

## GUIDELINES FOR INTERNATIONAL COLLABORATION /RESEARCH PROJECTS IN HEALTH RESEARCH

### International Health Division

An Indo-Foreign Cell (IFC) was set up in the Indian Council of Medical Research in the early 1980s to coordinate collaboration in biomedical research between India and other countries/ international agencies. The IFC was upgraded to the Division of International Health (IHD) in the year 2000.

### International Collaboration & Partnerships

The International collaborations are sought under bilateral, multilateral and/or regional collaborative framework for facilitating and strengthening interactions among governments, academia, institutions and industries in the research areas of mutual interest. Currently, India has several bilateral Science & Technology (S&T) cooperation agreements with other countries to facilitate cooperation in the areas of biomedical research between India and foreign countries. ICMR operates in close cooperation with the Indian Ministry of Health & Family Welfare, Ministry of Science & Technology, Ministry of External Affairs, Indian missions abroad and foreign missions in India for the international collaborations.

By and large, biomedical research / health sciences prominently figures in all bilateral agreements in the field of Science & Technology. In addition, there are few specific agreements signed by the Ministry of Health and Family Welfare with other countries as well as those signed directly by ICMR with International organizations/ Institutions.

The purpose of these agreements has been 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 equipments; and (iv) organization of joint scientific meetings, seminars, workshops, symposia in identified subjects of cooperation.

**The Memoranda of Understanding (MoU)/ Joint Statements signed between ICMR and various collaborating global bodies are outlined below:**

1. The **Indo-German** programme has been running in pursuance of Indo-FRG Agreement on Science & Technology signed in January/March, 1974 and subsequently under ICMR-GSF (now taken over by DLR, BMBF), Special Arrangement for cooperation in biomedical sciences signed in January/February, 1976. The ICMR- GSF cooperation was renewed in May, 1990 and further strengthened by signing of an addendum in November, 2005 at New Delhi/Bonn. The areas of cooperation under this agreement cover infectious diseases including AIDS, oncology, family planning and reproduction with special emphasis on birth control, health for mother and child, prenatal medicine, research on scientific basis of traditional medicine with emphasis on composition and pharmacological properties of natural products, environmental toxicology, drug development related to tropical diseases/infectious diseases, bioethics and other biomedical research aspects related to human health.
2. The **Indo-US Joint Statements / MoUs & LoI** signed between ICMR and

## NIH/CDC/DHHS, USA

- i. The Indo-US Joint Statement on **HIV/AIDS** was signed in 2000 and again in June 2006, which was further renewed in October 2011 in USA/India for an additional period of five years till October 2016. The renewed cooperation in the field of STD and HIV /AIDS intends to continue and develop cooperation in the field of basic, clinical, translational, prevention research, training and infrastructure strengthening.
  - ii. The Indo-US Joint Statement on **Diabetes Research** was signed in June, 2012 in USA. The collaborative research projects are mainly aimed for capacity building through scientific knowledge, technology and training needs, developing tools for disease control and prevention such as vaccine and collaboration on prevention, treatment and elimination of disease.
  - iii. The Indo-US Joint Statement on **Environmental and Occupational Health, Injury Prevention and Control** was earlier signed in 2000/2002 and was renewed in June, 2006 until October, 2011. This Jt Statement has been further renewed as MoU in June, 2015 at New Delhi to promote and develop cooperation in the field of Environmental and Occupational Health, injury prevention and control research, education and training, infrastructure development and capacity building.
  - iv. The Indo-US MoU among the NCI (AIIMS), MOH&FW, ICMR (DHR), DBT (M of S&T) and NCI (NIH), DHHS, Govt. of USA for **Cooperation on Cancer Research Prevention Control and Management** was signed in June, 2015 at New Delhi for establishment of the general framework of collaboration for promoting and conducting high quality research to strengthen evidence base necessary for cancer prevention, treatment and management.
  - v. Letter of Intent (LoI) between ICMR, New Delhi and Department of Biotechnology, Ministry of Science and Technology of the Republic of India and the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, DHHS, USA was signed in June, 2015 on **Antimicrobial Resistance Research**.
  - vi. The Indo-US Joint Statement on **Maternal & Child Health and Human Development Research** was signed in June 2000 in USA and renewed in June 2006 in USA to facilitate research collaboration that contributes to the global understanding of the causes of morbidity and mortality in women particularly mothers, children and adolescents (likely to be renewed).
3. An MoU was signed between **ICMR and Canadian Institutes of Health Research (CIHR), Canada** for cooperation in the field of biomedical sciences at New Delhi in January, 2005 wherein areas such as lifestyle diseases, public health & disease surveillance were identified for collaboration. Certain new areas of mutual interest such as Human development, Child and youth health; Infection immunity; Neurosciences, mental health & addiction have been included in the renewed MoU for collaboration signed in March, 2011 at New Delhi.
  4. An MoU between **ICMR and Helmholtz Association (HGF), Germany** for cooperation in Medical Research was signed in April, 2006 at Hannover, Germany during the visit by the then Prime Minister of India to Germany. ICMR and Helmholtz Association are distinguished research organizations in their home countries with outstanding scientific resources and technical facilities at their disposal. The areas of interest, which have been identified for

