# National Guidelines for Transfer of Human Biological Materials Outside Bhutan for Research Purposes

Ministry of Health

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## Foreword

The transfer of human biological materials across borders has become an essential component of global health research and collaboration. In Bhutan, the need to formalize the procedures governing these transfers has grown significantly with the expansion of research activities and international partnerships. Recognizing this necessity, the Ministry of Health is pleased to present the National Guidelines for Transfer of Human Biological Materials Outside Bhutan for Research Purposes.

This guideline is an important milestone in our efforts to ensure that research involving human biological materials adheres to the highest ethical and legal standards. It reflects Bhutan's commitment to safeguarding human dignity, protecting participant rights, and promoting equitable benefit-sharing from research outcomes. The provisions outlined in this document are grounded in international ethical frameworks, such as the guidelines developed by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO), while also incorporating Bhutan's unique cultural and legal contexts.

This guideline provides clear, standardized processes for obtaining ethical approvals, drafting and signing Material Transfer Agreements, and ensuring compliance with national and international regulations. By fostering transparency and accountability, it strengthens the trust between researchers, participants, and institutions, both within and outside Bhutan.

I express my gratitude to the High-Level Committee of the Ministry of Health, the Research Ethics Board of Health, and all other stakeholders whose dedication and expertise have been instrumental in developing this document. It is my firm belief that this guideline will serve as a cornerstone for advancing ethical research in Bhutan while contributing to the global body of knowledge.

As we move forward, I urge all stakeholders to adhere to these guidelines with the utmost integrity and commitment. Let us work together to ensure that Bhutan continues to uphold its values and responsibilities in the global research community.

With best wishes,

(Lyonpo Tandin Wangchuk)
Health Minister

## Acknowledgments

The Ministry of Health extends its deepest gratitude to all individuals and organizations who contributed to the development of the National Guidelines for Transfer of Human Biological Materials Outside Bhutan for Research Purposes. This document would not have been possible without their expertise, dedication, and collective efforts.

We sincerely thank the contributors for their instrumental roles in drafting and finalizing the guidelines:

- Tashi Penjor – Policy and Planning Division, Ministry of Health
- Mongal Singh Gurung – Policy and Planning Division, Ministry of ealth
- Tshering Choden – Legal Section, Ministry of Health
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- Tshering Samdrup – Policy and Planning Division, Ministry of Health
- Kinley Dorjee – Policy and Planning Division, Ministry of Health

Special appreciation is extended to the reviewers for their invaluable feedback and guidance, which have greatly enhanced the quality and relevance of the guidelines:

- Kinga Jamphel – Chairperson, High-Level Committee Sub-Committee (Director DHS MoH)
- Kuenzang Chhezom – Member, High-Level Committee Sub-Committee (Registrar KGUMSB)
- Tashi Norbu – MECRIT, Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB)
- Tshering Jamtsho – MECRIT, Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB)

The Ministry also acknowledges the efforts of the Research Ethics Board of Health (REBH), Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB), and all other stakeholders for their contributions to ensuring this document adheres to both national and international standards.

Finally, we express our gratitude to the High-Level Committee of the Ministry of Health for their approval and continued support in strengthening research ethics and governance in Bhutan.

## Executive Summary

The National Guidelines for Transfer of Human Biological Materials Outside Bhutan for Research Purposes have been developed to streamline the processes for transferring human biological materials for research purposes while safeguarding ethical standards and ensuring compliance with both national and international laws. The guidelines aim to provide a standardized framework for researchers, institutions, and regulatory bodies to follow when handling such materials, ensuring the protection of human rights, safety, and fair use.

The document outlines procedures for obtaining ethical and administrative approvals, drafting and executing Material Transfer Agreements (MTAs), and monitoring the compliance of recipients with the terms of transfer. It also defines roles and responsibilities for stakeholders involved in the process, including the Ministry of Health, Research Ethics Board of Health (REBH), and researchers.

Key components include:

- Clear steps for ethical review and administrative clearances.
- Detailed guidance on drafting and signing MTAs, including benefit-sharing provisions.
- Compliance monitoring and reporting requirements.
- Ethical and legal considerations aligned with international standards.

