BioSpectrum the business of Bio & Health Sciences

ICMR issues guidance on transfer of human biological material

16 June 2014 | News | By BioSpectrum Bureau

ICMR issues guidance on transfer of human biological material

As per the guidelines issued by the Ministry of Health and Family Welfare, government of India dated November 19, 1997, a Committee has been constituted to consider cases related to the transfer of human biological material for commercial purposes and/or evaluation of cases involving transfer of infectious biological material, human biological waste or other cases for commercial purposes from foreign research centers to Indian diagnostic laboratories or R&D centers or vice versa for analysis.

The recent notification from ICMR mentions that about 10 sets of applications including copies of documents are to be submitted by organizations, in English only. The format is available on its website.

The release mentions that separate applications should be submitted for import or export of biological samples as per requirement, separate applications should be submitted for transferring samples to or from different countries. A copy of the duly signed Material Transfer Agreement (MTA); Institutional or Independent Ethics Committee (IEC) clearance along with the composition of Ethics committee (if available in a foreign language, should be translated into English); a copy of the patient information sheet and informed consent form (as approved by IEC) giving details on the utilization of samples of the patient for a particular research or R&D study and the kind of benefit (direct/indirect or no benefit - as applicable) for appropriate decision making by the patient (if available in a foreign language, should be translated into English version); 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); a copy of the Memorandum of Understanding signed between Indian applicant and international agency defining the commercial benefits to each Party and separate copy of the details of the Intellectual Property Rights (if any) owned in terms of patents, copyright or an MoU signed by any of the Parties on the biological or genetic material being transferred for commercial purposes.

Also a copy of safety or operations manual being followed or adopted by the laboratory for workers involved in activities

involving possible exposure to pathogens through blood or other body fluids; copy of the disposal plan and necessary State pollution Control Board clearance (for disposal of biohazardous, potentially infectious leftover samples); copy of the contract or agreement with the disposal agency that the hazardous leftover bio-material will be collected, treated and disposed off as per current national regulations and a duly valid copy of DCGI approval issued to the study center for conducting Bioavailability/ Bioequivalence/ Pharmacokinetic analysis. A duly valid copy of approval for providing services under relevant disciplines such as diagnostics/ physical - chemical studies/toxicity studies /medical / biological testing etc, as applicable, from either of the following to be enclosed.
i) National Accreditation Board for Testing and Calibration Laboratories (NABL) certificate for diagnostic/clinical trial labs or Certificate of GLP compliance /DSIR certification as issued by the Ministry of Science and Technology, GoI in the relevant discipline as applicable. ii) Equivalent approval e.g. from College of American Pathologists (CAP) or any signatory of International Laboratory Accreditation Cooperation Arrangement."

The applicants need to submit an undertaking that the material being imported has been tested and free from HIV, Hepatitis B and C, Malaria and Syphilis.

For transfer of samples, the Indian applicant should follow the downloadable 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'.

The applicants are required to indicate the category under which the infectious substances or organisms fall. In addition to categories indicated as per UN class specifications in WHO guidelines(2013-14), the applicant should also refer to the relevant categories mentioned under Special Chemicals, Organisms, Materials, Equipment and Technologies (SCOMET) items in schedule of India's Foreign Trade Policy classification (downloadable) as well as Animal and Human pathogens scheduled as Risk Groups in the Ministry of Environment and Forests Notification,GoI,1989 (downloadable). Accordingly, the 'category' in terms of infectious nature or risk group of biological substances to be transferred is required to be assigned and indicated by the applicant.

Laboratory Biosafety Manual, World Health Organization -2004 (downloadable) should be followed by Indian applicants to implement basic concepts in biological safety and for the safe handling of pathogenic microorganisms in laboratories.

The Environment (Protection) Act, 1986 and the rules framed there under (downloadable) should be referred to by the applicants for disposal of biological material after due testing of biological samples is done.