F.No. INDO/FRC/442/2008-IHD
INDIAN COUNCIL OF MEDICAL RESEARCH
New Delhi, the 1st July, 2014
OFFICE MEMORANDUM

Subject: Consideration of international collaborative projects by Health Ministry's Screening Committee (HMSC) - further streamlining of the process

1. The HMSC meetings will be held at a regular interval of three months during March, June, September and December of a calendar year.

2. The Technical Divisions at ICMR should complete the review process within 3 months. If peer review meetings are organized for international collaborative projects (in their respective subject areas) at ICMR, members of HMSC (specifically from National AIDS Control Organization; DGAFMS, Ministry of Defence; Department of Biotechnology; Department of Science and Technology) should be invited as specified in a meeting of HMSC held on 25/3/08.

3. In case clarifications/revisions are required after technical review, the revised proposals should be reviewed and placed before HMSC for a decision within six months of receipt of the original proposal at ICMR.

4. The Investigators should submit all the necessary clearances (such as Institutional Ethics Committee clearance; Drug Controller General of India for clinical trials; duly signed Material Transfer Agreement or any other relevant clearance/document) during the submission of project to ICMR. Otherwise, the day on which these documents/clearances will be submitted to ICMR, will be considered the date of receipt of proposal in ICMR.

5. The Technical Divisions should ensure that necessary clearances (such as of institutional ethics committee for research involving human subjects/animal experimentation; of Drug Controller General of India for clinical trials); appropriately filled in and duly signed Material Transfer Agreement, in case of transfer of biological material or any other relevant clearance/document for an individual proposal are received before the experts meet.

6. The Technical Divisions must ensure that in case of international clinical trials (involving use of any new investigational / experimental drug, new applications of drug medical procedure / device) the regulatory requirements of DCGI should be fulfilled and necessary approvals must be submitted by the Indian PIs as per the latest amendments in the Drugs and Cosmetics Act, Govt. of India of January / February, 2013.

7. The Technical Divisions of ICMR should ascertain that the necessary requirements (as per the amended DCGI Act) are fulfilled by the PIs. It may be clearly indicated by the Programme Officers in overall comments and final recommendations of the Technical

Division in item no.45 (f) of ICMR summary sheet whether the research study under consideration is a clinical trial or not as per the provision of Drugs & Cosmetics Act. If yes, whether all the statutory clearances as per Govt. of India norms have been obtained.

8. If there is a specified and written deadline of an international funding agency and indicated by the PI at the time of submission of the proposal, the Technical Divisions should ensure and expedite the technical evaluation for consideration of Chairman, HMSC on file and the papers are to be sent to IHD for endorsement by HMSC in its next meeting. However, the decision of Chairman be conveyed to Indian PI by the Technical Division after Chairman's approval on file.

9. No incomplete proposal will be placed for consideration of HMSC. As per directions of HMSC supplementary agenda will not be entertained. The proposals should be submitted to IHD at least one month ahead of scheduled HMSC meeting.

10. The Technical Divisions at ICMR should immediately identify and inform IHD the name(s) of nodal officer(s) who would coordinate the processing of international collaborative proposals related to their respective divisions and ensure that the projects complete in all respect are submitted for consideration of HMSC.

11. The Technical Divisions should convey the decision of HMSC to the investigators within one week of receipt of approved minutes of HMSC in their Division (without waiting for DST's action for HLC).Proposals approved by HMSC are considered approved from security/sensitivity angle.

12. Investigators are advised to simultaneously submit their applications to the ICMR (Indian PI) and foreign funding agency (Foreign PI). Failing to do so will make PIs ineligible to seek concession under clause 6 above.

13. In view of indication at serial no 2 above, the Indian PI should submit the requisite documents/additional papers as requested by Technical Divisions at ICMR within the stipulated time as indicated by them, otherwise the project file will be considered by the concerned Technical Division as closed due to no response from PI.

This issues with the approval of Chairman, HMSC.

(Dr. Mukesh Kumar)
Head, IHD & Member Secretary, HMSC