This guideline seeks to foster a culture of accountability, transparency, and mutual respect in international research collaborations, supporting Bhutan's efforts to advance health research without compromising ethical integrity.

## Background and Rationale

The transfer of human biological materials[1] across borders for research purposes requires strict ethical and legal oversight to ensure the protection of human rights, safety, and the fair use of resources. Such transfers, commonly governed by Material Transfer Agreements (MTAs), must align with both national and international standards to uphold the ethical use of human biological materials and safeguard participants' rights.

In Bhutan, the Research Ethics Board of Health (REBH) was established by the Ministry of Health in January 2009 to ensure that all health-related research involving human subjects is conducted ethically. The National Health Policy 2011 mandates that any health-related research involving human participants must obtain prior ethical approval from REBH. This requirement aligns with the international "Guidelines for Health-related Research Involving Humans" issued by the Council for International Organizations of Medical Sciences (CIOMS) in partnership with the World Health Organization (WHO), which stipulates the need for comprehensive ethical review and formal agreements, such as MTAs, before biological materials are transferred. Similarly, an Institutional Review Board (IRB) was established at the Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB) in June 2021, primarily to facilitate ethical clearance for research involving human subjects conducted within the university or its affiliated institutions.

The Rules of Procedure for Treaty Making 2016 additionally require political clearance from the Ministry of Foreign Affairs (MoFA) and approval from the Lhengye Zhungtshog for legal instruments related to any matter with an external party. This process, reinforced by directives from MoFA in 2021, underscores the critical need to standardize the transfer of human biological materials within a legal framework that protects national interests, respects participant rights, and maintains the integrity of research processes.

To streamline these processes and ensure compliance with both domestic and international standards, the Ministry of Health has developed the “National Guidelines for the Transfer of Human Biological Materials Outside Bhutan for Research Purposes.” Approved by the High-Level Committee of the Ministry of Health, these guidelines establish a standardized procedure for managing requests, approving transfers, and monitoring compliance, thereby ensuring ethical handling of human biological materials and fostering international research collaboration.

1 For the purposes of this guideline, “human biological materials” include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, feces or excrement, saliva, or other bodily fluids.

## Effective Date

1. This guideline shall come into force on the 7th day of the 12th month of the wood female snake year corresponding to 4th day of February month of 2025.

## Purpose

2. This guideline establishes the procedures and requirements for transferring human biological materials for research purposes.

## Guiding Principles

3. All transfers of human biological materials outside Bhutan for any research must be governed by a Material Transfer Agreement (hereinafter referred to as "MTA").
4. The MTA must document the biological materials to ensure their retrievability.
5. The MTA must specify the range and duration of use, and outline the procedures for handling the materials at the end of the usage period (including benefit sharing) and clearly define the responsibilities related to these elements..

## Responsibilities of the Provider Investigator

6. The Provider[2] Investigator must obtain prior informed consent or informed assent from the research participants and their legally authorized representatives, as determined by the Research Ethics Board, before collecting and transferring biological materials.
7. The Provider Investigator must ensure that all necessary clearances and approvals required by laws and policies are obtained, including permission from the study sites, before the collection and transfer of human biological materials.

## Responsibilities of the Recipient

8. The Recipient[3] shall safeguard the transferred materials to prevent misuse and third-party transfer without prior written consent and approval from the Ministry of Health (hereinafter referred to as "MoH"), Royal Government of Bhutan (hereinafter referred to as "RGoB").

2 The entity transferring the human biological material from Bhutan, along with the designated Provider Investigator

3 The entity receiving the human biological material outside Bhutan, along with the designated Recipient Investogator

9. The Recipient shall inform relevant authorities within their organization about the conditions set forth in the MTA and the usage of the transferred materials.

## Reporting Requirements

10. Both the Recipient and Provider Investigator must submit six-monthly progress reports on the study to MoH / REBH.
11. If progress reports are not received on time, the Recipient and Provider Investigator must submit the report to the MoH within ten working days upon receiving the written reminder from MoH.
12. The full study results, including any confidential information, must be submitted to MoH upon completion of the study.

