Obtaining Informed Consent			
Category:	**Participant Recruitment and Management**		
SOP number:	02.003	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 standardized procedures for obtaining informed consent from participants at Nourah's Tissue Biobank. This ensures that all participants are fully informed about the biobank's research activities and provide voluntary consent before any samples or data are collected.

2.0 SCOPE

This SOP applies to all personnel involved in the process of obtaining informed consent from participants at Nourah's Tissue Biobank. It covers the procedures for ensuring participants understand the purpose of the biobank, their rights, and the nature of their involvement, in compliance with Institutional Review Board guidelines.

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
Principal Investigators (PIs)	Responsible for overseeing the informed consent process and ensuring ethical and regulatory compliance.
Biobank Coordinators	Responsible for managing the consent process, ensuring that all necessary information is provided to participants and that consent is obtained properly.
Research Assistants	Assist in explaining the consent form, addressing participant questions, and ensuring consent is documented.
IRB Committee	Reviews and approves the informed consent process, ensuring that it complies with ethical standards and regulatory requirements.

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
Participant information sheets	
Informed consent 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 step-by-step process for obtaining informed consent from participants at Nourah's Tissue Biobank. These procedures ensure that participants are well informed, and their consent is voluntary and properly documented.

6.1 PROVIDING INFORMATION TO PARTICIPANTS

1. Provide participants with a detailed Participant Information Sheet (PIS) that explains the purpose of the biobank, the types of samples collected (e.g., tissue, blood), the data collected (e.g., anthropometrics, clinical lab results, radiology scans), and the nature of their participation.
2. Inform participants that their participation is voluntary and that they have the right to withdraw at any time without any negative impact on their medical care or benefits.
3. Explain their right to ask questions at any point during the consent process and beyond.
4. Allow participants the opportunity to ask any questions regarding the biobank, its objectives, or their participation.
5. Address any concerns they may have about privacy, data security, or the potential risks and benefits of participating.

6.2 OBTAINING WRITTEN CONSENT

1. Present the informed consent form to the participant and explain its contents. Ensure that the form includes sections outlining the participant's voluntary involvement, the use of their samples, how their data will be handled, and their right to withdraw.
2. Give participants adequate time to review the consent form and discuss it with family members or legal representatives if necessary.
3. Once the participant is ready to consent, ask them to sign the informed consent form in the presence of a witness (if applicable).
4. The individual obtaining consent should also sign the form to confirm that the process was conducted in accordance with this SOP.
5. For vulnerable populations (e.g., minors, elderly with diminished capacity), ensure that an authorized representative is involved in the consent process as required by law and ethics.

6.3 DOCUMENTING THE CONSENT

1. Document the signed consent form in the LabVantage LIMS system, including the participant's ID, date of consent, and any special notes.
2. Store the signed informed consent form in a secure, accessible location, both physically and electronically, ensuring confidentiality is maintained.
3. Provide a copy of the signed informed consent form to the participant for their records.

6.4 REVISITING AND UPDATING CONSENT

1. If any significant changes occur in the research protocol or new information becomes available that affects participant involvement, participants must be informed, and a revised consent form must be signed.
2. If an updated consent form is required, re-consent must be obtained. Inform participants of the changes, provide a revised consent form, and follow the steps outlined for obtaining written consent.

6.5 PARTICIPANT WITHDRAWAL

1. If a participant wishes to withdraw from the biobank, ensure their request is processed promptly.
2. Update the LabVantage LIMS system to reflect their withdrawal and ensure that any remaining samples or data are handled in accordance with their withdrawal preferences (e.g., destruction or anonymization).
3. Provide the participant with a written confirmation of their withdrawal, including any actions taken regarding their samples and data.

6.6 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 "02.005 Obtaining Informed 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 Consent Form