Policy Document

Indian J Med Res 151, June 2020, pp 550-553
DOI: 10.4103/ijmr.IJMR_654_20

Quick Response Code:

Indian Council of Medical Research's International Collaboration & Partnerships; Health Ministry's Screening Committee: Facts, figures & procedures

Mukesh Kumar, Harpreet Sandhu & Reema Roshan

International Health Division, Indian Council of Medical Research, New Delhi, India

Received March 12, 2020

There is a great interest among various international agencies/countries in developing partnership with Indian research organizations, particularly with the Indian Council of Medical Research (ICMR) for biomedical research. The ICMR is actively involved in governance and co-ordination of partnerships with several international organizations and agencies. Various MoUs (Memorandum of Understanding)/ agreements of ICMR with international partners bring together the researchers and resources towards progression through shared research and innovation agenda. Growing collaboration during recent years is reflected through increased number of internationally funded/technically coordinated research projects in health research. However, for any international collaborative research study to be undertaken in India, certain regulatory requirements are to be fulfilled. This article summarizes the international partnerships of ICMR as well as the details of guidelines regarding submission of international collaborative research projects for the Health Ministry's Screening Committee (HMSC), which is a mandatory requirement before undertaking such projects.

Key words Collaboration - HMSC - international - partnership - research

The international collaborations are sought under bilateral, multilateral and/or regional collaborative framework to facilitate and strengthen interactions among governments, academia, institutions and industries in the research areas of mutual interest. Currently, India has several bilateral Science and Technology (S&T) cooperation agreements with other countries. The Indian Council of Medical Research (ICMR) operates in close cooperation with the Ministry of Health and Family Welfare (MoHFW), Ministry of Science and Technology (MoST), Ministry of External Affairs, Government of India (GoI), Indian missions abroad and foreign missions in India for the international collaborations. The biomedical health science research prominently figures in all bilateral agreements in the field of S&T. In addition, there are a few specific agreements signed by the MoHFW with other countries as well as those signed directly by the ICMR with its counterpart international organizations/institutions. Currently, there are 23 MoUs (Memorandum of Understanding)/LoIs (Letters of Intent)/Joint

Statements signed by the ICMR with various international organizations/institutes (*https://main.icmr.nic.in/content/guidelines*). These agreements/MoUs/LoIs are for: (*i*) exchange of scientific information; (*ii*) exchange of scientists/technicians for training under the projects; (*iii*) joint execution of scientific projects including support in the procurement of scientific equipment; and (*iv*) organization of joint scientific meetings, seminars, workshops and symposia in identified subjects of cooperation.

The HMSC is an inter-ministerial, high-level committee, constituted by the MoHFW, GoI, in the early 1980s. The purpose of this Committee is to consider and carry out screening of all projects in the field of health research involving foreign assistance and/or collaboration as well as periodically monitor the implementation and progress of bilateral agreements, extension of ongoing research projects and endorsement of transfer of human biological material.

Composition of HMSC

The ICMR acts as the technical arm for the HMSC and conducts technical review of the collaborative research projects. The International Health Division (IHD) in the ICMR Headquarters, New Delhi, is the Secretariat for HMSC and facilitates organization of meetings and placement of collaborative research projects before this Committee as a mandatory requirement. The international collaborative health research projects are scientifically evaluated/scrutinized by the Scientific Divisions at the ICMR Headquarters in the respective subject areas.

In October 2013, the MoHFW, GoI, approved the composition (also the current one) of the HMSC with the Secretary, Department of Health Research (DHR) as the chairman with the following members: Secretary, Health and Family Welfare or nominee; Additional Secretary and Director-General (DG), National AIDS Control Organisation (NACO) or nominee; Secretary, AYUSH or nominee, Ministry of AYUSH; DG of Health Services or nominee; Joint Secretary, DHR or nominee; DG of Armed Forces and Medical Services or nominee; Joint Secretary or Deputy Commissioner, Family Planning or nominee; representative, Ministry of External Affairs (MEA) Coordination Division; representative, Department of Economic Affairs (DEA), Ministry of Finance; representative, Department of Biotechnology (DBT), MoST; representative, Department of Science and Technology (DST), MoST; and Head, IHD, ICMR.

