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KNH-UoN ERC GUIDELINES FOR GENETIC RESEARCH AND BIOBANKING

Purpose/Objectives

These guidelines describe the KHN-UoN ERC minimal standards for ethical and scientifically sound research in genetics, stem cell, cryopreservation and related studies.

Scope: Genetic and stem cell research; cryopreservation

1. Appropriate tissue and data banking facilities shall be identified and effective management structures put in place to ensure security and confidentiality.
2. The facility must be institutional based with clearly defined Board of Management as the custodian. The board composition must comprise lay persons and key specialists including geneticists.
3. Evidence of certification of the facility including laboratories by a credible certifying body including regulatory/ legal bodies must be provided.
4. Each protocol must clearly define the specific nature of biomaterials intended for banking. Any additional nature of material should always be accompanied by new proposal e.g cord blood and placenta
5. Clearly indicate sources, processes and procedures of material acquisition.
6. All ethical issues involved must be adequately addressed in the protocol including:
    a. Consent processes for donors/ custodian implications.
    b. The informed consent should clearly state the rights of the donors; the amount of information that donors should be given; when it should be provided; when samples were taken or when used for research; how information should be provided (written or orally); to whom (if the donor has died or is incapacitated who should consent); and what the information should include (the disease studied, the methods, the funding, the location or the intended research proposed, etc).

c. Informed consent information shall include information about the consequences of DNA typing such as possible paternity determination.
d. Although biobanking poses no physical risk to the participants, consent for storage and use of specimens and data must be obtained from the participants.
e. Any future use of these samples will require approval by the KNH-UoN ERC.
f. Informed consent will not include any language through which participants are made to waive or appear to waive any legal rights. Translation into a language best understood by participants is mandatory.

7. The issues of attracting private investments and balancing this with the health good of the population must be declared. Potential to result to commercial gain e.g. gene patents, genetic tests introducing conflict between researcher's interest and those of participants should be disclosed in the consent documents and whether patients would share in any profits (benefit sharing). Otherwise commercialization of bio banking research shall not be permitted.

8. Legal implication including Intellectual property rights shall be appropriately addressed

9. The processing, justification and implications of handling of de-identification / delinking of specimen must be addressed.

10. Stringent institutional measures controlling access to material and audit of the same must be in place.
11. It may not be possible to define clearly all types of future studies, however care will be taken to minimize individual and group harms from future studies through appropriate handling/management of the specimens and/or data.
12. Duration of banking and quality assurance issues regarding viability of samples for intended purposes must be declared.
13. Biological material transfer shall be as per institutional and KNH-UoN ERC material transfer authorization.
14. Standard operating procedures (SOPs) for material disposal must be availed and must be as per the institutional and KNH-UoN ERC guidelines.
15. Handling of psychosocial challenges and impact of study and findings including but not limited to pre and post test counseling must be addressed.
16. In reporting and dissemination of all reports, patents, copyrights. etc, the identity of the repository bio bank must always be revealed.
    a. Whether and when and how to disclose individual research results to research participants will be determined by the research team in consultation with the ERC.
    b. Discussions/consultations will involve the clinical validity of the results and if the risk associations have been fully established based on the pool and quality of data.
    c. It should be noted that disclosure of a result from a single research project to a patient is at best not beneficial and at worst could be misleading or even harmful.

d. For Genetic research the analytical validity of the results are critical. Results to be given to patients should have been obtained from a certified laboratory if reporting on patient's specific results for diagnosis, prevention or treatment of any disease.
e. Genetic results will not be given to a participant who does not want them. An informed consent process will be put in place to offer opportunity to or not to receive results. This offer will be operational if the researcher is a physician and if all of the following apply:
    i. Findings are scientifically valid and confirmed.
    ii. Findings have significant implications for the research participant's health.
    iii. An intervention to ameliorate or treat the participants concerns is readily available.
f. The protocol will have a clear description of anticipated research findings and situations that might lead to decision to disclose the findings to a research participant and procedures for managing the disclosure. In absence of individual disclosures due to lack of clinical validity, the option of disclosing aggregate report overall study results shall be explored.

Approved for use date: _____