Ethical Guidelines for Collection, Usage, Storage, and Export of Human Biological Materials (HBM)

NATIONAL BIOETHICS COMMITTEE
PAKISTAN
Making of these guidelines

In the meeting of the National Bioethics Committee (NBC) held on 2\textsuperscript{nd} March 2015 in Muzaffarabad, Azad Jammu & Kashmir, members raised the issue of developing guidelines on transportation of Human Biological Materials (HBM) both within and outside Pakistan. This was in part due to a request from the Foreign Office which was concerned about unregulated export of HBM and in part due to concerns of many members who knew of HBM being stored for future use and also being sent abroad possibly for research purpose. It was decided unanimously that a sub-group of NBC members develop a comprehensive document titled “Ethical Guideline for collection, usage, storage and export of Human Biological Material.”

Dr. Aasim Ahmad (member NBC and Chair Research Ethics Committee (REC) of NBC) volunteered to take the lead and developed the first draft of the document with co-authors Ms Taranum Ruba Siddiqui and Ms Safia Bibi (Pakistan Health Research Council, Karachi office). The initial document went through several comprehensive reviews, revisions and modifications by Dr. Farhat Moazam (member NBC and Chair Health Care Ethics Committee (HCEC) of NBC), Dr. Aamir Jafarey and Dr. Jamshed Akhtar (members NBC) with some input from Dr. Farkunda Ghafoor and Dr. Munir Saleemi (members NBC).

The final draft was then circulated to all members of the NBC for their review and also discussed in the subsequent meeting held on (AA, add date, venue – I think we did this in 2 meetings) to obtain their input. The resultant document was uploaded on the NBC website on (provide date – from when to when) for public comments. In addition letters were sent requesting national universities, research institutes and individuals with interest in ethics and/or involvement in HBM research to give their comments on the document.

After reviewing and incorporating comments the guidelines were finalized on 18\textsuperscript{th} June 2016.
PREAMBLE

Collection and use of Human Biological Materials (HBM) especially for research purposes has greatly increased thereby also increasing transportation of HBM from developing to developed countries. Exchange of HBM between institutions and often across national boundaries has become essential in the pursuit of knowledge and for the advancement of science. The importance of the growth of this field cannot be denied but concurrently this also raises many ethical issues that must be recognized and addressed.

The global nature of the study of biology and its various offshoots such as genomics, proteomics or metabolomics (also now known as omics) has made such collaborations unavoidable. Recent advances in the field of genetics, biotechnology and bioinformatics have made it possible for researchers to access not only the health related information but also other personal information including the identifiable information with the use of HBM. This potentially exposes individuals and in many cases communities to psychological harms, including stigmatization and possibilities of exploitation. In Pakistan, as is generally in any developing country, it is important to understand the emerging ethical challenges related to the use of HBM, so as to avoid such issues which can undermine trust of the community for research and researchers. Since Pakistan is a developing country, we assume that import of HBM in Pakistan is not yet common but researchers and health institutions often export HBM from Pakistan to foreign centres for various reasons, as discussed below.

A proper framework / guidance need to be established to make these activities ethically sound.

PRIMARY OBJECTIVES

National Bioethics Committee of Pakistan has developed this document to facilitate researchers and, IRB/ERC/REC/ERB members while conducting or reviewing research on any kind of HBM in an ethical manner. This document discusses multiple aspects of HBM usage in medical research and provides ethical guidelines regarding collection, usage, storage and export of HBM.

These guidelines address important ethical issues that need to be considered when conducting research on HBM that:
1. Have already been collected, or will be collected, from patients for routine investigation/treatment;
2. Involves collection of HBM solely for the purpose of bio-banking and subsequent research.

These guidelines may also be used by regulatory authorities for drafting legislations regarding the collection, usage, storage and export of HBM.

It is recognized that with the rapid pace of advancement in biomedical science these guidelines will require regular review and revision. NBC will welcome input and comments to keep these guidelines relevant and robust.
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1. Introduction:

Human biological material (HBM) or materials of human origin means any material that comes from a person. These include, but are not limited to, blood, urine, saliva, pus or other bodily fluids; tissues; hair or nails; placenta, umbilical cord & cord blood; sperms, oocytes, left over frozen embryos following IVF & other products of conception; excess pathology tissues, and waste surgical tissues.¹

1.1. Purposes for collection of HBM

Emerging technologies and advances in biology have led to the discovery of multiple or varied uses of HBM. Common utilities of HBM are enumerated below

1.1.1. Clinical purpose

HBM is widely used for clinical purposes to facilitate diagnosis and prognosis of diseases, and also collected through therapeutic surgical interventions (excision of tissue, a segment of organ or even the whole organ) or for donation/transplant purpose.