Necessary regulatory requirements

The following regulatory requirements need to be fulfilled by the Indian researchers as part of documents at the time of submission of projects for HMSC's consideration: (*i*) Institutional Ethics Committee (IEC), animal experimentation clearance(s) from all centres/study sites involved in the study; (*ii*) Approval of Drugs Controller General of India in case of the global clinical trials; (*iii*) Registration with the Clinical Trial Registry of India, wherever required (launched by the ICMR in 2007); (*iv*) Foreign Contribution (Regulation) Act permission is mandatory for all institutes/agencies receiving foreign funds; (*v*) Non-government organizations (NGOs) are to be registered at NGO Darpan Portal, NITI *Aayog* and also submit certain other requisite documents; (*vi*) Requisite clearances, if a study involves working with radio-tagged material and recombinant DNA/genetic engineering work (issued by the BARC and DBT, respectively); (*vii*) Any transfer of biological material has to be an integral part of a collaborative research project, and a duly filled in Material Transfer Agreement needs to be submitted (*https://main.icmr.nic.in/content/guidelines*); (*viii*) Guidelines on foreign engagement on bio-safety/bio-security matters (dated December 2015) were prepared and issued by the Division of Disarmament and International Security Affairs, MEA (duly approved by the Cabinet Secretariat), for compliance to protect national security (Weapons of Mass Destruction Act, 2005; *https://www.mea.gov.in/Uploads/PublicationDocs/148_The-Weapons-Mass-destruction-And-Delivery-Systems-Act-2005.pdf* and overall framework of Biological and Toxin Weapons Convention; *https://www.un.org/disarmament/wmd/bio/*); (*ix*) The HMSC also addresses important issues such as safety during transfer of biological material, national security (research should not lead to development of biological weapons), risk from defence and internal security point of view and potential for commercial exploitation, visit by foreigners to sensitive areas in the country with due approval from the concerned ministry/department, GoI; and (*x*) The Nagoya Protocol on Access and Benefit Sharing (a new international treaty adopted under the auspices of the Convention on Biological Diversity in Nagoya, Japan, in 2010) which aims at fair and equitable sharing of benefits arising from

