

NIH GRANTS REQUIRING CLEARANCE BY THE GOVERNMENT OF INDIA

HHS OFFICE, NEW DELHI

QUESTIONS & ANSWERS
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This document provides general information regarding the review and approval process for NIH research grants in India.

Please note: This document is not issued by the Government of India (GoI). NIH grantees must comply with all current GoI regulations and guidance.

1. Which NIH projects require GoI Approval?

The GoI must approve NIH supported research awards that expend resources in India.

2. Who has the authority for approving Indo-US collaborative projects in India?

NIH research grants can be approved by the GoI Ministry involved in the research collaboration. Depending on the scope of the project, most NIH research awards are approved by the Ministry of Health and Family Welfare (MoHFW) or the Ministry of Science and Technology (MoST).

The Health Ministry Screening Committee (HMSC) reviews most NIH awards in biomedical and behavioral health research which involve human subjects or material, or which involve MoHFW institutions. The Indian Council for Medical Research (ICMR), part of the MoHFW, is the secretariat for the HMSC (See ICMR Guidance for International Collaborations <http://www.icmr.nic.in/guide.htm>)

MoST departments involved in research collaborations, including the Department of Biotechnology (DBT) (<http://dbtindia.nic.in/index.asp>) and the Council for Scientific and Industrial Research (CSIR) (http://rdpp.csir.res.in/csir_acsir/Home.aspx), approve NIH awards that involve MoST institutions. Other agencies that may be involved in giving clearance include the Department of Atomic Energy, Department of Education or Defense Research and Development Organization.

3. Are there other agencies that need to approve NIH projects?

The National AIDS Control Organization (NACO) reviews all NIH-funded HIV/AIDS awards, specifically related to therapeutics, operational research and patient care, as part of the HMSC review. The NACO review is undertaken to avoid duplication/overlap of collaborative research being undertaken in India and to screen studies which may not be in conformation with the existing National AIDS Control Program Guidelines.

Projects involving alternate systems of medicine are sent to AYUSH (Department of Indian Systems of Medicine) for comments/opinion. Both NACO and AYUSH are part of the MoHFW.

Clinical trials in India must be registered with the Drugs Controller General of India (DCGI) and must obtain approval from the DCGI. The Indian investigator is responsible for submitted requests for approval from the DCGI.

4. Who is responsible to apply for GoI clearance?

NIH grantees are responsible for compliance with all applicable regulatory requirements. Indian investigators (PIs and Co-PIs) are entitled and responsible to apply for GoI clearance for NIH collaborative projects in India.

5. When should the Indian investigator apply for ICMR clearance?

Since the HMSC approval process can take approximately 4-6 months (or longer in some circumstances), Indian co-PIs may consider submission of their grant application/proposal to ICMR simultaneously with submission by the US PI to NIH for review. If the ICMR/HMSC approval is obtained while NIH is making its funding decision, the project can be initiated promptly following that funding decision. Early submission for HMSC review is especially important for grants that will require additional approval at NACO, DCGI or AYUSH.

6. What is the composition of the HMSC?

The HMSC is chaired by the Secretary of the Department of Health Research, MoHFW. Other members include Secretary & Director General – NACO; Director General of Health Services, and representatives from Department of Health Research, MoHFW, Ministry of Science and Technology, Department of Biotechnology, Ministry of External Affairs, Ministry of Defense (DGAFMS) and Ministry of Finance.

7. How often does the HMSC meet?

The HMSC meets regularly at an interval of every three months on the 8th of the month. Meetings will be held on: March 8, June 8, September 8, and December 8.

8. What is the decision making process of the HMSC?

In addition to the technical soundness and scientific content of the protocol, the HMSC also considers:

- Relevance of the study objectives to India
- Role of the Indian and US PIs
- Justification for foreign funding/collaboration
- Importance of the study in the context of work/science in India and relevance to national health priorities

- Appropriate clearance; Ethical, IPR and security & sensitivity issues
- Technology transfer/capacity building through collaboration
- Number of grants awarded by NIH to the Indian PI

9. What documents are required by ICMR for clearance?

The Indian investigator must submit the following documents to ICMR for HMSC clearance. These documents should be submitted electronically (on a CD) as well as the requested number of hard copies.

1. 30 copies of Research Proposal (PHS 398 is acceptable; [PHS 398 Forms](http://grants.nih.gov/grants/funding/phs398/phs398.html) <http://grants.nih.gov/grants/funding/phs398/phs398.html>) along with necessary clearances such as IRB, DCGI, animal experimentation, MTA etc.
2. Five copies of ICMR Summary Sheet ([Download Form](http://icmr.nic.in/guide/summary.doc) (<http://icmr.nic.in/guide/summary.doc>)
3. Five copies of the Material Transfer Agreement (MTA) if any transfer of biological material is involved in the study [MTA](http://icmr.nic.in/guide/mta.doc) (<http://icmr.nic.in/guide/mta.doc>)
4. Five copies of DST check list ([Download Form](http://www.icmr.nic.in/guide/summarydst.doc) (<http://www.icmr.nic.in/guide/summarydst.doc>)
5. Five copies of DST project Summary Sheet ([Download Form](http://www.icmr.nic.in/guide/summarydst.doc) (<http://www.icmr.nic.in/guide/summarydst.doc>)

10. What additional documents are NGOs required to submit?

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

11. Is there any additional information that that the Indian investigator needs to provide to ICMR?

The Indian investigator needs to provide the information below:

- Role/Status/Expertise of the Indian Principal Investigator. (Note: this becomes particularly important when an NGO is the Indian collaborating institution).
- Availability of infrastructure and manpower in the institution.
- Justification for foreign collaboration and funding.
- Relevance to India's national health priorities.
- Role/Consent and biodata of the foreign collaborator.
- Aggregate budget with justification and annual budgets, in single currency (either rupees or dollars), including training as well as foreign exchange component if any.

- Nature of work to be done in Indian lab/institution and foreign collaborator's laboratory/institution.
- Number of previous international collaborative projects by the Indian PI approved by HMSC and their outcomes.
- Any potential for transfer of technology as an outcome of the project.
- Detailed and specific information on the transfer of human biological materials either from or to India. Please see the [MTA](http://icmr.nic.in/guide/mta.doc) form for more information. <http://icmr.nic.in/guide/mta.doc>
- Information pertaining to likely site visits (year-wise) by Indian and Foreign scientist(s) including duration and purpose of each visit.
- Institutional ethical clearance to be submitted at the time of submission of the proposal to ICMR.
- Appropriate clearances for research involving human subjects, radio-tagged material (for clinical and/or experimental purposes), recombinant DNA/genetic engineering work.
- The proposals involving ICMR institutes / centers should be submitted with the recommendations of the Scientific Advisory Committee (SAC) of the concerned institute/center.
- Mutual agreement on IPR claims.

12. Is there any other information that a PI should know about the clearance process

- The Indian PI is required to submit an electronic form of the documents on a CD in addition to the prescribed numbers of hard copies.
- The proposals can be submitted throughout the year.
- In case of any deadline prescribed by the concerned funding agency, the proposal must be submitted to ICMR at least six months in advance.

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Step by Step procedures for ICMR/HMSC review

