GUIDANCE FOR INVESTIGATORS FOR COLLABORATIVE BIOMEDICAL RESEARCH IN INDIA

This document provides information regarding review and approval process of Ministry of Health and Family Welfare for international collaborative research proposals. The information in this document is based on the experience of the HHS Health Office, U.S. Embassy, in India and has been reviewed by the staff of the Indian Council of Medical Research (ICMR).

(*Please note that this is not an official ICMR document. If there is any query contact Health Attaché's office)*

Q 1: What should a US investigator do for identifying an Indian collaborator?

A 1: US investigator should take the following into account:

- The Indian investigator has the qualifications and background to serve as the Co-Investigator/Co-Principal Investigator in the study.
- Indian institution should have the appropriate infrastructure facilities and institutional ethical and other review bodies.
- If the collaborating institution is a NGO, it has to be registered with the Government of India. The NGO needs to have a proper and regular auditing of accounts and its mandate needs to conform to the scope of the project.

Q 2: Why is approval of Government of India required?

A 2: Transfer of foreign funding into India for collaborative research projects require GOI clearance. The proposals involving overseas funding/ investigators requires approval by a Secretary of the concerned Ministry.

Q 3: Who has the authority for approving Indo-US collaborative projects in India?

A 3: It depends on the scope of the project. The Ministry of Health and Family Welfare or the Ministry of Science and Technology clear most of US-India HHS projects

i. Ministry of Health and Family Welfare- all health/biomedical research involving human subjects/material involving Ministry of Health and Family Welfare Institutions, ICMR institutes, medical schools, universities, public and private research and development institutes or NGOs
ii. Ministry of Science and Technology: all projects involving Ministry of S&T agencies like Department of Biotechnology (DBT), Council for Scientific and Industrial Research (CSIR), Department of Science and Technology

Q 4: Who applies for Government of India (GOI) clearance?

A. 4: Only Indian investigators are entitled to apply for GOI clearance for Indo-US collaborative projects.

Q 5: When does investigator apply for (GOI) clearance?

A 5: The proposals can be submitted throughout the year.

Please note that in case of NIH grant proposal, ICMR is recommending that Indian co-PIs should submit the proposal for review while the grant is being reviewed by funding agencies. This way ICMR/HMSC approval will be obtained while NIH is making funding decision and the project can be initiated promptly following funding decision, thus hastening the implementation by at least six to nine months (or more in exceptional cases).

Q 6: What is the Indian Council of Medical Research's (ICMR) role in relation to HMSC?

A 6: The ICMR is the secretariat of HMSC. Any collaborative project involving the Ministry of Health and Family Welfare institutions, ICMR institutions or government medical colleges; and/or any project with involvement of human subjects in any form e.g. as study subjects, human specimens, questionnaires, or tagged/labeled/named data involving private/autonomous institutions or universities brings the project within the purview of the Ministry of Health and Family Welfare for clearance. Applications for research projects requiring Ministry of Health and Family Welfare approval based on earlier description are to be submitted to ICMR for approval of Govt. of India through Health Ministry's Screening Committee (HMSC). ICMR reviews the project for scientific and technical purposes and after clarifications/modifications, if any, puts up the project for Health Ministry Screening Committee (HMSC) review.

Background: 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 2000. By and large, biomedical research / health sciences have figured in practically every bilateral agreement in the field of Science and Technology. In addition, there have been a few specific agreements signed by the ICMR/Ministry of Health and Family Welfare with US.

These agreements provide platform for:

Exchange of scientific information;

Exchange of scientists/technicians and joint execution of scientific projects, including support in the procurement of scientific equipment; and

Organization of joint scientific meetings, seminars, workshops, symposia on identified subjects of cooperation.

Q 7: What is Health Ministry Screening Committee (HMSC)?

A 7: HMSC is the committee that provides final approval for foreign-funded and/or collaborative project submitted by Indian collaborator. Proposals are considered for review and approval after ICMR's technical review. In the case of projects on HIV/AIDS, review by National AIDS Control Organization (NACO) and in case of projects involving alternate systems of medicine, review by AYUSH (Department of Indian Systems of Medicine) in the Ministry of Health and Family Welfare, is also undertaken prior to the HMSC meeting.

Q 8: What is the composition of the HMSC?

A 8: HMSC is chaired by Health Secretary with alternate chairman Director General-ICMR and other members include NACO- Director General, Director General of Health Services, and representatives from Ministry of Science and Technology, Department of Biotechnology, Ministry of External Affairs, Armed Forces Medical Services and Ministry of Finance.

Q 9: How often does the HMSC meet?

A 9: The HMSC meets after 3-4 months on an average. Please note that because of the competing demands on Chairperson/HMSC members' time, these meetings do get rescheduled.

Q 10: What is the decision making process of HMSC review?