cooperation, are infectious diseases, oncology & biomedical research related to health. Under this MoU, a virtual Indo-German Science Centre for Infectious Diseases (IG-SCID) was inaugurated in April, 2007 which was located at the Council's Headquarters and slated to promote research in identified areas of infectious diseases through joint research projects with Indian and German funding. The IG-SCID was in operation till 31<sup>st</sup> Dec. 2013. The organization of joint workshops, exchange of scientists/ researchers and execution of twinning projects were the modes of cooperation. Five areas of collaborative priority namely Genetic susceptibility, Vaccines & anti-infectives, Viral diseases (HIV/HCV), Animal models of infectious diseases and Zoonoses were identified under this programme.

This Indo-German collaboration has been extended and pushed further in the area of infectious diseases especially in translational research. The MoU between ICMR and HGF in May, 2011 was renewed by the Secretary, Department of Health Research, MOH&FW, GOI & Director General, ICMR from Indian side and the Scientific Director, Helmholtz Centre for Infection Research (HZI) from German side at New Delhi in the presence of the then Prime Minister of India and H. E. Chancellor of Germany. This MoU would provide the active translational efforts, which combine basic and clinical research and thus advance the fight against infections in biomedical research with long-term capacity building for researchers and scientists, in both the countries.

5. The **Indo-US Joint Statement** for Establishment of **International Centre for Excellence Research (ICER)** at National Institute for Research in Tuberculosis, Chennai was signed in June, 2003 and extended in May, 2008. The scientific focus is to continue ongoing activities and to expand cooperation in the areas of epidemiology, molecular biology, medical entomology, parasitology, immunology bacteriology, microbiology, virology etc. with emphasis on techniques for the prevention, diagnosis and treatment of tropical infections and allergic diseases. The collaboration is likely to be renewed further.
6. An MoU between **ICMR and University of Minnesota (UoM), USA** was signed in October, 2006 at New Delhi for the development and expansion of research, medical education and clinical programmes in the areas of medicine and public health. The purpose of this collaboration is to build upon the synergy of expertise on both sides for promotion and conduct of research. The initial research efforts will develop around areas such as field epidemiology, cardiovascular medicine, cancer, infectious diseases, immunology, metabolic diseases, obesity, diabetes and public health initiatives. Later in 2009, cancer and diabetes were identified to start with the collaborative projects through a joint call for proposals. The collaboration was further renewed in November, 2011 by both the sides.
7. An MoU between **ICMR and London School of Hygiene and Tropical Medicine, London (LSHTM), United Kingdom** was signed in February/September, 2009 at London and New Delhi to build upon the synergy of expertise of each party for the promotion and conduct of research in the areas of Public Health; Cardiovascular medicine; Cancer; Infectious diseases including vector borne disease; Metabolic diseases; Obesity/Diabetes; Research support to National Rural Health Mission of India. The collaboration is likely to be renewed further.
8. In February, 2010, **ICMR and Medical Research Council (MRC), United**