1.1.2. Research purpose

Medical research, be it clinical, basic or genetic, aims to improve life. All these types of research involve human participants. The collection of HBM may be done for research diagnosis, prognosis and treatment of the disease, where as basic research attempts to understand cellular, molecular, and pharmaco-genetic aspects of disease.²

1.1.3. Commercial purpose

Advances in the field of biotechnology have resulted in the commercial availability of numerous therapeutic and other products which are developed from HBM, for example the use of human hair and placenta in cosmetic industry. HBM also carries great significance in pharmaceutical industry where it can be used as raw material or as a precursor for research activities. These utilities have made the commercial use of HBM plausible. The most prominent example is the HeLA cells from Henrietta Lacks the first ‘immortal’ cells to grow in vitro. These have been sold all around the globe since 1950s.³

1.1.4. Biobanking or Archiving of human biological material

Though HBM is most commonly collected to gain immediate clinical information, but modern research directions in medical science such as omics and personalized medicine have introduced the concept of biobanking.

By definition, a biobank is a long-term storage and conservation facility for biological specimens, to support future scientific investigation.⁴ These can be commercial (for-profit companies are involved in procurement, handling, and distribution of human biological materials); public (owned by the Government); or public-private partnership. Disease-oriented biobanks usually have a hospital affiliation through which they collect samples representing a variety of diseases to look for biomarkers affiliated with disease.⁵ Population-based biobanks take samples from large numbers of all kinds of people to identify biomarkers for disease susceptibility in a general population.⁶
Biobanks can serve an important purpose for investigating the basis of disease, particularly when combined with health registries and population surveys.

1.1.5. Education purpose

HBM is also widely used in teaching and education. Medical students study and analyze blood, urine, and other body fluids. Studies of histopathology require the examination of various tissue samples including surgically resected tumors or diseased organs to distinguish between normal and diseased cells. Donated cadavers are used to teach anatomy to students about all the regions of the body. Preservation of surgically resected tumors or diseased organs (taken at autopsy) in medical museums to illustrate disease is also a common practice in some medical schools.

1.2. Categories of HBM

Based on the potential of human biological material to identify an individual, alone or in combination with other information, HBM are classified into different categories based on the initial purpose of collection either for clinical or research use. These include:

1.2.1. Repository collections

Specimens collected for clinical purposes are stored by diagnostic laboratories ranging from few days to as long as several years after use. These stored samples constitute repository collections which can include:

i. **Identified Specimens:** The materials are labeled with a direct identifier (e.g., name, personal health number). Materials and any associated information are directly traceable back to a specific individual.

ii. **Unidentified Specimens:** For these specimens, identifiable personal information was not collected or, if collected, was not maintained and cannot be retrieved by the repository.

1.2.2. Research Samples:

Samples collected for research use include

i. **Coded HBM:** Materials which do not contain direct identifiers rather codes are used for identification of specimens to maintain the confidentiality. Key that links the codes to individual is retained usually by principal investigator and depending on access to that code it may be possible to re-identify specific individuals.

ii. **Anonymized HBM:** Materials are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

iii. **Anonymous HBM:** Materials never had identifiers attached to them and risk of identification of individuals is very low.
1.3. Export or import of HBM

Transport of HBM from one country to another could be for a number of reasons. Potential reasons for export of HBM are discussed below;

1.3.1. Clinical utility:
Medical science is advancing at a very fast pace which has resulted in a gap between the developed and developing countries regarding the diagnostic and treatment facilities for various ailments. One of the main reasons for sending HBM overseas from developing countries is lack of availability of the required diagnostic or analytical facilities in the home country to facilitate diagnosis of a health problem.

1.3.2. Research purposes:
Multinational collaboration in the field of health or biomedical research is now common and requires sharing of resources, manpower, samples and technologies between countries to understand the health problems in different parts of the world. Although such collaborations are not uncommon between developed countries. HBM is being exported from developing countries to technologically advanced countries for research purposes due to limited scientific infrastructure available in the developing world.