A 10:

- HMSC may approve the project. In this case, ICMR send the approval letter to the Indian PI. The Indian PI should inform HHS office in New Delhi, so that we can send an official note to NIH. HMSC requires that Indian PI should submit yearly progress reports to ICMR.

- HMSC does not approve and ask additional information and/or may have some questions.

  Based on our experience, following questions are frequently asked:

  - What is the relevance of the objectives of the study to India?
  - What is the role of Indian and US PIs?
  - What is the necessity for foreign funding?
  - What is the importance of the project in the context of work/science in India?
  - Number of projects being handled by Indian PI at a time.

- HMSC may disapprove/reject the project, in which case the project cannot be initiated. Criteria for rejection could be wide ranging starting from significance of the work proposed, suitability of the investigators, capacity of the institution to support the work outlined in the project.

Q 11: How long does GOI take to approve a project?

A 11: Minimum time taken is anywhere between 6-9 months, depending on the timing of proposal submission, questions raised by HMSC, and the response of the investigators.

Q 12: What are the documents required to be submitted to ICMR?

A 12: Documents to be submitted to International Health Division, ICMR for International Collaboration in Biomedical Research throughout the year: (Formats for items 2,4,5,6 can be downloaded from ICMR web site)

1. 30 copies of Research Proposal (note: form PHS 398 is acceptable).

2. Five copies of ICMR Summary Sheet. (http://icmr.nic.in/guide/summary.doc)

3. All items (up to item no 43) of summary sheet are to be submitted by the Indian Investigator.

4. Five copies of MTA, in case any transfer of biological material is involved in the study.

5. Five copies of DST check list

6. Five copies of DST project Summary Sheet

The investigators are required to submit an electronic form of the above documents in a CD, in addition to the prescribed numbers of printed form of documents

Q 13: Is there any other information to be provided by the investigator?

A 13: The Indian investigator while submitting proposals for foreign collaboration should provide the following information:

(i) Role/Status/Expertise of the Indian Principal Investigator. (Note: this becomes particularly important when NGO is the Indian collaborating institution)

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

(iii) Justification for foreign collaboration and funding.

(iv) Relevance to India's national health priorities

(v) Role/Consent and biodata of foreign collaborator.

(vi) Budget with justification and year-wise break-up in single currency i.e $US or Rs. including training as well as foreign exchange component, if any.

(vii) Nature of work to be done in Indian lab/institution and foreign collaborator's laboratory/institution.

(viii) Number of previous international collaborative projects by the Indian PI approved by HMSC and their outcomes.

(ix) Whether there would be transfer of technology as an outcome of the project.

(x) 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 and quantity of material to be sent abroad; purpose/need of transfer; nature of investigation to be done utilizing the material; institution(s)/scientist(s) to whom material to be sent; along with their addresses; copy of Material Transfer Agreement (MTA). Available at http://icmr.nic.in/guide/mta.doc. The GOI guidelines for transfer of biological material is also available on ICMR website.

With the progress in the cellular and molecular biology the following points also become very important for careful consideration by scientists in preparing their proposals, as these have a bearing on the approval process by Government of India*:*

(a) Safety during transfer – risk of transportation;

(b) National security – the research should not lead to development of biological weapons;

(c) Risk (relative) from the defense and internal security point of view of the country;

(d) Intellectual Property Rights;

(e) Potential for commercial exploitation, such as by development of vaccines, diagnostics, therapeutics, drugs, *etc.*

Additional information that should be provided:

(i) Information pertaining to likely visits (year-wise) by Indian and Foreign scientist(s) including duration and purpose of each visit.

(ii) Institutional ethical clearance to be submitted at the time of submission of the proposal to ICMR

(iii) Appropriate clearances for research involving human subjects, radio-tagged material (for clinical and/or experimental purposes), recombinant DNA/genetic engineering work.

(iv) The proposals involving ICMR institutes / centers should be submitted with the recommendations of the Scientific Advisory Committee (SAC) of the concerned institute/center.

(v) Mutual agreement on IPR claims.

Q14: What are the additional documents that NGOs are required to submit?

A 14: i. The annual reports, statement of accounts, achievements and their role in the project.
ii. The role of the foreign collaborator
iii. Justification for the budget with the exact amount to be used under different heads with full explanation
iv. The composition of the ethical committee as per the ICMR ethical guidelines for biomedical research on human subjects.

Q 15: Who are the contact persons at the approval agency?

A 15: <u>Only the Indian investigator should contact the Indian agency. US investigators should contact HHS office in New Delhi</u>

Indian Council of Medical Research (ICMR)

http://icmr.nic.in

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Q 16: Who is the HHS point of contact at New Delhi, NIH and CDC?

A 16: Points of contact at:

New Delhi: Ms. Kiran Dhawan
HHS office for South Asia
US Embassy, Chanakya Puri,
New Delhi, India
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Step by Step procedures for ICMR/HMSC review