- Kingdom** signed a MoU at New Delhi to encourage joint research in a range of health areas including persistent, new and emerging infections; Chronic non-communicable diseases; Impacts of environmental change (including climate) on health. The collaboration is likely to be renewed further
9. A **Letter of Intent (LOI)** between **ICMR and European Union** for collaboration in cancer & neurodegenerative diseases was signed in March/April, 2011 at New Delhi/Brussels. A joint call for proposal was launched by ICMR in February, 2012. Three projects have been approved for funding by HMSC in 2013.
  10. An MoU between **ICMR and Global Alliance for Chronic Diseases (GACD)** was signed in April, 2011 at New Delhi. Some of the priority areas of collaboration proposed by GACD founding members are prevention of cardiovascular diseases; public health measures for the control of diabetes and obesity; characterization, quantification of risk factors (tobacco and environmental pollution), and development of control measures for chronic obstructive airways disease, cancer cardiovascular disease and other disorders; and implementation research of interventions to address these and other priorities. The addendum one, two and three to GACD secretariat funding and collaboration agreement were signed by ICMR in November, 2012, March, 2014 & June, 2014 respectively. Subsequently there were two call for proposals in the area of Hypertension & Type 2 Diabetes .
  11. An MoU between **ICMR and Foundation for Innovative New Diagnostics (FIND)** was signed in July, 2011 at New Delhi by Dr. V.M. Katoch, Secretary, Department of Health Research, Ministry of Health and Family Welfare, Government of India & Director General, ICMR and Dr. Giorgio Roscigno, Chief Executive Officer, FIND for collaboration on the effectiveness and feasibility of the introduction of new diagnostic tests for infectious diseases such as Tuberculosis, Malaria, HIV, Leishmaniasis and other communicable diseases.
  12. An MoU between **ICMR and Academy of Finland (AF)** was signed in November, 2012 at ICMR Hqrs, New Delhi by the Secretary, DHR & DG, ICMR and by the Vice President for Research, AF. The MoU would promote collaboration between Indian and Finnish researchers and scientific institutions in the areas of Chronic Non-Communicable Diseases, Diabetes and challenges in health services research through joint workshops and collaborative research projects.
  13. An MoU between **Department of Health Research (DHR) and National Institute for Health and Care Excellence (NICE), United Kingdom** was signed in June, 2013 at London on strategic and technical cooperation with regard to evidence – informed healthcare policy and practice. The MoU is to promote collaboration between India and UK for developing collaborative programme in implementation of Health Technology Assessment (HTA) based decisions into clinical policy and practice.
  14. An MoU between **ICMR and Research Council of Norway (RCN), Norway** was signed in October, 2014 at Oslo. This MoU is to encourage health research in a range of health areas of mutual interest, which currently include Human Vaccines; Infectious Diseases and Antimicrobial resistance.
  15. An MoU between **ICMR and International AIDS Vaccine Initiative (IAVI), USA** was signed in Oct/November 2014, respectively at New York /ICMR, New Delhi. This MoU between IAVI & ICMR is to collaborate and contribute

