



Indo-US Clinical Research Ethics Fellowship

Under the aegis of

Indo-US Vaccine Action Programme (VAP)

Request for Proposal

under

National Biopharma Mission,

Biotechnology Industry Research Assistance Council (BIRAC)

a PSU of Department of Biotechnology,

Ministry of Science & Technology, Government of India

(Program co-funded by World Bank)

&

Department of Bioethics

National Institutes of Health (NIH), USA

PROGRAM OVERVIEW – NBM:

Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals - “Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation”, also referred to as National BioPharma Mission (NBM).

BACKGROUND:

Towards strengthening the emerging biotechnology enterprise in India, the Department of Biotechnology (DBT), Ministry of Science & Technology has initiated the Mission Program entitled “Industry-Academia Collaborative Mission for Accelerating Discovery Research to Early Development for Biopharmaceuticals - Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation” (“Program”). Biotechnology Industry Research Assistance Council (BIRAC) setup by DBT is the Implementing Agency of i3Program (Program co-funded by World Bank loan).

The vision of the Program is to enable and nurture an ecosystem for preparing India’s technological and product development capabilities in biopharmaceuticals including vaccines, biologics, medical devices, and diagnostics to a level that will be globally competitive over the next decade.

REQUEST FOR PROPOSAL:

The Indo-US Clinical Research Ethics Fellowship Program has been jointly conceptualized by the Department of Bioethics, National Institutes of Health (NIH) and the Department of Biotechnology, GoI. The program has been designed to create leaders in the field of bioethics in India with the aim to specifically focus on capacity building in the area of clinical research ethics. After their training, and completion of the fellowship project, the fellows are expected to work towards capacity building in the area of clinical research ethics in India and establishment of centres of excellence in bioethics within research institutions. These centres of excellence are expected to serve as resource for research, training, guidance, and policy development, related to the ethics of clinical research in India.

APPLICATION TIMELINES: KEY DATES

RFP Publication	3rd August 2023
Closing of Application	18 th September 2023

OVERVIEW:

India's clinical research market has showed fast pace growth in the last decade and is expected to grow at an 8.7 percent compounded annual growth rate by 2025(as per the Fortune India report 2022) Bioethics is an important and critical component of clinical research in development of drugs, biopharmaceuticals, and medical devices. For capacity building in clinical research ethics in India, the Department of Biotechnology (DBT) of the Government of India and the Department of Bioethics at the Clinical Centre of the National Institute of Health (NIH) in the United States have collaborated to build capacity by providing research grants to early career scholars in bioethics (with a focus on clinical research) in India. The grant will be implemented through the Biotechnology Industry Research Assistance Council's (BIRAC) "Innovate in India (i3) Empowering biotech entrepreneurs & accelerating inclusive innovation", also referred to as National Biopharma Mission (NBM).

OBJECTIVE:

The objective of the program is to support motivated individuals with strong scientific background with interest in the field of bioethics. The present RFP for fellowship aims towards building a critical mass of trained scholars who will contribute actively to the international literature on clinical research ethics, and who will be able to advice clinical researchers, administrators and policy makers in India on emerging issues.

SCOPE:

The program will support research projects in the field of clinical research ethics including, but not limited to, ethical aspects of:

- Vaccine research and clinical trials
- Research participant recruitment in clinical research
- Informed consent for clinical research
- Research with stored biological specimens
- Return of unanticipated research results
- Research on novel technologies such as stem cells, CAR-T treatment, and gene therapy
- Controlled human infection models

- Research with specific vulnerable populations in interventional studies
- Research in new age technologies Artificial Intelligence/ Machine Learning (AI/ML), Data Sciences, Genomics) as applied in clinical Research.

WHO CAN APPLY:

Any interested professional having the following eligibility can apply with the endorsement letter in the desired format from the Host Institute. Selection of the Host Institute shall be subject to qualifying the eligibility criteria provided below.

ELIGIBILITY:

A. Fellow Applicant -

- The applicant should be an Indian citizen.
- The upper age limit for this fellowship is 45 years at the time of the submission of application, age will be calculated by taking the date of closure of the call.
- This RFP will consider applications from the following three groups:
 - i. MBBS/BDS/Bachelors in Traditional Systems of Medicine /Masters level training in Nursing/Paramedical Disciplines or Masters in Life sciences/Pharmaceutical sciences/Social Sciences/Ethics/Health Law with two years of experience and demonstrated interest in ethics and/or regulatory aspects of clinical research
 - ii. Clinician scientists with experience or training in ethics, working in institutions engaged in research who demonstrate an intent to take the learning from the fellowship forward for wider dissemination (preferably regionally or nationally).
 - iii. M.D./M.S./M.D.S./PG Degree in Traditional Systems of Medicine (hereinafter to be referred as “M.D./M.S.” only)/ Ph.D. in Health Sciences/Life sciences/Pharmaceutical sciences/Social Sciences/Health Law or equivalent degree related to health from a recognized university in India. In case of Ph.D., the PhD thesis should be relevant for clinical research ethics.