## Ownership and Intellectual Property

13. Ownership of the transferred material remains vested with the individual human subject or the RGoB and will be as per the terms of the MTA.
14. The Recipient and Provider Investigator shall inform the MoH,, of any confirmed new discoveries arising from the study within 30 days of confirmation.
15. The Recipient and the Provider Investigator shall not apply for any intellectual property rights without prior written approval from the MoH.

## MTA Signatories

16. For studies led by a budgetary body under RGoB , the MTA must be signed by the Minister of Finance as per the Public Finance Act, 2007 or the Finance Minister may delegate the concerned Minster to sign the MTA.
17. For individual-led studies, the MTA may be signed by the Provider Investigator after obtaining written approval from the Head of the concerned agency or institution.

## MTA Process

18. The Provider Investigator is required to complete and submit the draft MTA using the MTA Template as provided in Annexure I. This MTA, along with the research proposal shall be submitted to the Policy and Planning Division (hereinafter referred to as PPD), MoH, for administrative clearance.
19. The PPD will conduct an initial review of the MTA along with the research proposal request and forward the draft MTA to the Legal Services of MoH for vetting.

20. If deemed satisfactory, the PPD shall issue a conditional administrative clearance to enable the Provider Investigator to seek ethical clearance. This clearance will specify the requirement to obtain ethical clearance from either the Research Ethics Board of Health (hereinafter referred to as REBH) or an appropriate Institutional Review Board (hereinafter referred to as IRB) certified by the MoH. The conditional administrative clearance shall explicitly state: "This is not an approval for the signing of the MTA."

21. For studies led by a budgetary body under the RGoB, upon legal vetting of the draft MTA by the Legal Services and subsequently approved by the REBH or IRB, the PPD shall:

    1) Facilitate to seek political advice and clearance from the Ministry of Foreign Affairs and External Trade (MFAET),

    2) Facilitate to seek legal vetting from the Office of the Attorney General through Cabinet Secretariat;

    3) Facilitate to seek indemnification clearance from the Ministry of Finance.

    4) Upon getting clearance from the MFAET and OAG,, the final approval must be sought from the MOU Review Committee.

22. For individual-led studies, once the draft MTA has been legally vetted by the Legal Services and approved by the REBH or IRB, the PPD shall:

    1) Facilitate to seek political advice and clearance from the MFAET, and

    2) Facilitate to seek legal vetting from the OAG through Cabinet Secretariat.

    3) Upon getting clearance from the Facilitate to seek MFAET and OAG, the final approval must be sought from the of the MOU Review Committee

23. The Provider Investigator shall submit a copy of the signed MTA to the PPD, MoH, and the Legal Services, MoH, for record-keeping and for any follow-up requirement.

## Implementation and Compliance

24. All implementing Parties must adhere to this guideline to ensure proper handling and transfer of human biological materials for research.

25. The Parties are encouraged to use the MTA Template as provided in annexure I of this guidelines document.

## References


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7. Public Finance Act. (2007). Royal Government of Bhutan.
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9. Declaration of Helsinki. (2013). Ethical Principles for Medical Research Involving Human Subjects. World Medical Association.
10. Good Clinical Practice Guidelines (ICH E6). (2016). International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
11. National Biodiversity Centre (NBC), Bhutan. Tips on Material Transfer Agreement (MTA). Available at: https://nbc.gov.bt/tips-on-mta/

## Definitions and Abbreviations

### Definitions

1. Human Biological Material (HBM): Any biological specimen obtained from humans, including tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, feces or excrement, saliva, or other bodily fluids, used for research purposes.
2. Material Transfer Agreement (MTA): A legally binding agreement outlining the terms for transferring biological materials between parties.
3. Ethical Clearance: Approval obtained from an ethical review board to ensure that the research complies with ethical standards.
4. Benefit-Sharing: The distribution of benefits arising from the use of human biological materials, ensuring fairness and equity.
5. Confidential Information: Information related to the research and materials that is protected from unauthorized disclosure under the MTA.
6. Indemnification: Legal responsibility for any loss or damage caused in the course of the research.

