



National Institutes of Health
Health Research Institute
National Bioethics Committee for Research (NBC-R)

No. 4-87/NBC-HBM-Compliance/2026/ 271

Dated: 19 August 2026

CIRCULAR

To:

The Collectors of Customs / Directorate General of Customs, Pakistan Customs, Federal Board of Revenue at all Airports, Seaports, Dry Ports and Land Border Customs Stations of Pakistan handling export/transit consignments of Human Biological Material (HBM)/research samples.

Subject: IMPLEMENTATION OF THE NATIONAL GUIDELINES FOR COLLECTION, USAGE, STORAGE AND EXPORT OF HUMAN BIOLOGICAL MATERIALS (2020) FOR SHIPMENT OF RESEARCH SAMPLES AT CUSTOMS CLEARANCE POINTS.

Dear Sir/Madam,

1. This is with reference to the earlier memoranda/circulars issued by the Pakistan Health Research Council (PHRC), now the Pakistan Medical Research Council (PMRC), on the subject of collection, handling, storage, transportation and export of Human Biological Material (HBM) vide PHRC/PMRC. Ref No. 4-87/NBC/16/2660 dated Jan 31, 2017 and NIH/HRI Memo No. 4-87/NBCR-Vol-34/23/1094 dated January 3, 2024 whereby the regulatory requirements governing export of HBM from Pakistan were communicated to all concerned quarters, including the Federal Board of Revenue/Pakistan Customs.
2. This Circular relates specifically to the shipment of human biological samples collected under approved research studies/protocols and dispatched internationally to collaborating research institutions, laboratories or sponsors for research purposes such as testing, analysis or collaborative studies. The National Guidelines for Collection, Usage, Storage and Export of Human Biological Materials, 2020, jointly developed and launched by the National Institutes of Health (NIH) and the Ministry of Foreign Affairs on 17 July 2020, lay down the mandatory regulatory framework governing the collection, use, storage, transportation and export of such research samples originating in Pakistan. The Guidelines available at <https://nbcPakistan.org.pk/assets/national-guidelines-for-collection%2c-usage%2c-storage-and-export-of-human-biological-materials-20202.pdf> require, inter alia, (i) approval of the research protocol by the concerned Institutional Review Board (IRB)/Ethics Committee, (ii) prior approval of the National Bioethics Committee for the collection and/or export of the research samples, and (iii) an export/transit/transshipment license or No-Objection Certificate from the Strategic Export Control Division (SECDIV), Ministry of Foreign Affairs, before any research sample/human biological material is shipped out of the country. Pakistan Customs, as the last regulatory checkpoint before physical exit of any such consignment, plays a critical role in enforcing this framework.
3. It has been observed that, despite the aforementioned Guidelines and earlier communications on the subject, consignments of research samples declared or suspected to contain Human Biological Material have, in certain instances, been presented for export clearance without the requisite regulatory approvals, or have been mis-declared as general cargo/diagnostic specimens to avoid scrutiny. Such lapses are in violation of the National Guidelines and expose the country's biosafety, biosecurity and public health interests to serious risk.
4. All Collectorates and Customs Stations are, therefore, once again reiterated to implement the National Guidelines in true letter and spirit at every point of examination and clearance, with immediate effect. In particular, the following essentials shall be ensured to be in place:
 - No consignment of research samples declared, labeled, or suspected to contain Human Biological Material shall be allowed export/transit clearance unless accompanied by (a) evidence of the concerned Institutional Review Board (IRB)/Ethics Committee approval for the underlying research protocol, (b) a valid National Bioethics Committee (HRI/NIH)



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- approval letter, and (c) a valid export/transit license or NOC issued by SECDIV, Ministry of Foreign Affairs in case of pathogen shipment.
- The Goods Declaration (GD) shall be cross-checked NBC's approval and SECDIV license/NOC for consistency of consignor/consignee (sending institution and receiving research laboratory/collaborator) details, description, quantity and reference numbers of the samples, together with the approved research protocol/project reference and the Material Transfer Agreement (MTA) reference where applicable.
 - A dedicated register/log of all HBM consignments examined and cleared at each Collectorate/Customs Station shall be maintained, with copies of the supporting NBC approval, SECDIV license/NOC and GD retained for audit and verification purposes.
 - Any consignment of research samples presented for export/transit that is declared, suspected, or discovered to contain Human Biological Material without the requisite IRB/Ethics Committee, NBC and SECDIV approvals/documentation, or that is found to be mis-declared, shall be detained and immediately reported to HRI-NIH, NBC and SECDIV, and shall not be released pending regulatory clearance or investigation, as the case may be.
 - A nodal/focal Customs officer shall be designated at each major Collectorate, international airport, seaport, dry port and land border station (including but not limited to Karachi, Lahore, Islamabad, Torkham and Wagah) for coordination with NBC at HRI-NIH, and SECDIV on HBM-related consignments.
 - Customs examination and clearance staff posted at export terminals shall be sensitized/trained on identification of HBM consignments and the requirements of the National Guidelines and this Circular.
5. Non-compliance or lapses in the enforcement of the above requirements shall be viewed seriously and may attract action under the applicable laws besides referral to the concerned regulatory and law-enforcement authorities.
6. The Federal Board of Revenue/Pakistan Customs is requested to ensure strict compliance with the above and to circulate the contents of this Circular to all concerned Collectorates, Customs Stations and examination staff with immediate effect. An acknowledgment of receipt and compliance may kindly be furnished to this Institute within fifteen (15) days of the date of issuance of this Circular.
7. For any clarification or guidance regarding the regulatory requirements for export/transit of Human Biological Material, the undersigned/HRI-NIH's NBC focal person may be contacted at +92-051-9206092 email: faiza.bashir.hri@nih.org.pk

This issues with the approval of the Competent Authority.

Dr. Faiza Bashir
Research Director/
National Focal Person
National Bioethics Committee (NBC)
Health Research Institute-NIH
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Copy for information and necessary action to:

- Chairman, Federal Board of Revenue (FBR), Islamabad
- Director General, Strategic Export Control Division (SECDIV), Ministry of Foreign Affairs, Islamabad
- Secretary, Ministry of National Health Services, Regulations & Coordination, Islamabad
- Director General, Directorate General of Customs Intelligence & Investigation-FBR
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