Withdrawal of Consent			
Category:	**Participant Recruitment and Management**		
SOP number:	02.004	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 outline the procedures for managing the withdrawal of consent from participants in Nourah's Tissue Biobank. This ensures that participants who choose to withdraw their consent have their wishes respected, and their data and samples are handled accordingly, in compliance with ethical and legal guidelines.

2.0 SCOPE

This SOP applies to all personnel involved in managing participants who wish to withdraw their consent from participation in Nourah's Tissue Biobank. It includes the process for documenting the withdrawal, removing or anonymizing data and samples, and ensuring that the withdrawal is fully respected.

3.0 ROLES AND RESPONSIBILITIES

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

Biobank Personnel	Responsibility
Principal Investigators (PIs)	Responsible for overseeing the withdrawal process and ensuring that the participant's request is executed ethically and in compliance with Institutional Review Board (IRB) guidelines.
Biobank Coordinators	Responsible for processing participant requests for withdrawal, ensuring all steps are followed, and documentation is complete.
Research Assistants	Responsible for updating the LabVantage LIMS system to reflect the participant's withdrawal and managing data/sample removal or anonymization as required.

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

Withdrawal request form	

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 steps involved in managing the withdrawal of consent from a participant at Nourah's Tissue Biobank, including updating records, handling samples, and removing or anonymizing participant data.

6.1 PARTICIPANT REQUEST FOR WITHDRAWAL

1. Participants may submit a withdrawal request either verbally or in writing (via email, phone, or in-person).
2. If the request is received verbally, ask the participant to complete a formal withdrawal request form to document the withdrawal in writing (Appendix A).
3. Provide the participant with any necessary information about the withdrawal process, including their options for sample and data handling.
4. Acknowledge receipt of the withdrawal request by contacting the participant and confirming that their request will be processed.
5. Record the date and method of the request in the participant's file.

6.2 CONFIRMING CONSENT WITHDRAWAL OPTIONS

1. Confirm with the participant whether they wish to have their samples and data:
2. Destroyed: The samples and all associated data will be completely removed from the biobank and destroyed with the help of "Destruction of Samples and Data Checklist" Form (Appendix B).
3. Anonymized: The samples will be anonymized, meaning all identifiable information will be removed, and the data may be retained for research without participant identification.
4. No Further Use: The samples and data will no longer be used for future research but may be retained in the biobank.
5. Document the participant's decision regarding how their samples and data should be handled.
6. Ensure that the participant fully understands the implications of each option before finalizing the withdrawal process.

6.3 PROCESSING THE WITHDRAWAL

1. Log into the LabVantage LIMS system to update the participant's record, marking the participant as withdrawn from the biobank.
2. Indicate whether the samples and data should be destroyed, anonymized, or retained for no further use, based on the participant's preference.
3. Destruction: If the participant requests sample destruction, ensure that all samples are located and destroyed in compliance with biobank disposal procedures. Record the date and method of destruction in the LIMS system.
4. Anonymization: If the participant requests anonymization, ensure that all identifying information is removed from their samples and data in the LIMS system. Cross-check to confirm that all identifiers have been removed.
5. No Further Use: If the participant chooses this option, mark the samples and data as no longer available for future research, but retain them in the storage facility.
6. Update any electronic or paper-based data associated with the participant to reflect their withdrawal.
7. If destruction or anonymization is requested, ensure that the data is appropriately removed or modified.

6.4 CONFIRMING WITHDRAWAL WITH PARTICIPANT

1. Once the withdrawal process has been completed (including sample destruction, anonymization, or marking data as no longer usable), notify the participant via their preferred method of contact.
2. Confirm that their withdrawal has been processed according to their preferences.
3. Record the details of the withdrawal process, including all actions taken (destruction, anonymization, etc.), in the participant's file.
4. Ensure that all relevant parties (e.g., the Principal Investigator, Biobank Manager) are informed of the completed withdrawal.

6.5 INCIDENT MANAGEMENT

1. In case of any deviations from the use of approved informed consent forms (e.g., outdated versions used, missing information), document the incident and notify the Biobank Manager immediately.
2. Implement corrective actions to mitigate any impact on participant consent.
3. Complete an incident report detailing the deviation, corrective actions taken, and any follow-up measures required.
4. Submit the report to the Quality Assurance Officer for review and documentation.

7.0 REFERENCES

1. CTRnet SOPs "02.006 Withdrawal of consent"
2. Declaration of Helsinki.
   http://www.wma.net/en/30publications/10policies/b3/index.html
3. Human Tissue and Biological Samples for use in Research. Operational and Ethical Guidelines. Medical Research Council Ethics
   http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002420
4. Best Practices for Repositories I. Collection, Storage and Retrieval of Human Biological Materials for Research. International Society for Biological and Environmental Repositories (ISBER).
   http://www.isber.org/Search/search.asp?zoom_query=best+practices+for+repositories
5. National Bioethics Advisory Commission: Research involving human biological materials: Ethical issues and policy guidance, Vol. I: Report and recommendations of the National Bioethics Advisory Committee. August 1999.
   http://bioethics.georgetown.edu/nbac/hbm.pdf
6. US National Biospecimen Network Blueprint
   http://biospecimens.cancer.gov/resources/publications/reports/nbn.asp

8.0 REVISION HISTORY

SOP No.	Date Revised	Author	Summary

9.0 APPENDICES

Appendix A - Nourah's Tissue Biobank Withdrawal of Consent form

Appendix B - Destruction of Samples and Data Checklist