

GUIDELINES FOR INTERNATIONAL COLLABORATION / RESEARCH PROJECTS IN HEALTH RESEARCH

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. An 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. An ICMR INSERM, France MoU has been in place in pursuance of Indo-French Science & Technology Agreement signed in July, 1978. The ICMR-INSERM MoU was signed in February, 1989 at New Delhi and renewed in January, 2000 for cooperation in various areas of biomedical research and health sciences. The areas of collaboration are infectious diseases (tuberculosis, HIV/AIDS, malaria, leishmaniasis), human genetics/genomics, neurosciences and surveillance/epidemiology using modern techniques, stem cell research, pharmacogenetics, genetics of cancer, polymorphism, viral hepatitis, leptospirosis, epidemiological data base, development of surveillance tools like registries and genetic susceptibility of infectious diseases. Newly

added areas are bioethics and clinical research. Further areas of cooperation which are of mutual interest are added from time to time during the Joint Working Group meetings organised regularly in India and France.

A Letter of Intent (LOI) between ICMR and INSERM for collaborating and setting up of an International Associated Laboratory (IAL) in the field of Immunology/Haematology was signed in December, 2010 at New Delhi between Secretary, Department of Health Research, MOH&FW, GOI & Director General, ICMR and CEO, Chairman, INSERM during the visit by delegation of His Excellency, the President of France to India.

- 3. The Indo-US Joint Statement on Emerging and Re-emerging Infections and Disease Surveillance was signed in June, 2005 (and further expanded in November, 2005) and other three Joint Statements on HIV/AIDS, Maternal & Child Health and Human Development & Research and Environment & Occupational Health were signed in 2000/2002 and renewed in June, 2006 by the then Hon'ble Minister for Health and Family Welfare, Govt. of India during his visit to USA. The Joint Statement on HIV/AIDS was further renewed in October, 2011, whereas other two are to be renewed. An Expression of Interest for joint research in Diabetes was signed in December, 2011 by ICMR, India & NIH, USA at New Delhi and the Joint Statement is under consideration.
- 4. A Memorandum of Understanding was signed between ICMR and Canadian Institutes of Health Research, 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.
- 5. 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 Hon'ble 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 is 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 organization of joint workshops, exchange of scientists/ researchers and execution of twinning projects are 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 have been identified under this programme.

This Indo-German collaboration has been extended and pushed further in the area of infectious diseases especially in translational research by signing the renewed MOU between ICMR and HGF on May 31, 2011 by Dr. V. M. Katoch, Secretary, Department of Health Research, MOH&FW, GOI & Director General, ICMR from Indian side and Prof. Dirk Heinz, Scientific Director, Helmholtz Centre for Infection Research(HZI) from German side at New Delhi in the presence of Hon'ble Prime Minister of India Dr Manmohan Singh and H. E. Chancellor of Germany Dr Angela Merkel. 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.

- 6. An MoU between ICMR and University of Minnesota, 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. In November, 2006, an MoU between ICMR and International Clinical Epidemiology Network (INCLEN) Trust International, Executive Office, New Delhi was signed at New Delhi to collaborate in the areas of health research and capacity building. These efforts would enhance the capabilities of Indian research institutions and enthuse faculty to take up collaborative research activities and projects. This collaboration is dedicated towards improving the health of disadvantaged populations by promoting equitable health care through networking by conducting collaborative interdisciplinary research on high priority health problems and by training future generation of leaders in health care research.
- 8. A letter of intent for collaboration between **ICMR and Boston University**, USA was signed in October, 2007 at Boston as a follow up of visit by the President, Boston University and his team to India in September, 2007. This cooperation is likely to enhance the collaboration between the two institutions in the identified areas of emerging infectious diseases and public health training. The collaboration in research and application in other areas of mutual interest in emerging infectious diseases and public health education has additional common interest and synergistic capacity under the proposed MOU. Both sides have also shown interest in developing a clinical trials network, basic and applied cancer research and cardio-vascular disease as well as risk factors such as diabetes, obesity and genetics including the linkage of population based research.
- 9. An MoU between ICMR and University of California Los Angeles (UCLA), USA was signed in October / November, 2007 in USA and New Delhi for collaboration in the areas like education and training programmes in clinical translational research; basic and fundamental health related sciences including immunology, virology, molecular biology, genetics, stem cell, nanotechnology; communicable diseases including HIV /AIDS, tuberculosis, hepatitis, STD, respiratory, diarrhoeal diseases; non-communicable diseases including cancer, CVD, auto-immune diseases, diabetes, neuro-degenerative diseases; social behavioural sciences related to drug abuse, obesity, disease prevention, patient and family care; public health sciences including epidemiology, biostatistics, health services, environmental and community health, public policy and law; international health /economic issues related to health as well as information technology applications for health education and care.

- 10. An MoU between ICMR and George Institute for International Health, & Faculty of Medicine, University of Sydney, Australia was signed in November, 2007 at Hyderabad for collaboration in the areas of public health and clinical aspects of chronic diseases, HIV/AIDS, road traffic injuries as well as health systems. Subsequently in 2010, it was proposed by both Parties to include Maternal and Child Health as another area of mutual interest for collaboration. The collaboration is likely to be renewed further in 2012.
 - 11. The ICMR and Karolinska Institute, Sweden signed an MoU in July/August, 2009 at New Delhi /Stockholm to collaborate in the areas of Non-communicable diseases (specifically diabetes mellitus & cardiovascular diseases including control of tobacco, alcohol & junk food); Maternal and Child Health; Sexual and Reproductive Health; HIV, TB, Malaria; Emerging infections; Human Resource Development.
 - 12. An MoU between ICMR and London School of Hygiene and Tropical Medicine, London, 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.
- 13. In February, 2010, **ICMR and Medical Research Council, United Kingdom** signed an 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.
- 14. 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.
- 15. 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.
- 16. 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.