- their experiences and resources on AIDS Vaccine development and evaluation of one or more safe and effective AIDS vaccines primarily for use in, but not limited to, India and other biomedical tools for prevention of AIDS based on mutual agreement. The collaboration will in the form of specific research projects.
16. An MoU between **ICMR** and the **Russian Foundation for Basic Research (RFBR), Russia** was signed in December 2014 by the Secretary, DHR, MOH&FW, GOI & DG, ICMR from Indian side and the Chairman, RFBR Board from Russian side at New Delhi in the presence of the Hon'ble Prime Minister of India and H.E. the President of Russia. This cooperation in Health Research is in specific areas such as Oncology, Bioinformatics & bio-imaging, Neurosciences, New generation vaccine research and Research in HIV/AIDS.
  17. An MoU between **ICMR** and **University of Sydney, Australia** was signed in January/February/March, 2015 at New Delhi and Sydney respectively for collaboration in the areas of public health and clinical aspects of chronic diseases, HIV/AIDS, road traffic injuries, maternal and child health, health systems and other area of mutual interest falling within scope of this MoU for collaboration.
  18. An Memorandum of Intention (MoI) between **ICMR** and **Swedish Research Council for Health Working Life and Welfare (FORTE)** was signed on 1<sup>st</sup> June, 2015 at Stockholm, under India -Sweden agreement on cooperation in the field of healthcare and public health. The MoI is to increase bilateral cooperation between Sweden and India in the field of Ageing and Health between two countries to enhance the understanding of demographic change and impact of migration on physical and mental health and well-being of the elderly forms and systems of care of the elderly and use of ICT assistive technology and addressing issues related to nutrition in elderly. The collaborative projects through a joint call for proposals are expected in near future.
  19. An MoU between **ICMR** and **Drugs for Neglected Diseases Initiative (DNDi)**, Switzerland was signed in October, 2015 by the Secretary, DHR, MOH&FW, GoI & DG, ICMR and the Executive Director, DNDi at New Delhi for cooperation in neglected diseases.
  20. A Memorandum of Understanding (MoU) between **ICMR** and **National Health and Medical Research Council (NHMRC)** Australia was signed on 28<sup>th</sup> January 2016 from ICMR side and on 10<sup>th</sup> February 2016 by NHMRC. The MoU is to increase bilateral cooperation between Australia and India in the field of infectious diseases, chronic diseases pursued via each party's membership of the Global Alliance for Chronic Diseases, public health and clinical aspects of chronic diseases, HIV/AIDS, Road traffic injuries, Maternal and child health and Health systems.
  21. A Letter of Intent LoI between **ICMR** and **National Institute of Infectious Diseases (NIID)** of Japan was signed On Antimicrobial Resistance Research on 16<sup>th</sup> April 2016 in Japan. The collaboration is in the area of Development of integrated surveillance program covering epidemiology data and genomic data of antimicrobial resistance in each country and Mutual exchange of information of molecular and epidemiological data of antimicrobial resistance by

developing of comparable surveillance program in each country.

Various activities have been initiated under these Joint Statements and MoUs. Several workshops on topics of mutual interest have been organized and many of exchange visits by the Indian Investigators under the approved collaborative research projects have been funded by ICMR. Under these MoUs/Jt. Statements, the collaboration has fruitfully led to publication of several research papers as well as transfer of technology and infrastructure strengthening of Indian research institutes. The cooperation is reviewed through annual meetings of Joint Working Group or Joint Steering Committee organized in India and respective countries from time to time.

### **HEALTH MINISTRY'S SCREENING COMMITTEE (HMSC)**

Applications for research projects involving foreign assistance and/or collaboration in biomedical/ health research are to be submitted by the Indian investigators to ICMR for approval of Govt. of India through Health Ministry's Screening Committee (HMSC). It is a High Level Committee constituted by the Govt. of India in early 1980s to screen & approve the international collaborative proposals in the field of biomedical health research. It has the representatives from the Ministry of Health & F.W. (Department of Health, Family Planning, NACO, AYUSH and DGHS); Ministry of External Affairs; Ministry of Finance; Department of Biotechnology; Department of Science and Technology; Directorate General of Armed Forces and Medical Services and is chaired by the Secretary, Department of Health Research (DHR), MOH&FW, GOI.

The International Health Division at ICMR is the secretariat for HMSC and facilitates technical review of the collaborative proposals for placement before this Committee as a mandatory requirement. This Committee meets regularly at every month under the chairmanship of Secretary, Department of Health Research, Ministry of Health and Family Welfare, Government of India and papers complete in all respect are received in IHD, a month before the HMSC meeting from various technical divisions at ICMR Hqrs after technical evaluation by them.

The Indian collaborator is required to submit the proposal and related papers to ICMR in prescribed format. The list of documents/necessary clearances to be submitted along with the details on international collaboration is available on ICMR website: <http://www.icmr.nic.in>. The research proposal is required to be submitted in the prescribed format of the concerned Funding agency/Foundation. If there is no prescribed format, proposal is to be prepared using ICMR format which can be downloaded from the ICMR website.

