biobank administrative staff will acknowledge receipt of the request within one working day and forward it to the biobank manager for review.

6.2 INITIAL REVIEW BY BIOBANK MANAGER

1. The biobank manager will review the request to confirm sample availability checks the biobank's inventory for sufficient and suitable samples.
2. The initial review will take one to two working days. If samples are available and eligible, the request will be forwarded for further review.
3. If samples are unavailable or the request is ineligible, the requester will be notified accordingly.
4. Upon confirmation, the biobank manager will notify the requester of sample eligibility and availability and inform them that the request will proceed to the scientific committee and institutional review board for approval.

6.3 SCIENTIFIC AND ETHICAL REVIEW

1. Scientific committee review:
    a. The request is reviewed by Natural and Health Science Research Center's scientific committee to assess the scientific validity, feasibility, and alignment with the biobank's mission.
    b. The scientific committee typically requires two to three weeks to complete the review.
2. Institutional Review Board (IRB) Approval:

   a. The General Administration of Health Affairs' IRB evaluates the request for ethical compliance, including considerations of participant privacy, consent, and data protection.
   b. The IRB review is conducted concurrently with the scientific committee review.
3. Notification of approval:
   a. If both the scientific committee and the IRB approve the request, the biobank manager will notify the requester of the approval.
   b. If either body denies the request, the biobank manager will inform the requester and provide feedback or recommendations for resubmission, if applicable.

6.4 MATERIAL TRANSFER AGREEMENT (MTA) AND SAMPLE RELEASE

1. Upon approval, the requester will receive a Material Transfer Agreement (MTA) outlining the terms and conditions for sample use and transfer. The MTA includes details on:
   a. Sample release process: procedures for sample collection and transfer from the biobank.
   b. Transportation methodology: packaging, shipping, and handling requirements for sample transport.
2. The requester must review, sign, and return the MTA to the biobank before samples are released.
3. Once the signed MTA is received, the biobank will arrange for sample release in accordance with the MTA's terms.
4. Samples will be packaged and shipped in compliance with applicable biosafety and transportation regulations.

6.5 EVALUATION OF SERVICES PROVIDED

1. After the sample release and payment confirmation, the requester will receive a link to a Microsoft forms survey to evaluate the biobank's services.
2. The survey will assess the following aspects of the biobank's service:
3. Efficiency and responsiveness: timeliness and quality of communication throughout the request process.
4. Sample quality: satisfaction with the condition and suitability of samples provided.
5. Overall experience: general feedback on the request and release process.
6. Suggestions for improvement: opportunity for the requester to provide recommendations for enhancing biobank services.
7. Survey responses will be reviewed periodically by the biobank manager and Biobank Oversight committee to identify any areas for improvement.
8. Summary reports will be generated to help the biobank continuously improve its request handling processes.

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: Research Application Form

Appendix B: Research Scoring System