### Abbreviations

- HBM: Human Biological Material
- MTA: Material Transfer Agreement
- MoH: Ministry of Health
- REBH: Research Ethics Board of Health
- IRB: Institutional Review Board
- KGUMSB: Khesar Gyalpo University of Medical Sciences of Bhutan
- CIOMS: Council for International Organizations of Medical Sciences
- WHO: World Health Organization
- OAG: Office of the Attorney General
- PPD: Policy and Planning Division
- HLC: High-Level Committee

## Annexure I: Human Biological Material Transfer Agreement (MTA) Templates

HUMAN BIOLOGICAL MATERIAL TRANSFER AGREEMENT
FOR THE TRANSFER OF BIOLOGICAL HUMAN MATERIALS
FOR NON-PROFIT RESEARCH PURPOSES

This Human Biological Material Transfer Agreement ("MTA") is between [ ] ("PROVIDER") and [ ] ("RECIPIENT"), located at , for the transfer of human biological material, with or without accompanying data, for research purposes as further defined below.

**PARTIES TO THE AGREEMENT**

PROVIDER: the entity transferring the human biological material, along with the designated Provider Investigator; and

RECIPIENT: the entity receiving the human biological material, along with the designated Recipient Investigator.

Both entities, hereinafter individually referred to as "Party" or collectively as "Parties".

This MTA shall come into effect on the date of the last signature below.

RECIPIENT and PROVIDER agree as follows:

1. PROVIDER shall transfer to the RECIPIENT the (specify the material ...) along with relevant(specify.... ) data, collectively referred to as "Human Biological Material" .
2. Descriptive title of RECIPIENT's research with Human Biological Material is: ("Research Project").
3. RECIPIENT SHALL use the Human Biological Material for the approved research purposes. Any commercial use, including selling,commercial screening, or transfer to third parties shall be prohibited.
4. PROVIDER SHALL:
   a. Provide RECIPIENT with personally identifiable information or the code to personally identifiable information with Human Biological Material: ☐ Yes ☐ No
   b. If Box "Yes" is checked above, then RECIPIENT's shall use the Human Biological Material:

1) Relevant privacy rights and requirements;

Applicable human subjects regulations and guidance, which may include Good Clinical Practice Guidelines (ICH E6 Good Clinical Practice), CIOMS International Ethical Guidelines for Health-related Research Involving Humans, and the Declaration of Helsinki amongst others.

2) RECIPIENT's SHALL:

a. maintain any transferred personally identifiable information in a secure manner that restricts access by any individual not involved in the Research Project (e.g., for paper records – locked file cabinets or continual physical presence in a room that locks, or for electronic records – encryption and password protection);

b. remove or destroy the information that identifies the individual who is the subject at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the Research Project; and

c. make no further use or disclosure of the information unless approved by the PROVIDER, except as required by law.

5. RECIPIENT represents that it has obtained ethical approval, as appropriate, to use Human Biological Material.

6. THE RECIPIENT AGREES THAT THIS HUMAN MATERIAL MAY NOT BE USED IN HUMANS OR FOR ANY DIAGNOSTIC, PROGNOSTIC, OR TREATMENT PURPOSES.

7. The Human Biological Materials shall be handled only by RECIPIENT Investigator and research team that are under the direct supervision of RECIPIENT Investigator. Any transfer of Human Biological Material to other than RECIPIENT Investigator's research team requires the advanced written approval of PROVIDER.

8. The Provider shall obtain prior informed consent or informed assent from the participants and their legally authorized representatives, as determined by the REBH/IRB, before collecting and transferring human biological materials.

9. The Provider shall ensure that all necessary clearances and approvals required by law and policy are obtained, including permission from the study sites, before the collection and transfer of human biological materials.