Note:

- Those who have submitted their Ph.D. thesis and are awaiting award of degree are also eligible to apply, but their selection will be subject to the condition that they would have submitted thesis before the expiry of the validity of the award offer.
- Those who are appearing in the final examinations of their M.D./M.S./M.D.S./ PG Degree (MD/MS) in Traditional Systems of Medicine and are waiting for their final result are also eligible to apply, but their selection will be subject to the condition that they should have their final result before the expiry of the validity of the award

offer issued in this regard by BIRAC.

- The fellows will **NOT** be allowed to work with their guide/co-guide and in the same department/institute from where they have earned their Ph.D./M.D./M.S./M.D.S. degree. The award will provide both a fellowship and a research grant.
- Preference will be given to applicants who hold a permanent/tenured position in any Institution/University recognized in India complying with the eligibility.
- It is desirable that the applicant should have an excellent track record (i.e., a track of peer reviewed publication or clinical research projects).
- Applicant cannot have more than one fellowship at a given point of time.
- Applicant should have a valid passport before execution of the “Award Letter” and be eligible for an appropriate U.S. visa.

B Host Institute:

- Recognized Universities/ Institutes established under statutes/ Academic Research Institutes/ Research Foundation/ Medical, Dental or Traditional Medicine Colleges established as a legal entity under the relevant Laws of India having at least 51% Indian stakeholders (owners/partners/trustees/members/associates etc.) are eligible as a Host Institute (each one shall hereinafter be referred to as “Host Institute”). The Host Institute could be Public (Central/State)/Private, registered under or as a Trust, Society, Non-profit Organization or Corporations.
- The Host Institute should have a department or active project-based engagement in Life Sciences or health related streams (Biotechnology/Biosciences/ Agriculture/ Horticulture/ Food technology streams/ Medical sciences/ Dental sciences/ Indian Systems of Medicine/ Law etc.) for technical support and expertise in bioethics field such as, but not limited to ethics, law, sociology, and public health.
- The Host Institute should be at least 3 years or older.
- Presence of supportive clinical trial infrastructure facilities, and a history of (clinical) research projects is a must.
- It is desirous for the Host Institute to have Network of experts, collaborators who can provide technical/business mentorship to fellows.
- Intent to provide a faculty post and /or set up a department focused on clinical research ethics.
- The Host Institute should endorse a commitment of a minimum 40% of the time for

tenured candidates of institute i.e., the fellows and 100% of the time for adhoc/temporary/contractual candidate towards the fellowship.

- Availability of IP, regulatory, business support to the fellows.

EXPECTATION FROM FELLOW APPLICANT:

- The Fellow Applicant must either be already working with, or first identify the host institution, and seek its concurrence under which the proposed research objectives will be pursued. Request for transfer of fellowship will not be entertained after completing one year under the fellowship program in a particular institution/organization, except under compelling circumstances for which the fellow and his Host Institute should submit proper justification prior to transferring the fellowship, which is up to the Competent Authority of BIRAC to review and approve.
- The proposal should be original and have a clearly defined plan with details of proposed activities, specific milestones and timelines, and the budget estimates.
- The Applicant will identify a host institute in India and a mentor at Department of Bioethics, NIH (<https://www.bioethics.nih.gov/>).
- The selected Applicant and the Host Institute for the present program shall enter into an agreement with BIRAC.
- The funding support shall be duly acknowledged when publishing/showcasing/presenting project particulars or outcomes as prescribed by BIRAC.
- The Fellowship requires the fellows to work full-time during the duration of the Fellowship and cannot combine it with any other concurrent Fellowship from other funding organizations or be in receipt of any other type of financial assistance except the salary they are entitled to get for the position held at the time during this fellowship program, if any. If the applicant is an employee, a No Objection Certificate from his/her employer must be furnished along with the application by the Fellowship applicant.
- If selected the Applicant shall not engage herself/himself anywhere else or take up any other assignments during the entire period of this Fellowship.
- A cordial relation with the Host Institute shall be maintained by the Applicant for the entire duration of this fellowship program. Any future disputes arising between the Host

Institute and the selected Fellow shall not impact the Clinical Research Ethics activity under this Program and shall be resolved amicably without BIRAC intervention. An undertaking mentioning the Dispute resolution Procedure between the Host Institute and the Fellow shall be submitted by the Fellow and Institute to BIRAC.

