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ICMR to facilitate commercial human biomaterial transfer

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As per the guidelines issued by the ministry of health and family welfare, government of India, of India dated November 19, 1997, a committee has been constituted by director general (DG), Indian Council of Medical Research (ICMR) to consider the cases related to transfer of human biological material for commercial purposes. This will be a continuous process and ICMR will process the applications four times in a year. The future deadlines for submission of applications would be last date of January, April, July and October in each calendar year.

The evaluation of cases where infectious biological material/samples are proposed to be transferred from foreign research centers to Indian diagnostic laboratories/research centers or vice versa for analysis; transfer of human biological waste material or any other cases for commercial purposes will be considered by this committee.

Ten sets of the application including copies of the following documents are required to be submitted by the applicants to ICMR. A copy of the duly signed Material Transfer Agreement (MTA) along with a copy of Institutional/Independent Ethics Committee (IEC) clearance along with the composition of Ethics committee. A copy of the Informed consent/undertaking of individual patient(s) agreeing to the utilization of said biological samples for a particular study/purpose. The undertaking should also clearly state that the patient is willing /not willing (as agreeable to patient) to claim any commercial benefit on the product developed as a result of work carried out on his/her biological samples.

The applicants have to also submit a copy of the import certificate as issued by the relevant foreign regulatory authority to the foreign laboratory receiving the Indian biological samples. A copy of the Memorandum of Understanding signed between Indian laboratory and international agency defining the commercial benefits to each party. A copy of the valid recognition letter as issued by office of drug controller general of India (DCGI) for approval as bioavailability/bioequivalence study centre (for laboratories where biological samples are being received for BA/BE studies).

For transfer of samples, the Indian applicant should follow the 'Guidance on regulations for the transport of Infectious

substances (2009-2010)' as published by World Health Organization. There are specific packing instructions as per United Nations class (6.2) specifications to be followed during transport of infectious substances. Unless otherwise declared the biological materials such as blood and/or blood components; dried blood spots and faecal occult blood; medical or clinical wastes are to be considered under the 'infectious substance category'.

The applicants are required to indicate the category under which the infectious substances/organisms fall. In addition to categories indicated as per UN class specifications in WHO guidelines(2009-10), the applicant should also refer to the relevant categories mentioned under SCOMET items in schedule of India's Foreign Trade Policy classification as well as Animal and Human pathogens scheduled as Risk Groups in the Ministry of Environment and Forests Notification,GoI,1989. Accordingly, the 'category' in terms of infectious nature/risk group of biological substances to be transferred is required to be assigned and indicated by the applicant.