The Indian counterpart or Principal Investigator will be funded for the collaborative project by ICMR under the bilateral MoUs signed by ICMR and research projects received through call for proposal mechanism advertised by the concerned Technical Divisions of ICMR.

The information provided in this write-up is based on the experiences of investigators and ICMR during the past years and aims to assist the scientists in developing Indo-foreign collaborative proposals for research in biomedical sciences. An Office Memorandum dated 01<sup>st</sup> July, 2014 on HMSC is on ICMR website: [http://icmr.nic.in/icmrnews/OM\\_IHD.pdf](http://icmr.nic.in/icmrnews/OM_IHD.pdf).

### **Forms and other details:**

## 1. For Indo-German collaboration:

For ICMR-BMBF collaboration, the joint call for proposals is advertised under the MoU by the ICMR and BMBF on their respective websites from time to time along with details on subject area and required documents to be submitted in specific formats.

## 2. For Indo-US collaborations:

- i. For Indo-US collaboration for **Prevention of STD and HIV / AIDS** under the joint statement, call for proposals are advertised by the ICMR and NIH on their respective websites from time to time along with details on subject areas/topics and required documents to be submitted in specific formats.
- ii. For Indo-US collaboration for **Maternal and Child Health and Human Development** under the joint statement, call for proposals are advertised by the ICMR and NIH on their respective websites from time to time along with details on subject areas/topics and required documents to be submitted in specific formats (under renewal).
- iii. For Indo-US collaboration for **Environmental and Occupational Health, Injury Prevention and Control** under the MoU, call for proposals are advertised by the ICMR and NIH on their respective websites from time to time along with details on subject areas/topics and required documents to be submitted in specific format.
- iv. For Indo-US collaboration for **Diabetes Research** under the joint statement, call for proposals are advertised by the ICMR and NIH on their respective websites from time to time along with details on subject areas/topics and required documents to be submitted in specific format.
- v. For ICMR-UoM (University of Minnesota, USA) collaboration under the MoU, call for proposals will be advertised by the ICMR and UoM on their respective websites from time to time along with details on subject areas/topics and required documents to be submitted in specific format.
- vi. For ICMR -International AIDS Vaccine Initiative, (IAVI), USA collaboration under the MoU, call for proposals will be advertised by the ICMR and IAVI on their respective websites along with details on subject areas/topics and required documents to be submitted in specific format.

For details on grants by NIH, USA you may log on to website <http://www.nih.gov/> or Contact Office of Health Attache & HHS Office, US Embassy in India, Shantipath, Chankayapuri, New Delhi - 110 021. (Tel. 24198030, Fax 24198770)

## 3. For Indo-UK collaboration

- i. For ICMR-Medical Research Council (MRC), UK collaboration the



joint call for proposals are advertised under the MoU, by the ICMR and MRC on their respective websites from time to time along with details on subject areas/topics and required documents to be submitted in specific format (under renewal)..

- ii. ICMR- London School of Hygiene and Tropical Medicine, London (LSHTM), UK collaboration the joint call for proposals will be advertised under the MoU by the ICMR and LSHTM on their respective websites from time to time along with details on topics and required documents to be submitted in specific format (under renewal).
4. **For Indo-Canada collaboration:** For ICMR- Canadian Institutes of Health Research (CIHR), the joint call for proposals will be advertised by the ICMR and CIHR on their respective websites from time to time along with details on topics and required documents to be submitted in specific format.
5. **For ICMR-GACD collaboration:** For ICMR-Global Alliance for Chronic Diseases (GACD) the joint call for proposals are advertised by the ICMR and GACD on their respective websites from time to time along with details on topics and required documents to be submitted in specific format.
6. **For ICMR-EU collaboration:** For ICMR-European Union, the joint call for proposals is advertised under the LoI by the ICMR and European Union on their respective websites from time to time along with details on topics and required documents to be submitted in specific format.
7. **For Indo-Finland collaboration:** For ICMR and Academy of Finland (AF), the joint call for proposals will be advertised under the MoU by the ICMR and AF on their respective websites from time to time along with details on topics and required documents to be submitted in specific format.
8. **For Indo-Norway collaboration:** For ICMR and Research Council of Norway (RCN), the joint call for proposals will be advertised under the MoU by the ICMR and RCN on their respective websites from time to time along with details on topics and required documents to be submitted in specific format.
9. **For Indo-Russia collaboration:** For ICMR and Russian Foundation for Basic Research (RFBR), the joint call for proposals will be advertised under the MoU by the ICMR and RFBR on their respective websites from time to time along with details on topics and required documents to be submitted in specific format.
10. **For Indo-Sweden collaboration:** For ICMR and Swedish Research Council for Health Working Life and Welfare (FORTE), the joint call for proposals in the field of Ageing and Health will be advertised under the MoI by the ICMR and FORTE on their respective websites.