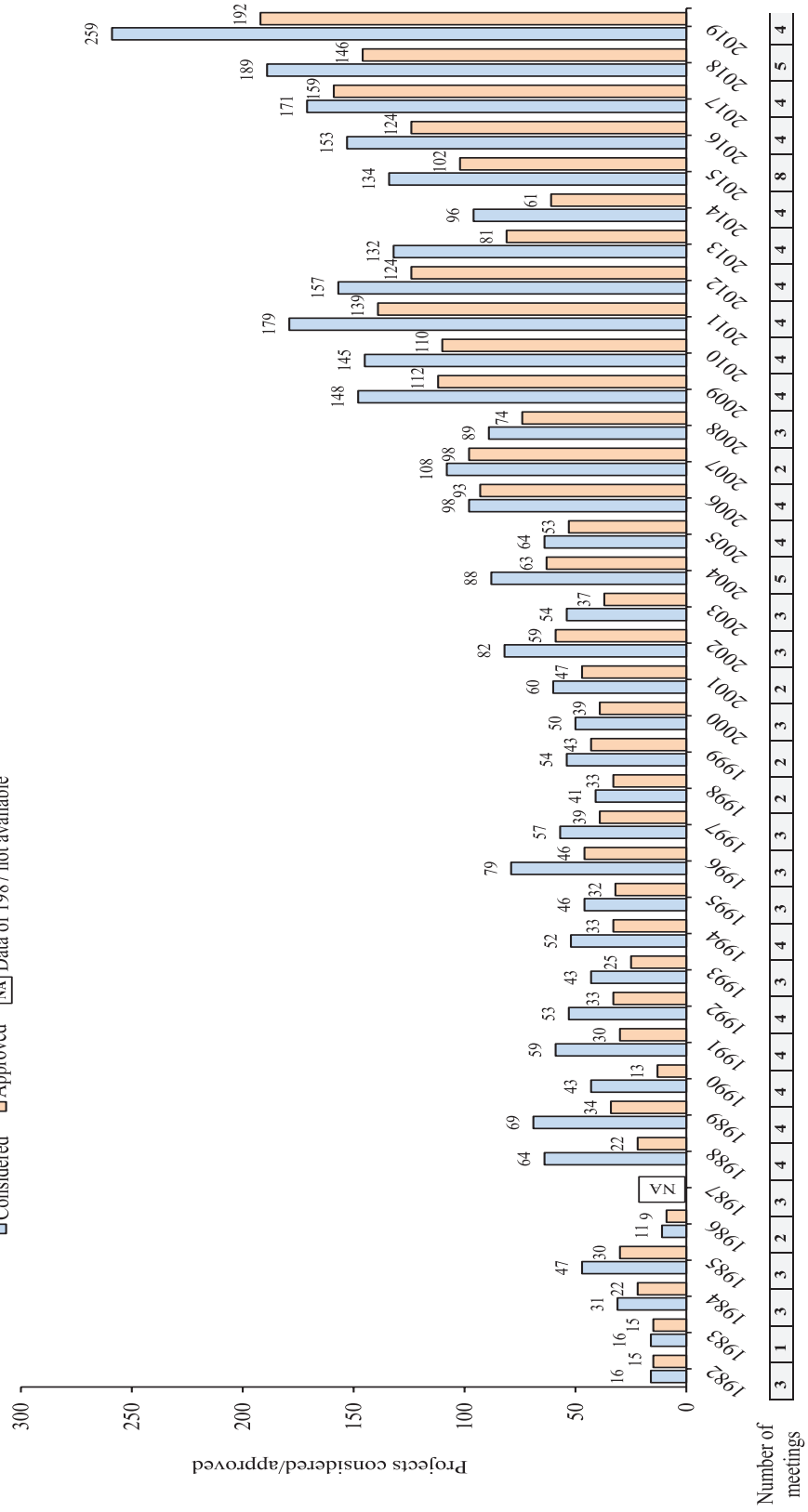

Figure. International projects considered and approved during 1982 to 2019 by the Health Ministry's Screening Committee.

the utilization of genetic resources is required to be followed.

Organization of HMSC meetings

Since the beginning of 2020, HMSC meetings are held at a regular interval of alternate months in a calendar year. The Indian researchers desirous of having foreign assistance and/or collaboration in health research can upload their projects online through ICMR's HMSC portal (*www.icmrextramural.in*) for the approval of GoI through HMSC. The projects can be submitted to ICMR for HMSC consideration throughout the year unless there is a prescribed deadline in a specific Call for Projects under an ICMR bilateral/ multilateral programme.

The peer-reviewed projects are considered by the HMSC for a final decision. A total of 133 meetings have been organized since the inception of HMSC (from 1982 to 2019, Figure). In the meetings held during January 2000 to March 2020, a total of 2494 projects were considered, of which 1946 projects were approved by the HMSC. Lists of projects approved by the HMSC in the last 20 years (*w.e.f.* January 2000 onwards) are available on the ICMR website under: Collaborations > International > List of Approved Projects (*https://main.icmr.nic.in/content/international-collaborative-projects*).

Steps taken for streamlining HMSC procedures

The IHD periodically updates the guidelines for international collaboration and HMSC procedures; however, during the past two years, the ICMR has taken up the following steps to further streamline the process: (*i*) In October 2017, an Advisory was issued by the then Secretary, DHR, and Chairperson, HMSC, to State Principal Secretaries/Institutes/ Medical Colleges/MoST Secretaries advising HMSC clearance to be obtained by Principal Investigators (PIs) for international collaboration and instructed their respective IECs to indicate a clause in clearance to ensure that PIs should obtain HMSC approval before initiation of the study; (*ii*) In March 2019, the Secretary, DHR, and DG, ICMR issued letter to State Governments advising not to allow collection of human samples by private organizations, international stakeholders, NGOs *etc*. without prior approval of the ICMR particularly for research purposes; (*iii*) In September 2019, the DHR, MoHFW has notified that the IECs shall register online with the DHR; (*iv*) In January 2020, the Secretary, DHR, and DG, ICMR issued an advisory to Indian researchers to comply with HMSC procedures for undertaking international collaborative research; (*v*) In March 2020, it has been decided to stop fast-track mechanism of approval of international projects, except in extremely exceptional cases (to be decided on case-to-case basis) in view of increased frequency of HMSC meetings (held every alternate month); and (*vi*) The ICMR/DHR, GoI, is in the process of formulating a rule making prior approval mandatory for undertaking international collaborative research projects and transfer of human biological material, as some countries have specific legislations, such as Medical Research Act/Code for regulation of medical research in a country.

Further detailed information on international collaboration for Indian researchers/investigators and the guidelines for HMSC are available on the ICMR website (*http://icmr/nic.in/guide.htm*). Related information and requisite documents to be uploaded along with necessary downloadable forms/formats, *etc*. are also available.

***Conflicts of Interest*:** None.

For correspondence: Dr Mukesh Kumar, Head, International Health Division, Indian Council of Medical Research, Ansari Nagar, New Delhi 110 029, India
e-mail: mukeshk.hq@icmr.gov.in