Notification of Significant and Relevant Findings			
Category:	**Participant Recruitment and Management**		
SOP number:	02.005	Version	1.0
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1.0 PURPOSE

The purpose of this SOP is to outline the procedures for notifying participants at Nourah's Tissue Biobank of significant and relevant findings that arise from research using their samples and data. This ensures that participants are informed about findings that could impact their health or medical care while maintaining ethical and regulatory standards.

2.0 SCOPE

This SOP applies to all personnel involved in identifying and communicating significant findings from research studies that may have implications for participants' health or well-being. It includes the process for determining which findings warrant notification and how notifications should be managed in accordance with Institutional Review Board 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 identifying significant and relevant findings and determining whether they warrant participant notification.
Biobank Coordinators	Responsible for managing the communication of findings to participants and ensuring that all notifications are properly documented.
Clinical Team (if applicable)	Provides input on the potential health impact of the findings and assists in communicating findings to participants.
Institutional Review Board (IRB)	Ensures that the process for notifying participants is ethically sound and follows regulatory guidelines.

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

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 process for identifying significant and relevant findings and notifying participants, ensuring that communications are handled ethically, confidentially, and in a timely manner.

6.1 IDENTIFYING SIGNIFICANT AND RELEVANT FINDINGS

1. The research team, led by the Principal Investigator, regularly reviews study data to identify findings that may have health implications for participants.
2. Significant and relevant findings typically include genetic mutations, biomarkers, or other health indicators that could influence a participant's health care or treatment decisions.
3. If a potential finding is identified, consult with clinical experts to determine the medical relevance and significance of the finding.
4. The clinical team may provide additional insight into the urgency and health implications of the finding.
5. The Principal Investigator, in collaboration with the research team and the clinical experts, determines whether the finding should be communicated to the participant.
6. This decision must align with ethical standards and Institutional Review Board guidelines.

6.2 NOTIFYING PARTICIPANTS

1. Contact the participant using their preferred communication method. If notifying by phone or in person, ensure that a witness (e.g., a member of the clinical team) is present during the discussion.

2. Provide the participant with the notification letter during the conversation, or if applicable, via a secure method (e.g., mail, encrypted email).
3. Use plain language to explain the finding and its potential implications for the participant's health. Answer any questions the participant may have.
4. Provide guidance on the recommended next steps, which may include seeking medical advice, further testing, or follow-up with a health care provider.
5. Offer the participant the opportunity to speak with a member of the clinical team or a genetic counselor (if applicable) to provide additional explanation or support.
6. Ensure that participants have access to resources for further action, including contact information for medical specialists or support services.

6.3 DOCUMENTING THE NOTIFICATION

1. Document the notification in the LabVantage LIMS system, including the date of notification, the method used, and any follow-up actions taken.
2. Maintain a record of the participant's response, including whether they plan to follow up on the finding with a healthcare provider.
3. Store copies of the notification letter and any related correspondence securely, ensuring that participant confidentiality is maintained at all times.

6.4 FOLLOW-UP WITH PARTICIPANT

1. If the participant requests further information or clarification, ensure that they have access to clinical experts who can provide additional support.
2. Schedule a follow-up call or meeting if needed to discuss the participant's concerns or provide updates on the finding.
3. Record any actions taken by the participant based on the finding (e.g., scheduling a medical appointment) and document this in the LabVantage LIMS system.
4. Collect feedback from the participant regarding the notification process and use it to improve future communications.

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 "02.007 Notification of Significant and Relevant Findings"
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