

GOVERNMENT OF INDIA

Ministry of Health & F.W., Department of Health, Nirman Bhawan, New Delhi.

F. No. L. 19015/53/97-IH (Pt.): 19 November 1997

OFFICE MEMORANDUM

Subject: Guidelines for exchange of human biological material for biomedical research purposes

The Ministry of Health & F.W. issued an Office Memorandum No. L. 20025/90/90-F, dated 27 February 1992, which permitted the restricted transfer of biological material abroad under certain circumstances for research/diagnostic purposes. The OM also indicated that the Director-General, ICMR, would be the nodal point to clear all such proposals.

2. The need for revised/expanded guidelines has been felt over the past two years. Accordingly, the Ministry of Health & F. W. has taken necessary steps in this regard.

3. The revised guidelines in respect of HUMAN BIOLOGICAL MATERIAL, in supersession of this Ministry's Office Memorandum No. L. 20025/90/90-F, dated 27 February 1992 are prescribed as under:

I. Definition

Human material with potential for use in the biomedical research: Organs and parts of organs; Cell and tissue; Sub-cellular structures and cell products; Blood; Gametes (sperm and ova); Embryos and foetal tissue; Wastes (urine, faeces, sweat, hair, epithelial scales, nail clippings, placenta, etc.); Cell lines from human tissues;

The sources of these materials could be from patients following diagnostic or therapeutic procedures, autopsy specimens, donations of organs or tissue from living or dead persons, foetal tissues, body wastes or abandoned tissue. Human material could also be held in tissue banks and used for research.

II. Transfer

Guidelines for considering requests for transfer of biological material abroad for research/diagnostic purposes and requests for transfer of biological material from abroad to Indian institutions for research purposes:

(i) Exchange of material for diagnostic or therapeutic purposes for individual cases may be done without restriction, if this exchange is considered necessary by the doctor(s) in charge of the patient. No permission needs to be sought from any authority for this purpose.

(ii) Exchange of material from and to recognized laboratories such as WHO Collaborating Centres or WHO Reference Centres may be allowed as part of their routine activities relating to quality control, quality assurance, comparison with reference material, etc., without having to seek permission from any authority.

(iii) Where exchange of material is envisaged as part of a collaborative research project, the project proposal as a whole must be routed through the appropriate authorities (details under 'III' below) for evaluation and clearance. The exchange of human materials should be an integral part of a collaborative project, which should have been approved by the Institutional Review and Ethics Committee, and not be a separate activity.

(iv) The availability of facilities within India for carrying out certain investigations need not prevent collaboration with scientists in other countries for the same investigations, including transfer of human material, if required.

(v) On the issue of technology transfer/training of Indian scientists abroad/training of foreign scientists and students in India, and visits by the foreign collaborators to their Indian partners' laboratories to work with Indian material, there should be no restrictions on the visits of scientists to the laboratories concerned. However, any field work to be undertaken in the community and other sensitive issues would have to be regulated according to the rules of the Government.

(vi) In order to protect the rights of the Indian study subjects as well as Indian scientists/ organizations, Memoranda of Understanding and/or Agreements on Material Transfer should be entered into between the collaborating partners (Indian and foreign). These should, according to the requirements of case under consideration, include items pertaining to identification of collaborating or sending/receiving parties, background, the material to be transferred and its quantities, purpose of transfer, the research to be carried out using the material, confidentiality, intellectual property rights, filing of patents, arrangements for future commercial exploitation, reporting, publication rights, indemnification, termination of agreement, assignation or transfer of agreement/rights, safety norms to be observed, shipping arrangements, 'qualified user' information, and any other matter that may be relevant to the particular exchange of material.

III. Mechanism

Mechanism for processing requests for transfer of biological material abroad for research/diagnostic purposes:

(i) Agencies and Departments such as ICMR, CSIR, ICAR, Department of Biotechnology and Department of Science and Technology could make use of these guidelines and take decisions accordingly on the requests from their respective institutions.

(ii) The Director-General of Health Services/Ministry of Health & F.W. could utilize the guidelines and take decisions on the requests from the DGHS/Health & F.W. Ministry administered institutions, as also on referrals, if any, from any other government/agency/department not covered under (i) above.

(iii) Autonomous Institutions and Institutions of National Stature such as PGIMER, Chandigarh; AIIMS, New Delhi; Sree Chitra Tirunal Institute of Medical Sciences & Technology, Thiruvananthapuram; and Sanjay Gandhi Post-Graduate Institute of Medical Sciences, Lucknow, and similar institutions of national stature, could be empowered to take decisions on their in-house proposals for foreign collaboration, by following the guidelines.

(vi) Private institutions engaging in collaboration directly with foreign institutions should send their requests to ICMR. If, however, they are also collaborating with an Indian institution as part of the collaborative programme with a foreign institution (for example, between a private institution and a CSIR laboratory collaborating with a foreign institution), then the appropriate central agency (CSIR in the example cited) may decide on the request according to all relevant guidelines.

(v) Biomedical research project proposals for foreign collaboration from medical colleges, universities and institutions under the UGC may be routed through ICMR.

(vi) State Health authorities may take the decision in respect of institutions under their administrative control.

(vii) All foreign collaborative projects in biomedical research (after scrutiny and decision by the respective agencies/Departments as described above from (i) to (vi) are to be placed before the Health Ministry Screening Committee (HMSC) for final endorsement. This would mean that all institutions, agencies and departments would have to send their proposals to the ICMR for obtaining such endorsement by the HMSC, as ICMR is the Secretariat for the HMSC at present.

(viii) It is essential for information to be available in a central location. This could be the Secretariat of the HMSC, i.e. the ICMR Headquarters.

IV. Exchange of biological material for commercial purposes

Guidelines for Exchange of Biological material for Commercial purposes:

The ICMR has been advised to set up a Committee consisting of experts from relevant fields for deciding each proposal on a case-by-case basis and to furnish their views to the Government for consideration. The Committee, in addition to biological material, will also consider proposals involving transfer of medicinal plants and biological molecules developed in the laboratories, after seeking inputs from the relevant experts, if such transfer is for commercial purposes and a proposal in this regard is received from the Foreign Investment Promotion Board (FIPB). A minimum of three months' time would be required to process the FIPB proposals.

sd. (Ashok Mehta)
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