1.3.3. Biobanking:
The emerging interest towards personalized medicine requires access to big data, and biobanked materials are the obvious source of such data. These biobanks may be commercial, public or public-private partnership. For decades HBMs from developing countries particularly African countries along with the respective data are being sent to and stored in developed countries (where biobanking facilities are available) for uncertain secondary use. It is common knowledge in Pakistan that HBM is exported possibly for the purpose of biobanking and that the material exported for clinical or research purposes may be (or may have been) exported and biobanked in the absence of a material transfer agreement (MTA).

2. Ethical issues in research involving the use of HBM

2.1. Informed Consent

With the advancement in biomedical research the ethical and legal issues in research on human biological samples are also increasing. In Pakistan currently no ethical guidelines or legal precedent is available for this issue. Most of contemporary ethical issues are related to absent, uninformed, or poorly informed and understood consent from individuals for the use of their human biological samples. At times even outright deception can be employed. The recent case of Diabetes Project with Havasupai Indian tribe in the USA is one such example of research deception and misconduct. Obtaining a proper informed consent, comprehended and given voluntarily by the individual from whom HBM is sought (even if anonymized), lies at the heart of ethical research. The absence of such consent means disrespecting and violating the rights of individuals to control the use of their bodily tissues for research even if it is considered of
potentially little or no risk to them. An appropriate informed consent is also a means to protect individuals and communities from potential harms including inadvertent breach of confidentiality, stigmatization, and emotional and psychological repercussions.

In industrialized countries, the field of medicine is evolving towards personalized or precision medicine that relies on patients’ genetic information. This has lead biomedical research towards individual genome sequencing raising ethical issues about appropriate and robust informed consent. A recent initiative by the US government called Precision Medicine Initiative (PMI) aims to revise the 25 year old Common Rule known as codified at 45 CFR part 46.\textsuperscript{10} If approved, proposed amendments will make it easier for researchers to perform research using bio-banked materials without renewed consent if the donor had previously consented for storing his or her samples in a bio-bank. While this may facilitate research, the proposal has given rise to several potentially troubling ethical issues that are being currently discussed.

Research, whether national or multinational in nature, using HBM from people from countries like Pakistan adds complexities to the informed consent process due to local contexts. These include collective, hierarchical, and family centered decision making processes rather than by individuals.\textsuperscript{11} In addition, the tremendous existing power differentials (due to levels of education, social status, economics, etc.) between physicians/researchers and research participants makes the research participant especially vulnerable to exploitation and deception. It is important that physicians/researchers be aware of and are sensitive to these factors and they must employ appropriate steps to facilitate and ensure that the informed consent process is not coercive but respects the rights of research participants to make choices regarding use of their tissues.

When biological material is to be obtained from children, incapacitated adults, and other vulnerable groups such as prisoners, the proposed research should directly relate to them or their disease, and their inclusion should be based on scientific reasons and not on the convenience of the researcher. In the case of minors/incapacitated adults the consent should be taken from parents/legal guardians. For mature minors who require a legal consent from guardians, researchers should ensure that they understand the proposed research on their tissues and also seek their permission/assent for it.

2.2. Ownership of HBM

Once a tissue or organ is collected or excised out of the body (for any reason) the question of ownership of that HBM arises. This is a complex issue as humans do not have legal or propriety rights on their organs and tissues. However, some believe that in the medical and scientific realm it may be considered as property.\textsuperscript{12}

Several concepts have emerged as a result of this debate on ownership of HBM. The person from whom the HBM originated is referred to as the owner (or contributor a term being used more often), who is the person who ought to set the terms and conditions for the use of that HBM through the process of informed consent. The institution that takes the HBM then becomes the custodian of the tissues and agrees to use this HBM as outlined by the consent. If the custodian has to send this HBM to another party (if allowed by the consent) then it is custodian’s responsibility to make sure by having a Material Transfer Agreement (MTA) that use
of this tissue by the next party which becomes the possessor who, still remains confined to the terms of the consent under which it was taken.

2.3. Privacy and Confidentiality

An individual’s health related information is considered sensitive and must be treated as private and confidential.