10. All Confidential Information that is transferred between PROVIDER and RECIPIENT is subject to the following:

    1) All information exchanged under this MTA shall be clearly marked "CONFIDENTIAL" by the Parties and safeguarded for a period of three (3) years post disclosure.. Any Confidential Information that is orally disclosed must be reduced to writing and marked "CONFIDENTIAL" by the providing Party and such notice must be provided to the receiving Party within thirty (30) days of the oral disclosure.

    2) For the purposes of this MTA, Confidential Information includes any scientific or business data relating to the Human Biological Material that a Party asserts are confidential and proprietary, except for data that:

        a. have been published or otherwise publicly available at the time of disclosure to the receiving Party; were in the possession of or were readily available to the receiving Party without being subject to a confidentiality obligation from another source prior to the disclosure;

        b. have become publicly known, by publication or otherwise, not due to any unauthorized act of the receiving Party;

        c. the receiving Party can demonstrate it developed independently, or acquired without reference to, or reliance upon, such Confidential Information; or

        d. are required to be disclosed by law, regulation, or court order.

11. RECIPIENT shall not contact or make any effort to identify individuals who are or may be the sources of Human Biological Material, without specific written approval from the PROVIDER.

12. RECIPIENT shall comply with all laws, rules and regulations applicable to the handling and use of the Human Biological Material.

13. The ownership of the human biological materials shall remain vested with the individual human subject or the RGoB as specified in the MTA.

14. Both the Parties shall inform the MoH, RGoB, of any confirmed new discoveries arising from the study within 30 days of confirmation.

15. The Parties r shall not apply for any intellectual property rights related to the Human Biological Material without prior written approval from the RGoB.

16. Both the Parties must submit six-monthly progress reports on the study to MoH / REBH.

17. In cases of delayed reporting, both the Parties shall submit the report to the MoH within ten working days upon receiving the reminder from MoH.

18. The full study results, including any confidential information, shall be submitted to MoH upon completion of the study.

19. In all oral presentations or written publications concerning the use of Human Biological Materials, RECIPIENT shall acknowledge PROVIDER's contribution of Human Biological Material unless requested otherwise by PROVIDER.

20. Any Human Biological Material delivered pursuant to this MTA is understood to be experimental in nature and may have hazardous properties. PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF HUMAN MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

21. No indemnification for any loss, claim, damage, or liability is intended or provided by either Party under this MTA. Each Party shall be liable for any loss, claim, damage, or liability that said Party incurs as a result of said Party's activities under this MTA.

**Governing Law and Jurisdiction:**

22. The agreement and any issues, dispute or claim arising out of or in connection with it or its subject matter or its formation shall be governed by the laws of Bhutan and shall be construed in accordance with the laws of Bhutan and its jurisdiction.

**Dispute Resolution**

23. Any dispute in relation to this Material Transfer Agreement shall be resolved mutually and amicably between Parties.

24. In the event of failure in resolving the dispute amicably, the matter shall be referred to the Royal Court of Justice.

**Validity**

25. This MTA shall be valid for a duration of —------- Years unless renewed by the parties.

**Termination**

26. This MTA may be terminated by either party, at any time, by giving —----- months written notice if either party commits a breach of its obligations as specified in this agreement

27. When the Research Project is completed or this MTA is terminated, whichever comes first, any unused Human Biological Material shall either be destroyed in compliance with all applicable statutes and regulations or shall be returned to the PROVIDER INVESTIGATOR as requested.

The Parties have executed this MTA by their respective duly authorized officers on the day and year hereinafter written. Any communication or notice to be given shall be forwarded in writing to the respective addresses listed below.

**FOR PROVIDER:**

(Signature of Authorized Official)
Date

(Printed Name and Title)

Mailing Address for Notices:

**FOR RECIPIENT:**

(Signature of Authorized Official)
Date

(Printed Name and Title)

Mailing Address for Notices:

**RECIPIENT INVESTIGATOR:**

I have read and understood the terms and conditions of this MTA and I agree to abide by them in the receipt and use of the Human Material.

(Signature) Date

# Annexure II: MTA PROCESS AND DECISION CHART