BioSpectrum the business of Bio & Health Sciences

ICMR calls for applications for transfer of human biological material

16 January 2015 | News | By BioSpectrum Bureau

ICMR calls for applications for transfer of human biological material

In a continuous process of allowing the transfer of biological materials for research purposes, the ICMR will process the applications four times in a year. Deadlines for submission of applications would be January 31; April 30; July 31 and October 31 of each calendar year.

As per the guidelines issued by the ministry of health and family welfare vide dated November 19, 1997, a committee has been constituted to consider the cases related to transfer of human biological material for commercial purposes and/or the evaluation of cases involving transfer of infectious biological material/ human biological waste material/ any other cases for commercial purposes from foreign research centers to Indian diagnostic laboratories/R&D centers or vice versa for analysis.

Besides a copy of the duly signed Material Transfer Agreement (MTA), the concerned organizations would have to submit a copy of the Institutional/Independent Ethics Committee (IEC) clearance. Among the other documents to be submitted are a copy of the import certificate as issued by the relevant foreign regulatory authority to the foreign laboratory receiving the Indian biological material (wherein export is concerned); the Memorandum of Understanding signed between Indian applicant and international agency defining the commercial benefits to each Party; copy of the 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.

In addition to it, the interested firms would have to present a copy of safety or operations manual being followed/adopted as safety procedures by your laboratory for the workers involved in activities involving possible exposure to pathogens through blood or other body fluids; copy each of the disposal plan and necessary State pollution Control Board clearance (for disposal of biohazardous, potentially infectious leftover samples);copy of contract/agreement with the disposal agency that the hazardous left over bio-material will be collected, treated and disposed off as per current national regulations.

Also, a duly valid copy of DCGI approval issued to study centre for conducting Bioavailability/ Bioequivalence/ Pharmacokinetic analysis and valid copy of approval for providing services under relevant discipline such as diagnostics/

physical - chemical studies/toxicity studies /medical / biological testing etc, as applicable, from either National Accreditation Board for Testing and Calibration Laboratories (NABL) or certificate for diagnostic/clinical trial labs or Certificate of GLP compliance /DSIR certification as issued by the Ministry of Science & Technology, GoI in the relevant discipline as applicable.

An undertaking that the material being imported has been tested and free from HIV, Hepatitis B & C, Malaria and Syphilis. For transfer of samples, the Indian applicant should follow the WHO document 'Guidance on regulations for the transport of Infectious substances (2013-2014)'. 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'.