The custodian of HBM should be clear about the intended use of that material and related information. This information must be disclosed and permission sought from the owner in the form of Informed consent as mentioned earlier. HBM must not be used beyond owner’s will. If custodian needs to send HBM to a third party then he/she must ensure that privacy and confidentiality terms as set between owner and custodian are not compromised and that third party consents to abide by those terms. It is also advisable that prior to the material transfer to third party, any identifiable information be coded to further protect the confidentiality.

2.4. Commercial uses and Benefit sharing

The Universal Declaration on Bioethics and Human Rights states in Article 15, “Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries”\(^1\). The commercial use of HBM without sharing benefits with the donor is unfair as it violates principle of reciprocity. However a fine balance needs to be maintained as benefits may raise ethical concerns regarding inducement. Access to medical care and/or drugs stemming from the research, provision for new diagnostics, support for health services and capacity-building facilities for research purposes may be regarded as suitable forms of compensation or benefit sharing.

3. Guidelines for collection, usage and storage of Human Biological Materials

Human biological material may be taken for many purposes as enlisted in this document. Collection, storage and use of HBM for research and other purposes exclusively require a valid informed consent. If HBM is taken for clinical purpose and further research on these samples is planned then consent for the diagnostic and treatment purposes must be separate from the consent for the use of remaining samples in research.\(^14\) A clear explanation should be given to the potential research participants. In cases where 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 Research Ethics Committee’s approval be sought prior to initiating research. Different approaches have been suggested to obtain informed consent for HBM\(^9\) (Annexure -1)
3.1. 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 is it going to be stored

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

3.1.2. Blanket/generic consent for future research in which purpose of the research and other important information is unknown is not recommended (Annexure -1).

3.1.3. Ideal consent in which patients have the most control is a tiered consent. In this consent different levels of permissions are granted to researcher in an explicit way. Modified WHO tiered consent form is available as (Annexure -2).

3.1.4. Tiered consent must contain at least the following important information:

i. Type of HBM collected and the purpose of its collection

ii. Whether HBM will be used further for other research unconnected with this research, including the type of disease in which future research might be done.

iii. Whether HBM will be exported to other country/ies. Mention names of country/ies. Give provision to participant to mention exceptions for any country where participant might not want to send his/her samples. (Guidelines for Export of HBM are mentioned below).

iv. What will be the duration of sample storage and when, where and how will it be disposed or destroyed?

v. Whether this sample will be used for biobanking (either in public or commercial biobank). Options must be given to participant that they may delinked/anonymized or may keep their sample identifiable.

vi. Whether the consent has clearly explained genetic research. Specific consent explaining what genetic research implies must also be taken if HBM is going to be used for genetics research.

vii. The consent should clearly declare if the sample will be used for commercial purposes and if any methodology will be used for benefit sharing.

viii. How will privacy and confidentiality of the participant be maintained

3.1.5. For research on HBM samples which had been previously collected for routine treatment or diagnostic procedure, it is suggested that consent should be taken from these patients. If this is not feasible or practical, then approval from Institutional Research Ethics Committee (REC) is mandatory before using these samples in research, providing reasons as to why re-consent is not possible.

3.2. Confidentiality and privacy should be maintained throughout the research

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

3.2.1. If samples are sent to third party, all parties must abide by privacy and confidentiality terms.

3.2.2. Confidentiality must be ensured by implementing appropriate security measures to prevent unauthorized access and restrict data.

3.2.3. Prior to sending the HBM to third party identifiable information must be coded

3.2.4. The level of anonymization and process should be approved by the Institutional Research Ethics Committee
3.2.5. Privacy should also be maintained at the time of reporting the results. In case of genetic research it must be ensured that any group or community will not be stigmatized by the research outcome.

4. Guidelines for oversight of Human Biological Material for export

It is strongly recommended that the government establish appropriate measures so that all research proposals involving export of HBM are submitted to the NBC-REC for review.

It is also strongly recommended that government makes appropriate legislation for export of HBM.