**For assistance from WHO:** The form as prescribed by SEARO, WHO, New Delhi, may be used. For details, visit Website: <http://www.searo.who.int/index.html>

**For assistance from other foreign Funding Agencies/Organizations/ Foundations:** The prescribed format of the concerned agency is to be used. If there is no prescribed format, proposals are to be prepared by using ICMR



Format [Download](#) Form.

**National Funding Agencies:** Indian investigators are also advised to look out for periodic call for proposals issued under various bilateral or multilateral collaborative programmes by other Indian agencies (such as DBT;DST;CSIR etc) supporting Health/Biomedical research.

### Some Important Tips:

- I. Please ascertain from foreign collaborator whether he/she would be willing to submit the proposal under above-mentioned joint collaborative programmes or under other foreign grants.
- II. If the foreign collaborator agrees to do so, you may obtain the relevant form from the concerned funding agency's website. You may also fill in the ICMR summary sheet for international collaborative projects up to item no. 43.
- III. The Indian & foreign investigators should submit their proposals to ICMR and respective foreign funding agency simultaneously for review.

The following **general information** is to be given in the documents while submitting proposals for foreign collaboration/ assistance by Indian investigators for HMSC consideration:

- i. Role/Status/ Expertise of the Indian Principal Investigator along with the CV and consent of all Co-investigators (if any).
- ii. Availability of infrastructure and manpower in the parent institution.
- iii. Justification for foreign collaboration/funding.
- iv. Relevance to India's national health priorities.
- v. Role, consent and bio-data of foreign collaborator/co-investigator(s).
- vi. Budget with justification and year-wise break-up in single currency i.e. Indian currency including training as well as foreign exchange visits component, if any.

Apart from the technical details such as rationale for the study objectives, review of literature, materials and methods, techniques to be used etc, the following **additional information** is required for a collaborative project:

- i. Nature of work to be done in Indian lab/institution and in foreign collaborator's laboratory/institution.
- ii. Number of ongoing international collaborative projects (duly approved by HMSC) being undertaken by the Indian PI and the outcome of such approved projects (publications, patents, etc.)
- iii. Whether there would be transfer of technology as an outcome of the project.
- iv. Whether there would be transfer of human biological material from India to the foreign lab, or vice-versa and if so the requisite details for the same, such as nature, number and quantity of material to be sent abroad;

purpose/need of transfer; type of investigation(s) to be done utilizing the material; institution(s)/scientist(s) to whom material is to be sent along with their addresses; a duly signed Material Transfer Agreement (MTA).

NOTE : In case of transfer of human biological material , under the collaborative proposals, guidelines issued by the Ministry of Health and Family Welfare, Govt. of India, New Delhi, vide O.M. No.L.19015/53/97-IH(Pt.) dated 19th Nov. 1997 are to be followed. [DOWNLOAD GUIDELINES.](#)

With the progress in the area of cellular and molecular biology, the following points have become quite important for consideration by scientists during preparation of the proposals, as these may have a bearing on the approval process:

- a) Safety during transfer – risk of transportation of biological material. Adequate precautions need to be taken.
- b) National security – the research should not lead to development of biological weapons.
- c) Risk (relative) from the defence and internal security point of view of the country.
- d) Intellectual Property Rights issues, if any.
- e) Potential for commercial exploitation, such as by development of vaccines, diagnostics, therapeutics, drugs, etc.
- v. Information pertaining to likely visits (year-wise) by Indian and foreign scientist(s) including duration and purpose of each visit. All visits are required to be approved by ICMR & regulatory authorities of Government of India. Papers need to be submitted, at least 6-8 weeks in advance along with CV, passport details, consent visits to be undertaken by Indian /foreign PI etc.
- vi. Institutional Ethics Committee (IEC) clearance to be submitted for each of the participating centers/sites at the time of submission of the proposal to ICMR. The project is likely to be deferred by HMSC in the absence of IEC clearance certificate & IRB/IEC should be registered with the Licensing Authority.
- vii. For research projects involving clinical drug trials, clearance from office of Drugs Controller General of India (DCGI) is to be submitted by Indian PI to ICMR. The project also needs to be registered with the Clinical Trial Registry in ICMR (CTRI). For details visit Website: [www.ctri.nic.in](http://www.ctri.nic.in)
- viii. Appropriate clearances for research involving human subjects, animal experimentation /radio-tagged material (for clinical and/or experimental purposes), recombinant DNA/genetic engineering work are to be submitted.
- ix. Institutes receiving foreign assistance should ensure to have the requisite FCRA clearance as per the requirement of DEA, Min. of Finance, GOI.
- x. The proposals submitted by ICMR institutes / centers should submit the recommendations of the Scientific Advisory Committee (SAC) of their institutes/centres.
- xi. Mutual agreement on IPR claims addressing the IPR issues is to be submitted, if applicable.

- xii. The regulatory requirements of DCGI should be fulfilled and all necessary approvals as per the latest amendments by GOI of Jan/Feb 2013 in the Drugs and Cosmetics Rules 1945 should be followed /fulfilled by the Indian PIs.
- xiii. The latest decision of DCGI and Hon'ble Supreme Court of India on Clinical Trials of new drug entities would be applicable on such studies.

**Documents to be submitted to International Health Division, ICMR  
(by Indian Investigators only)**

1. Twenty-five copies of Research Proposal (in the ICMR format, if specific format of foreign agency not available ([Download Form](#))).
2. Twenty-five copies of ICMR Summary Sheet ([Download Form](#)). All items (up to item no 43) of summary sheet are to be filled in by the Indian Investigator.
3. Twenty-five copies of MTA, duly signed by both the Parties, in case any transfer of biological material is involved in the study ([Download Form](#)).
4. The proposals to be submitted by Non-Governmental Organizations (NGOs) should be accompanied with the following additional documents/justifications:
  - i. The annual reports, statement of accounts, achievements and their role in the project.
  - ii. Justification for the budget with exact amount to be used under different heads with full explanation.
  - iii. The composition of the Institutional Ethics Committee as per the ICMR ethics guidelines for biomedical research on human subjects.
5. The Investigators are required to submit four copies of the electronic form of above documents (at Sr.nos.1-4) in Compact Disc (i.e.4 CDs) in addition to the prescribed number of printed form of documents.
6. Duly signed DST summary sheet ([Download Form](#)) and DST Check list ([Download Form](#)) to be submitted by Principal Investigators to the concerned Technical Division of ICMR after the due approval of proposal by HMSC.

**Note:**

1. Approximate time taken for peer review & processing at ICMR is 3-4 months. The requisite clearances /documents as required should be submitted by the PIs to avoid undue delay.
2. Indian investigators are required to obtain HMSC clearance for international collaborative projects. ICMR receives applications from Indian PIs only.
3. The proposals can be submitted throughout the year unless there is a prescribed deadline in a specific call for proposal under a bilateral programme.

4. In case of any deadline prescribed by the concerned foreign funding agency, the proposal should be submitted to ICMR along with the documentary evidence from the funding agency, as the case may be.
5. No incomplete proposals are placed for consideration of Health Ministry's Screening Committee (HMSC).

#### **CONTACT PERSONS AT ICMR**

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