GUIDELINES FOR HANDLING, STORAGE AND TRANSPORTATION OF HUMAN BIOLOGICAL SPECIMEN

Human Biological Material(s) (HBM) of human origin means any material that comes from a person. These include, but are not limited to blood, urine, saliva or other bodily fluids; tissues; RNS, DNA, hair or nails; placenta, umbilical cords and cord blood; sperms, oocytes, left over frozen embryos following IVF, and other products of conception; excess pathology tissues, and waste surgical tissues. A **Material Transfer Agreement** (MTA) is a contract that governs the **transfer** of tangible **research** materials between organisations, when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.

REQUIREMENTS

i) The Institution exporting HBM shall be transparent about the purpose for which they wish to export HBM and demonstrate that the purpose they are exporting for cannot be achieved within the country and will significantly contribute to value addition in the field of science.

ii) All HBM must be accompanied by the informed consent form of the person whom the tissue(s) belong to or his/her Legally Authorised Representative (LAR).

iii) The informed consent should include details of the owner's agreement that his/her sample be sent abroad (including the country to which it is being exported).

iv) In circumstances where signed consent forms is not possible (e.g. in cases where researcher has anonymised the samples be exported), the Principal Investigator should provide a copy of the information sheet.

v) The information sheet will only be acceptable if the researcher is able to provide assurance that the consent was in place.

vi) The MNTRH-IREC may also grant a waiver to consent participants under the following circumstances when it is not practically possible to obtain the consent;

   a. The proposed research is going to contribute significantly to the understanding of some local health problem and that the overall benefit to research is real and substantial.
   b. Potential risk to the privacy or well-being of the participants is minimal e.g. use og unidentified archival specimen.
   c. The nature of any existing consent relating to collection and storage and use of material.
   d. Whether the research proposal is an extension of closely related to a previously approved research project.
   e. The justification presented for seeking waiver of consent, including the extent to which it is impossible, difficult or intrusive to obtain consent.

vii) A material transfer agreement (MTA) shall be signed by the institutions of both importing and exporting countries whenever they wish to transport the HBM.

viii) The PI should present the MTA for each batch of sample to be exported to MNTRH-IREC for scrutiny and approval.

ix) The MTA should define the rights, obligations and restrictions for both the importer and exporter with respect to the materials and any derivatives, and any confidential information exchanged with the material.

x) The MTA shall also encompass intellectual property rights (actual or potential) of the material and any derived products, permitted use of material or information exchanged, liabilities of both parties (including storage, distribution and disposal of HBM), arrangements for confidentiality maintenance of provider information, rights to publication of recipient research results and any other associated legal issues that the provider and recipient may wish to specify in the transaction.

xi) After approval by MNTRH-IREC, the PI shall apply to the National Commission for Science, Technology and Innovation that will verify and satisfy itself that the shipment is justified and does not infringe on the rights of individuals, communities and the country.

xii) The National Commission for Science, Technology and Innovation will register the application and issue a no objection letter and where appropriately requested, authority to carry out research.

xiii) The PI shall then submit the application to the Ministry responsible for health for a shipment permit.

GUIDELINES FOR COLLECTION OF HBM

i) At the time of collection of HBM individuals have the right to know for what purpose this material will be used, the nature of research risk, where will it be stored and for how long it is going to be stored.

ii) If HBM was taken for clinical purposes and research on these samples is planned then consent for the samples taken for the diagnostic and treatment purposes must be sought from the patients using a separate consent for the use of remaining samples in research.

iii) A clear explanation should be given to the potential research participants. In cases in which stored biological samples are to be used when no consent was obtained for research, or the samples are not individually identifiable, and there is no potential harm to persons from whom the samples were obtained, it is still required that MNTRH-IREC approval be sought prior to initiating research.

iv) Consent form must be explicit and separate from that used for routine surgery/procedure; it must clearly mention the use of HBM in research.

v) Blanket/generic consent for future research in which purpose of the research and other important information is unknown is **not recommended.**

vi) For research on HBM samples that had been previously collected for routine treatment or diagnostic procedure, it is suggested that consent should be taken for these patients.

10.3 GUIDELINES FOR TRANSPORTATION OF HBM

i) For labelling, packaging and handling, World Health Organisation (WHO) guidance on regulations for the Transport of Infectious Substances must be followed.
ii) Appropriate modes of transport, suitable routes and arrangements with people involved must be planned and arranged in advance in accordance with recommended international standards.
iii) Professional courier services must be used whenever possible and should be IATA compliant.

10.4 CONFIDENTIALITY AND PRIVACY SHOULD BE MAINTAINED THROUGHOUT THE RESEARCH

HBM custodian is responsible to protect and standardise usage, storage, access, export and disposal of the tissue.

i) If samples are sent to third party, all parties must abide by privacy and confidentiality terms.
ii) Confidentiality must be ensured by implementing appropriate security measures to prevent unauthorised access and restrict data.
iii) Prior to sending the HBM to third party identifiable information must be coded.
iv) The level of anonymisation and process should be approved by the MNTRH-IREC.
v) Privacy should also be maintained at the time of reporting the results. In case of genetic research, it must be considered that any group or community will not be stigmatised by the research outcome.