Many compelling reasons already listed above exist for export of HBM from developing to developed country countries. In addition to research benefits, the exportation of HBM may also have tangible public health benefits because of knowledge transfer. However, despite potential benefits, export of HBM may result in several ethical and legal implications since it involves collection, storage and distribution of information that may result in harm to individuals or groups. Lack of ethical guidance and regulations regarding procurement and distribution of HBM can pose serious international risk to donors as well as recipients of HBM. Hence Governments where institutions (clinical laboratories or R & D organizations) are involved in import or export of HBM must develop some policies or regulations for controlling import and export of HBM to safeguard and protect their individuals and communities against any harm or exploitation. Development of such regulations must take into consideration the input of clinicians, scientists, health regulators, lawyers, ethicists and representatives from civil society and especially donors.

All the aforementioned guidelines for the collection, storage and use of HBM in research are applicable for the export of any HBM. Additionally, any institution or researcher who wishes to export HBM from Pakistan must also follow the guidelines below.

4.1. Approval from National Bioethics Committee (NBC) must be sought before exporting any HBM from Pakistan for research purpose.

4.1.1. Duly filled in application form of NBC-REC (Research Ethics Committee) along with a copy of the proposal must be submitted to NBC for approval. The application form is available at [http://nbcpakistan.org.pk/download.html](http://nbcpakistan.org.pk/download.html) and guidelines for Collection, Usage, Storage and Export of Human Biological Materials are available at [http://nbcpakistan.org.pk/guidelines.html](http://nbcpakistan.org.pk/guidelines.html)

4.1.2. Approval letter of institutional Ethical Review Committees of exporting institution from Pakistan must also be submitted to the NBC with the application form.

4.1.3. Evidence of ethical clearance from the institutional Ethical Review Committee of the institution where HBM is being exported must also be submitted to NBC.
4.1.4. Copy of Material Transfer agreement (MTA) between the two institutions must also be submitted.

4.2. **The institution exporting HBM should be transparent about the purpose for which they wish to export HBM.**

4.2.1. The institution exporting HBM should present a valid purpose for which they wish to export HBM. They must be able to demonstrate to NBC that the purpose for which they are exporting for cannot be achieved within the country. For example researchers sending samples for particular tests that are not available within the country and the results of which can contribute significantly to the knowledge regarding a health problem in their own country is a valid scientific reason to send samples abroad.

4.2.2. Institutional and National Bioethics Committee will evaluate if the justification proposed is acceptable for HBM being transported for research.

4.3. **Any HBM to be exported must be accompanied by the written informed consent from donor (or owner) or his/her legally authorized representative.**

4.3.1. Any HBM to be exported must accompany a written informed consent from donor or owner *i.e.* the person whom tissues belong to or his/her legally authorized representative.

4.3.2. All the requirements of informed consent as described earlier in the consent section must be satisfied for a valid informed consent. Additionally for export purposes the signed consent forms from donor/ owner/ Legally Authorized Representatives (LAR) must explicitly mention that he/she agrees that his/her sample be sent abroad (including the country to which it is being exported) for that specific research.

4.3.3. In cases where it is not possible to submit signed consent forms (in case where researcher has anonymized the samples to be exported or in case the owner or contributor is dead or un-locatable) a copy of the information sheet may be acceptable if researcher assures that the consent was in place. However, this is not recommended and is likely to be an exception rather than a rule.

4.3.4. A waiver to consent of participants may also be granted by NBC in some cases when it is not practically possible to obtain the consent. NBC will evaluate the proposal for following points while considering a waiver:

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

4.4. **Appropriate guidelines must be followed for transportation of HBM.**

4.4.1. For labeling, packaging and handling, World Health Organization (WHO) guidance on regulations for the Transport of Infectious Substances 2011-2012\textsuperscript{15} must be followed.

4.4.2. Appropriate modes of transport, suitable routes and arrangements with people involved must be planned and arranged in advance in accordance with recommended international standards.

4.4.3. Professional courier services must be used whenever possible.

4.5. **Material Transfer Agreement between institutions of both importing and exporting countries must be signed.**

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

4.5.2. MTAs 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.

4.5.3. It must 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.

4.5.4. It is mandatory to submit a copy of MTA to NBC while seeking permission for the export of HBM. (Draft MTA agreements are attached as Annexure 3 & 4 which have been modified from the MTA of the Aga Khan University and Indian Council of Medical Research’s MTA.)
## 5. Annexure 1

