Developing and Revising Consent Forms

Category:	**Participant Recruitment and Management**		
SOP number:	02.002	Version	1.0
Prepared by:	Mr. Meshal M. Al-Sharafa	Original Date:	Sep 2024
Approved by:	Dr. Alaa Abdullah AlMasud	Effective Date:	

1.0 PURPOSE

The purpose of this SOP is to establish standardized procedures for developing and revising informed consent forms used in participant recruitment at Nourah's Tissue Biobank. This ensures that all consent forms comply with ethical guidelines, Institutional Review Board requirements, and clearly communicate the rights and responsibilities of participants.

2.0 SCOPE

This SOP applies to all personnel involved in the creation, review, and revision of informed consent forms for studies conducted at Nourah's Tissue Biobank. It covers both the development of new informed consent forms and the periodic revision of existing forms to ensure compliance with updated regulations or research protocols.

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 development and content of the informed consent form, ensuring that it complies with study protocols and ethical standards.
Biobank Coordinators	Assist in drafting and revising informed consent forms and ensuring that all relevant information is accurately included.
Legal Counsel (if applicable)	Provides legal review to ensure the form complies with institutional and legal regulations.
IRB Committee	Reviews and approves informed consent forms to ensure compliance with ethical 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
Template for the informed consent form	Biobank office 1.614
Current institutional and regulatory guidelines for consent	
Study-specific protocol documents	
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 of 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 developing new informed consent forms and revising existing forms at Nourah's Tissue Biobank. These procedures ensure clarity, ethical compliance, and alignment with evolving research needs.

6.1 DEVELOPING NEW INFORMED CONSENT FORMS

1. Review the study protocol to identify the objectives, procedures, and participant involvement that must be communicated to potential participants.
2. Consult with the Principal Investigator and Biobank Coordinator to ensure all relevant details are included.
3. Develop an informed consent form using the approved institutional template. (Appendix A) The form must clearly state the purpose of the biobank, the nature of the research, and the participant's role.
4. Include clear explanations of sample collection (tissue, blood, etc.), data collection (anthropometrics, clinical lab results, radiology scans), and potential risks and benefits.
5. Ensure the informed consent form covers all participant rights, including the voluntary nature of participation, the right to withdraw at any time, and data confidentiality.
6. Review the form to make sure it is written in plain language that is easily understandable for the target participant population.
7. Submit the draft to the Institutional Review Board for ethical approval and to legal counsel (if applicable) for regulatory compliance.
8. Incorporate any feedback or required changes from the review process.

6.2 REVISING EXISTING INFORMED CONSENT FORMS

1. Revisions to the informed consent form may be prompted by updates in the study protocol, changes in regulatory guidelines, by request of the institutional review board (IRB) or feedback from participants.

2. The Principal Investigator or Biobank Coordinator initiates the revision process, ensuring the form reflects the most current information.
3. Modify the informed consent form to reflect any new procedures, risks, or benefits that were not previously included.
4. Review all sections of the form, ensuring that any new data collection methods, sample handling, or participant rights are appropriately documented.
5. Submit the revised form to the Institutional Review Board for re-approval.
6. Ensure that all revisions are compliant with current ethical standards and legal regulations.

6.3 APPROVAL AND DOCUMENTATION

1. Once approved by the Institutional Review Board, finalize the informed consent form, ensuring all required signatures are obtained (Principal Investigator, Biobank Manager).
2. Store the final version of the informed consent form electronically in the LabVantage LIMS system.
3. Maintain a log of all versions of the informed consent form, noting dates of revision and approval.
4. Ensure all recruitment personnel are trained on the revised informed consent form, understanding any changes in protocol or participant interaction.
5. Provide the updated forms to participants as required.

6.4 MONITORING AND FEEDBACK

1. Regularly monitor the use of the informed consent forms to ensure they are up-to-date and being used correctly in participant recruitment.
2. Solicit feedback from participants on the clarity of the consent form during the recruitment process.
3. Adjust as necessary based on participant input or feedback from clinical teams.

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 “02.002 Developing and Revising Consent Forms”
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 - Consent Form for Full Review Studies

Appendix B - Research Registration Form