17. An MoU between **Academy of Finland (AF) and ICMR** was signed in October/ November 2012 at Helsinki and New Delhi. 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.

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 agreements, 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

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., Ministry of External Affairs, Ministry of Finance, Department of Biotechnology, Department of Science and Technology, Directorate General of Armed Forces and Medical Services, Directorate General of Health 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 an interval of every three months (normally in 1st half of March, June, September & December of each year) 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: <u>http://www.icmr.nic.in</u>. 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. In certain cases, where there is a specified and written deadline of an international funding agency, the technical evaluation is expedited for consideration of Chairman, HMSC.

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.

Forms and other details:

1. For Indo-French collaboration

For ICMR-INSERM collaboration, the joint call for proposals is periodically advertised under the MoU by the ICMR and INSERM on their respective websites along with details on topics/subject areas and

required documents to be submitted in specific formats.

2. For Indo-German, collaboration

i. 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

ii. For ICMR-HGF collaboration, the joint proposals are received as a follow-up of Joint workshops. The information on the MoU between ICMR and HGF / HZI and its activities is available on ICMR /IG-SCID website. http://www.icmr.nic.in/igscid/index.html.

3. 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.
- iii. For Indo-US collaboration for Environment and Occupational Health 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.
- iv. For ICMR-UoM (University of Minnesota, USA) collaboration under the MoU, call for proposals are 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 formats.

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

4. 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 formats..
- 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 formats.

5. Indo-Canada collaboration: For ICMR- Canadian Institutes of Health Research (CIHR), the joint call for proposals are 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 formats.

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

7. 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

8. 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 following

agencies:

- a) Indian Council of Medical Research (ICMR)
 V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi - 110029, India
 Tel. 26589794, 26588980 Extn. 237,
 Tele fax. 26589492
 E-mail: icmrhqds@sansad.nic.in
 Website: http://www.icmr.nic.in
 b) Department of Biotechnology (DBT)
- Block 2, 7th Floor, CGO Complex, Lodhi Road, New Delhi –110003 Tel. No.011-24363939, 24363012 Fax No.011-24362884 Website: http://www.dbtindia.nic.in
- c) Department of Science & Technology (DST)

Technology Bhavan, New Mehrauli Road, New Delhi –110016 Tel. No. 011-26567373, 26962819 Fax. No. 011-26864570, 26862418 E-Mail: dstinfo@.nic.in Website: http://www.dst.gov.in d) **Council of Scientific & Industrial Research (CSIR)** Anusandhan Bhavan, 2, Rafi Ahmed Kidwai Marg, New Delhi-110001 Tel. No. 011-23710158, 23710138 Fax. No. 011- 23710618 E-Mail: <u>root@csir.res.in</u> Website: http://www.csir.res.in

Some Important Tips:

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.

- IV. 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 foreign projects up to item no. 43.
- V. The foreign & Indian investigators should submit their proposals to ICMR and 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 their CV and consent of all Coinvestigators, if any.

(ii) Availability of infrastructure and manpower in the parent institution.

(ii) Justification for foreign collaboration/funding.

(ii) Relevance to India's national health priorities.

(iv) 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 component, if any.

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

- (i) Nature of work to be done in Indian lab/institution and in foreign collaborator's laboratory/institution.
- 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.
- (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: <u>www.ctri.in</u>
- (viii) Appropriate clearances for research involving human subjects, animal experimentation /radiotagged material (for clinical and/or experimental purposes), recombinant DNA/genetic engineering work are to be submitted.

(ix) The proposals submitted by ICMR institutes / centers should submit the recommendations of the Scientific Advisory Committee (SAC) of their institutes/centres.

(x) Mutual agreement on IPR claims addressing the IPR issues is to be submitted, if applicable.

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

25 copies of Research Proposal (in the ICMR format, if specific format of foreign agency not available (<u>Download Form</u>).

25 copies of ICMR Summary Sheet (<u>Download Form</u>). All items (upto item no 43) of summary sheet are to be filled in by the Indian Investigator.

Five copies of signed DST Project Summary Sheet (Download Form).

Five copies of signed DST Check list (Download Form).

Five copies of MTA, duly signed by both the Parties, in case any transfer of biological material is involved in the study (<u>Download Form</u>).

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.
- vii. The Investigators are required to submit an electronic form of the above documents (at Sr. nos. 1-6) in a Compact Disc in addition to the prescribed numbers of printed form of documents.

Note:

- 1. Approximate time taken for peer review & processing at ICMR is 4-6 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.
- 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

Dr. Mukesh Kumar Head Dr. Harpreet Sandhu Scientist D International Health Division

International Health Division

mukeshk@icmr.org.in

sandhuh@icmr.org.in

Indian Council of Medical Research V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi - 110029, India

Tele fax. 91-11-26589492 Tel. 26589794, 26588980 extn. 237

Website :<u>http://www.icmr.nic.in</u>