### Approaches to Obtaining Informed Consent

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<td>Specific consent</td>
<td>Consent is taken for use of HBM for a specific research project. If participants give permission they are re-contacted for each new research project.</td>
<td>Participant has full control, has full information about risk/benefit about the study</td>
<td>Cumbersome, not cost effective, may lead to loss of valuable data, difficult to locate participants and participants may have to be reached multiple times.</td>
</tr>
<tr>
<td>Open, generic or blanket consent</td>
<td>Individual gives consent to any kind of future use of tissue and unlimited time duration for storage. Participants give permission to use HBM for any research in future with no time limits on storage.</td>
<td>Extensive usage, least burdensome and most cost effective (no need to re-contact), no loss of data and participants avoid being re-contacted.</td>
<td>Least control over use of HBM, loss of data of participants that may consent to some use, provides nothing about future risks or benefits so not truly informed consent and participants cannot reconsider about HBM use.</td>
</tr>
<tr>
<td>Tiered or broad consent</td>
<td>Individual may agree to various options for future use including general or specific consent on whether disease related or non-related, genetic use, time and use for commercialization. Participants is given a list of options that they can choose</td>
<td>Participant retains some control of HBM for future use, reduces burden on researchers as compared to specific consent</td>
<td>Gives less leeway to participants if they want to participate in new research later which could not have been anticipated earlier and makes consent form to complex.</td>
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These include types of future research (genetic and commercial) and duration of storage, and gives flexibility to participants and being re-contacted.

| Presumed, opt-out or implicit consent | Here it is presumed that the individual gives blanket consent for future use unless they opt-out. It is presumed that participants have given general consent unless they specifically opt out or do not give permission. | Lowest cost, no burden on researcher, maximizes usage of HBM participants avoid being re-contacted. | Least control over HBM use, all disadvantages of general consent and in addition requires specific action to prevent usage, it requires a high degree of awareness among general population |
6. Annexure 2

Sample Consent Form (WHO)
Certificate of Consent

☐ I wish my [TYPE OF SAMPLE i.e. blood, tissue, etc] I have provided for this research project to be immediately destroyed after this research is over. (Tick one choice)

☐ I do not allow my sample to be sent outside Pakistan.

☐ I allow my [TYPE OF SAMPLE] sample to be sent outside Pakistan [anywhere or except ----countries].

☐ I allow my [TYPE OF SAMPLE i.e. blood, tissue, etc] I have provided for this research project is unused or leftover after completion of this research to be store under following conditions. (Tick one choice from each of the following boxes).

☐ I want my [TYPE OF SAMPLE] sample to be destroyed after ____ years.

☐ I give permission for my [TYPE OF SAMPLE] sample to be stored indefinitely

AND (if the sample is to be stored)

☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research but only on the same subject as the current research project : [give name of current research]

☐ I give my permission for my [TYPE OF SAMPLE] sample to be stored and used in future research of any type which has been properly approved except genetic research.

☐ I give permission for my [TYPE OF SAMPLE] sample to be stored and used in future research except for research about [NAME TYPE OF RESEARCH].

AND

☐ I give permission for my [TYPE OF SAMPLE] to be stored and used for commercial purposes.

☐ I want my identity to be removed from my [TYPE OF SAMPLE] sample.

☐ I want my identity to be kept with my [TYPE OF SAMPLE] sample.

questions about it and my questions have been answered to my satisfaction. I consent voluntarily to have my samples stored in the manner and for the purpose indicated above.
Print Name of Participant__________________

Signature of Participant__________________

Date(Day/month/year)________________________

If illiterate

A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Print name of witness__________________ AND Thumb print of participant

Signature of witness__________________

Date (Day/month/year)________________________

Statement by the researcher/person taking consent

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

1.

2.

3.

I confirm that the participant was given an opportunity to ask questions about the nature and manner of storage of the samples, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.
Print Name of Researcher/person taking the consent__________________________

Signature of Researcher /person taking the consent__________________________

Date ____________________________

    Day/month/year
Material Transfer Agreement

MODIFIED FROM AKU DRAFT MTA

[Rs. 100 Stamp paper]
Material and Information Transfer

Agreement for Research Use

Agreement made this ___ day of _________ (hereinafter the “Effective Date”); by and between [Name of institution] (hereinafter referred to as “XYZ”) a statutory body corporate established and existing under the laws of Pakistan at [Address] through its Department of ______________ and ______________________, __________________________ (hereinafter referred to as “Recipient”).

