Participant Recruitment into Nourah's Tissue Biobank

Category:	**Participant Recruitment and Management**		
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Approved by:	Dr. Alaa Abdullah AlMasud	Effective Date:	

1.0 PURPOSE

The purpose of this SOP is to outline the standardized procedures for recruiting participants into Nourah's Tissue Biobank. This ensures compliance with ethical guidelines, including Institutional Review Board (IRB) requirements, and guarantees that participants are informed, consented, and enrolled properly for research purposes across the defined research focus areas. To promote participation, Nourah's Tissue Biobank team and associated and collaborating clinical professionals at Natural and Health Research Center, King Abduallah bin Abdulaziz University Hospital and other institutions should work to ensure that appropriate patients are recruited.

2.0 SCOPE

This SOP applies to all personnel involved in the recruitment of participants into Nourah's Tissue Biobank. It covers the process of recruiting patients from King Abdullah bin Abdulaziz University Hospital and from other hospitals, ensuring that all recruitment is done ethically and in compliance with IRB guidelines.

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 recruitment efforts, ensuring ethical conduct, and obtaining appropriate IRB approvals.
Biobank Coordinators	Responsible for managing the recruitment process, communicating with potential participants, and ensuring all documentation and consent forms are completed.
Research Assistants	Assist in screening, consenting, and recruiting participants, and entering data into the LabVantage LIMS system.
IRB Committee	Responsible for reviewing and approving the recruitment protocols, both for in-hospital patients and external participants.

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
Informed Consent Form	Biobank office 1.614
Participant Recruitment Log	
Recruitment protocol documents	
IRB approval letters (for internal and external hospitals)	
Data protection and privacy guidelines	
Recruitment scripts and brochures	

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 of participant recruitment into Nourah's Tissue Biobank. It covers recruiting participants from King Abdullah bin Abdulaziz University Hospital and external hospitals, ensuring adherence to IRB requirements and ethical guidelines.

Informed consent is obtained either before or after a medical procedure (e.g. surgery) that yields a potentially available biospecimen.

6.1 IDENTIFYING POTENTIAL PARTICIPANTS (INCLUSION CRITERIA)

1. Through King Abdullah bin Abdulaziz University Hospital:
    a. Access patient databases from the hospital's clinical units that are aligned with the biobank's research focus areas (Cachexia, Sarcopenia, Aging, Lifestyle, Health, Metabolic Syndrome, Oncology).
    b. Collaborate with clinical teams (e.g., oncology, geriatrics) to identify eligible patients.
    c. Review patient clinical records to confirm eligibility according to inclusion/exclusion criteria defined in the study protocol.
2. From External Hospitals:
    a. Submit IRB applications to the relevant external hospital's IRB committee for recruitment approval.
    b. Once approved, coordinate with the external hospital's clinical staff to identify eligible patients.
    c. Ensure patient data is only accessed after obtaining ethical approvals and agreements between institutions.

6.2 INFORMED CONSENT PROCESS

1. Pre-Procedures
    a. Provide potential participants with the Nourah's Tissue Biobank pamphlet, explaining the purpose of the biobank and their involvement.
    b. Discuss with participants the types of samples that will be collected (tissue, blood, etc.) and the associated clinical data (e.g., anthropometrics, clinical lab results, radiology scans).
    c. Ensure the participant understands the risks and benefits of participating in the biobank before signing the informed consent form.
    d. Allow the participant to ask questions and provide sufficient time for them to review the Informed Consent Form (Appendix A)
    e. Obtain written consent from the participant before any sample or data collection takes place.
    f. For vulnerable populations (e.g., elderly or those with impaired capacity), additional steps may be required to ensure informed consent, such as involving a legal representative.
    g. Participants must be informed that their involvement in Nourah's Tissue Biobank is voluntary, and they can withdraw at any time without any impact on their medical care or relationship with the biobank or hospital. Their decision to not participate will not affect any services or benefits they are entitled to.
2. Post Procedures
    a. Biospecimens may be collected before obtaining patient consent. However, the biospecimen must remain in temporary storage at an agreed-upon location and will be treated as an identifiable specimen during the consent period.
    b. No research or processing of the biospecimen is permitted until the patient's consent status is determined and documented.
    c. The length of the consent period is defined in consultation with the local Institutional Review Board (IRB) and typically lasts until the completion of the patient's diagnosis. The duration may vary depending on the site and disease, typically ranging from 3 months to 1 year.
    d. During this period, the biobank must track the consent status of the biospecimen and determine whether the patient has:
    e. Consented to the use of the biospecimen for research,
    f. Declined to provide consent, or
    g. Made no decision regarding consent.

h. Until the consent status is known, biospecimens will remain in temporary storage. They may not be accessed for research purposes during this period.
i. The storage facility must comply with all relevant biospecimen handling and security standards to ensure the integrity and confidentiality of the specimen.

6.3 DATA AND SAMPLE COLLECTION

1. Inform participants about the sample collection procedure, including tissue samples, blood samples and derivatives, anthropometrics, clinical lab results, and radiology scans.
2. Coordinate with clinical and laboratory teams to schedule the collection of these samples.
3. Ensure that participant details, consent forms, and collected sample information are entered into the LabVantage LIMS system for tracking and management.

6.4 PARTICIPANT FOLLOW-UP AND WITHDRAWAL

1. Periodically update participants on the status of the study or their contribution to the biobank.
2. Ensure that participants are informed of any future sample collections or research developments related to their participation.
3. If a participant wishes to withdraw from the biobank, ensure that their request is processed promptly.
4. Update the LabVantage LIMS system to mark the participant as withdrawn and take appropriate steps to anonymize or destroy their samples, depending on their withdrawal preferences.

6.5 ETHICAL COMPLIANCE AND CONFIDENTIALITY

1. For patients from King Abdullah bin Abdulaziz University Hospital, ensure recruitment is done under the IRB approval of the hospital.
2. For participants from other hospitals, ensure IRB approval is obtained from the external hospital's IRB before recruitment begins.
3. Ensure that all participant data is kept confidential, in accordance with data protection laws and ethical guidelines.
4. Use only de-identified or anonymized data for research purposes unless explicit consent is provided for identifying information.

6.6 INCIDENT MANAGEMENT

1. In case of any deviations from the SOP (e.g., failure to obtain proper consent), document the incident and notify the Biobank Manager immediately.
2. Implement corrective actions to mitigate any ethical or procedural issues.
3. Complete an incident report detailing the deviation, corrective actions taken, and any follow-up measures required.
4. Submit the report to the QA Officer for review and documentation.
5. Complete an incident report detailing the spill, cleanup actions, and any follow-up measures taken.

7.0 REFERENCES

1. CTRnet SOPs "02.001 Participant Recruitment into A Tumour Biobank Program"
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