Requesting Additional Survey Information

Category:	**Participant Recruitment and Management**		
SOP number:	02.006	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 requesting additional survey information from participants at Nourah's Tissue Biobank. This process ensures that any supplemental survey data collection is done in an ethical and systematic manner, while maintaining participant confidentiality and adherence to Institutional Review Board guidelines.

2.0 SCOPE

This SOP applies to all personnel involved in requesting additional survey information from participants. It covers the process for initiating requests for extra data, obtaining informed consent, and documenting the collection of new information using the LabVantage LIMS system.

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 request for additional survey information, ensuring compliance with ethical standards.
Biobank Coordinators	Assist in managing the communication with participants, ensuring that additional survey requests are properly documented and tracked.
Research Assistants	Conduct the outreach to participants, handle survey distribution, and ensure data is accurately entered into the LIMS system.
IRB Committee	Reviews and approves any new survey questions or processes, ensuring they comply with ethical 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
Template for the Amendment request	
Informed consent form (if required for additional data collection)	
Survey distribution tools (e.g., electronic survey platforms or printed forms)	
Ethical guidelines and data privacy policies	
Institutional Review Board feedback and approval documents	

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 procedures for requesting additional survey information from participants at Nourah's Tissue Biobank, ensuring ethical data collection and proper documentation.

6.1 IDENTIFYING THE NEED FOR ADDITIONAL INFORMATION

1. Identify the need for additional survey information based on study progress, emerging research questions, or gaps in the initial data collection.
2. The Principal Investigator, in collaboration with the study team, determines what supplemental data is required.
3. Develop new survey questions or modify existing ones to gather the required information.
4. Ensure the questions align with the research objectives and that they are clearly worded for participant understanding.
5. Submit the new survey questions and data collection methods to the Institutional Review Board for approval with the amendment request form (Appendix A).
6. Await IRB feedback and approval before proceeding with contacting participants.

6.2 REQUESTING PARTICIPANT CONSENT (IF REQUIRED)

1. If the additional survey information involves new data collection not covered by the original consent form, participants must be informed of the reasons for requesting the new data.

2. Provide the participants with an updated consent form explaining the purpose of the additional survey and any potential risks or benefits.
3. Ensure participants understand the request and their rights to decline participation in the additional survey.
4. Document the consent process, obtaining written consent before proceeding with the additional data collection.

6.3 SURVEY DISTRIBUTION

1. Use approved communication scripts to contact participants and inform them of the request for additional survey information.
2. Distribute the survey via the appropriate medium (e.g., email with a survey link, paper forms, or phone interviews) based on participant preferences and availability.
3. Record which participants have responded to the survey and track participation rates.
4. Send reminders, as necessary, to participants who have not yet responded, ensuring the tone remains respectful and non-coercive.

6.4 DATA COLLECTION AND DOCUMENTATION

1. Collect the completed surveys and enter the data into the LabVantage LIMS system.
2. Ensure that the additional data is linked to the correct participant profiles and that no identifying information is shared beyond the research team.
3. Review the data for completeness and accuracy.
4. Follow up with participants if any responses are unclear or require further clarification.
5. Ensure that all additional survey data is stored securely and that participant confidentiality is maintained at all times.
6. Adhere to data protection and privacy guidelines as outlined by Nourah's Tissue Biobank policies.

6.5 REVIEW AND ANALYSIS OF ADDITIONAL DATA

1. Once all additional survey data has been collected, the research team reviews the new information to ensure it meets the study's needs.
2. Integrate the new data into the existing dataset for analysis. Ensure that it is clearly marked as additional survey information for transparency during research reporting.
3. Update the LabVantage LIMS system to reflect the new data fields and integrate them with the pre-existing participant data for comprehensive records.

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 "02.003 Requesting Additional Survey Information"
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 - Application for IRB Approval of Research Amendment