WHEREAS, _________________ of the Recipient is providing technical and intellectual assistance to XYZ in a study titled ‘_________________________’ (hereinafter the “Study”) and _________________ from XYZ (the “Local PI”) is responsible for conceptualizing and designing the Study and for identification and collection of patient samples.

AND WHEREAS, XYZ requires further processing of Biological Material (as defined below) including _________________ collected for the Study and Recipient has agreed to assist XYZ with this matter.

AND WHEREAS, Recipient and XYZ now wish to enter into this Material Transfer Agreement solely to outline the responsibilities related to the transfer and usage of the Biological Material.

The parties hereby agree to the following:

1. The Biological Material and information is being used for not for profit research purposes. “Biological Material” shall mean any biological samples collected from the Study participants in Pakistan during the Study which shall not be used for any other purpose.

2. The usage of the Biological Material will be only for the purposes outlined in the Study Protocol. The usage for any secondary purposes will be decided after discussions between and with the mutual consent of both the parties.

3. Neither Recipient, nor XYZ will use the Biological Material in a way that would violate the participants consents obtained for the Study and shall comply fully with all applicable environmental, health and safety laws and other applicable regulations with respect to its use.
4. The Biological Material is of an experimental nature and is provided without warranty of fitness for any purpose, or any other warranty or representation, whether express or implied.

5. Upon completion of the study, any remaining Biological Material acquired from XYZ pursuant to this agreement will be returned to XYZ. For the avoidance of doubt Recipient shall own absolutely and is entitled to retain and use without restriction (subject to paragraph 11) the data, results and information it generates through performance of the work it carries out under the Study Protocol (the “Results”).

6. No new experiment/analysis (including analysis of biological samples) shall be performed by Recipient without the prior consent of XYZ. The Local PI has the right to retain the part / copy of the biological sample/strains / left over samples in XYZ repository for reference and further research if consent was taken prior to collection.

7. The Local PI agrees that it shall follow the agreed Protocol, all relevant written instructions of, applicable local laws and regulations, compliance to biosafety and all relevant laboratory guidelines in the transfer of the Biological Material (attached laboratory guidelines hereto) and any associated data in relation to the Biological Material.

8. The Biological Material will be de-identified subject to the consent by the Local PI before being used for research.

9. All intellectual property rights in all materials, specifications, and other technical and commercial information related to the Study in existence prior to the Effective Date (“Background IP”) and any patents, inventions, copyrights, database rights, design rights, (whether registered or not and all applications for any of the foregoing), whenever and howsoever arising and all other similar forms of intellectual property, subsisting now or at any time in the future that solely and directly relate to the Biological Material (“Material IP”) and any documentation or instructions provided by the XYZ shall remain vested in XYZ. All other patents, inventions, copyrights, database rights, design rights (excluding Results) and any intellectual property rights that may subsist in them generated by Recipient as a result of its work under the Study Protocol (“Other IP”) shall be jointly owned in equal undivided shares by Recipient and XYZ.

10. XYZ hereby grants to Recipient a non-exclusive, perpetual, irrevocable, worldwide, royalty free licence, sub-licensable with the prior consent of XYZ to academic institutes and researchers in receipt of Recipient funding to Material IP solely for internal, non-commercial research purposes only. Recipient and XYZ each hereby grants to the other a non-exclusive, perpetual, irrevocable, worldwide, royalty free licence to Other IP solely for its own internal, non-commercial and academic research purposes save that Recipient may with the prior consent of XYZ sub-license such license to academic institutes and researchers in receipt of Recipient funding.

11. Recipient hereby agrees to supply the Results to XYZ. Any publication or other proposed disclosure in relation to the Results shall be a collaborative effort between the parties and prior to publication each party shall consult with the other and mutually agree in good faith and in the interests of scientific advancement the form and content of the publication or other disclosure. Neither of Recipient nor XYZ shall disclose the Results to any third party without the consent of the other party until the Results have been published in accordance with this paragraph 11. XYZ agrees and confirms that Recipient will be given appropriate acknowledgment and due credit of their contribution in the completion of the Study and Recipient agrees that XYZ and __________________ shall be acknowledged
as the source of the Biological Material and given credit in accordance with academic custom.

12. Both parties have the right to terminate this agreement forthwith at any time by means of written notice to the other. In the case of any termination Recipient shall discontinue all use of the Biological Material and, at XYZ’s discretion, promptly return or destroy all unused Biological Material.

13. Recipient agrees to maintain or cause to be maintained in confidence all information received from XYZ under this Agreement (collectively “Confidential Information”). Notwithstanding the foregoing, the obligation of non-disclosure shall not apply to the following:

   a. information that is or becomes publicly available through no fault of Recipient;

   b. information that is already independently known to Recipient, as shown by its prior written records, or

   c. information that is disclosed to Recipient on a non-confidential basis by a third party with the legal right to do so or who is not otherwise bound by confidentiality obligations;

   d. information that is or becomes public knowledge as required by law.

14. Any communication given under or in connection with this Agreement shall be in writing and shall be delivered personally or sent by courier to the address of each party stated above or sent by email, in the case of the Recipient to ___________________________ and in the case of XYZ to ___________________________.

15. The parties agree to try to settle any conflict arising from the performance of this Agreement amicably by negotiations between senior executives of the parties.

15. Neither party may, without the prior written consent of the other, assign or transfer, delegate or subcontract to any third party any of its obligations hereunder.

16. If any provision of this Agreement is or becomes for any reason whatsoever invalid, illegal or unenforceable, it shall be divisible from this Agreement and shall be deemed to be deleted from it and the validity of the remaining provisions shall not be affected in any way.

17. The parties acknowledge that this Agreement constitutes the entire understanding between parties and that it has not been induced to enter into the agreement in reliance on, nor has it been given, any representation, warranty or other statement of any nature whatsoever other than those set out in the agreement.
IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Signed for and on behalf of ___________________ in presence of

Witnesses:

1. ___________________  ___________________
   Name:  Designation:

2. ___________________
   Name:  Designation:
Material Transfer Agreement

MODIFIED FROM INDIAN COUNCIL OF MEDICAL RESEARCH

Please specify: IMPORT/EXPORT of biological material

1. Name and address of the Institution/Agency providing the bio-material (Sending Party):

2. Name and address of the Institution/Agency where material is to be sent (Receiving Party):

Nature/type of bio-material to be transferred.

1. Whole blood/Serum/Plasma/Urine/other Body Secretions/Excretions/Body cavity fluid/Tissue/Cell culture/Microbial product/Nucleic acid/ others - Pl. specify the source.

2. Number of biological samples to be transferred.

3. Quantity/volume of samples to be transferred.

4. Period/duration (months/years) over which material to be transferred. (Pl. also indicate the frequency of transfer of material)

5. Purpose of transfer of biological material. Please specify.
   i) Bioavailability/Bioequivalence/Pharmacokinetic studies
   ii) Clinical trials
   iii) Diagnostic testing
   iv) Quality Assurance/Calibration for maintaining high standards of Indian laboratories
   v) Any other purpose – pl. specify

6. Purpose and need of transfer of the material:
   For a) Research purposes b) Commercial purposes

   a) If for Research purposes: Type of research/investigations to be carried out using the bio-material (Brief description in 250 words).
   b) If for Commercial purposes: Details of commercial activity and type of research/investigations to be carried out using the bio-material (Brief description in 250 words).
The transfer of biological material is governed by the following conditions:

1. The receiving Institution/Agency shall be the only user of the bio-material.
2. The bio-material shall not be transferred to any other person/agency in any circumstances.
3. The Memorandum of Understanding shall be signed between Indian applicant and international agency defining the commercial benefits to each Party.
4. Details of the Intellectual Property Rights (if any) owned in terms of patents, copyright or an MoU/agreement signed by any of the Parties on biological/genetic material being transferred for commercial purposes to be submitted.
5. No patent/intellectual property issues shall be filed on any product or process developed with this bio-material without the written consent of the Agencies involved.
6. The requesting Institution indemnifies the donor Institution from all damages that may occur due to improper handling of the bio-material.
7. The present MTA shall only be applicable for the said purpose and cannot be transferred/assigned to any other Agency/Institution.
8. The brief report/certificate of safe utilization and disposal shall be provided within 3 months of the last use of imported biological material in prescribed format.

Signature (with seal):
(Sending Party)

Signature (with seal):
(Receiving Party)

Date: Date:
9. References