- The Applicant shall always ensure to submit all the necessary documents sought by the Host Institute within the given time period, to be submitted further to BIRAC.
- The Applicant must seek the consent of Host Institute if she/he intends to be away from the institute (except for field work related to the project) continuously for a period of more than eight weeks.
- Proper and complete documents regarding the fellowship project shall be submitted by the Fellow without any delay as per the Fellowship milestones and on completion of the Fellowship program.
- The Fellowship grant shall be solely utilized for the purpose of the project.
- The Fellow will be under the administrative control of the Host Institute where she/he would be working on the Fellowship and will be subject to the Rules and Regulations of the Institute concerned.

ROLE & RESPONSIBILITIES OF HOST INSTITUTE:

- The Host Institute with the selected Applicant shall enter a tripartite agreement – Host Institute, Applicant, and BIRAC
- Endorsement letters from the Host Institute need to be routed through the Head of the Institute/Director/Dean. The Head of the Host Institute shall appoint the selected Fellow as a point of contact *i.e.* as a project investigator for BIRAC.
- The Head of the Institution, where research work will be carried out, must certify that full equipment, laboratory and other facilities are available in the Institution for the proposed work and these will be made available to the applicant throughout the fellowship program without any additional cost from the fellows.
- Annual Progress Report and financial statements at the end of each financial year shall be submitted by the Host Institute to BIRAC most positively within 30 days of the end of each financial year.
- The host institution should provide necessary administrative and infrastructural support to the fellow applicant throughout the fellowship program.

- Host Institute shall be solely responsible to process further and deposit the Fellowship grant directly in the bank account of the selected for the project.
- The following documents should be sent to BIRAC after the duration of the Fellowship is completed:
 - a. Final Consolidated Statement of Expenditure (in duplicate), giving expenditure financial year wise (FY) from date of start till date of completion;
 - b. Utilization Certificates (FY wise) for all FYs (in duplicate) matching with Statement of Expenditure figures in that FY;
 - c. Project Completion Report (PCR) with list of publications, patents/copyright filed.
 - d. DD/ cheque for the unspent grant, drawn in favor of 'BIRAC'
 - e. Host Institute should provide endorsement letter(s) to the selected Fellow the intent to engage her/him after training in taking the work forward, with assured sustaining commitment from the Fellow.
 - f. Selected Applicant along with Host Institute are responsible for the timely submission of progress report, utilization certificate, project closure report (PCR), refund of unspent balance amount etc. at the end or early closure of the project.

NATURE OF SUPPORT AND FUNDING BY BIRAC:

- The research projects will be funded at recognized academic and/or research institutions, national laboratories and other recognized R&D institutions carrying out clinical research and/or has clinical trial infrastructure qualifying the eligibility criteria as provided in eligibility section above. No funding shall be provided to the selected Fellow directly by BIRAC.
- BIRAC shall not be responsible for any delay in disbursement of grant caused by the selected Fellow and host institute in submitting the required documents sought by BIRAC from time to time.
- The grant carries a fellowship honorarium of **Rs.2.00 lakh per annum** for candidates who have a permanent position in the host institute or are not availing any monthly fellowship; and of **Rs.85000/- per month** for temporary/contractual/adhoc position candidate (*refer Table 1 below*) hereinafter referred to as Fellowship Grant. The selected Fellows shall avail only one salary either from the Fellowship or from the place

of employment.

Table No.1

S.no.	Details	Total Fellowship Grant for each selected fellow candidate [in lakhs (INR)]
1	a) Fellowship with permanent position or	6.00
	b) Fellowship without permanent position	30.60

- In addition to the fellowship, a research grant, not exceeding **Rs. 40 Lakhs for a period of three years for each selected fellow candidate**, will be provided to pursue their research in the field of bioethics. This research grant will be provided in instalments upon completion of milestones. Grant under the recurring and non-recurring head's may be divided under the sub-heads of a) Manpower (One project associate) b) Equipment's & Accessories c) Consumables d) Travel for training & conferences e) Outsourcing (specific to survey, data collection & statistics) f) Contingency (this shall also cover overhead charges or operational expenses to Host Institute). The budget allocation for each head must be provided by Fellow along with application as per his/her research plan.
- Flexibility is provided to the Fellow for utilizing the Research Grant as per the needs of the research work. However, the sanction of the grant under specific budget head and sub-heads shall be subject to evaluation by the expert committee and as per BIRAC norms.
- Research projects must be budgeted on a milestone basis. **Funding will be awarded for 3 years, subject to the applicant complying with agreed milestones.** Funds will be released on achievement of each milestone.
- The release of the next instalment of the grant will be considered only after submission of (a) Proper Utilization Certificate and Statement of Expenditure, financial year wise i.e., from 01st April to 31st March and (b) Annual Progress Report at BIRAC.
- The selected Fellow shall be eligible for 2-3 months' short focused visit for the purpose of research provided in the scope to the NIH's Department of Bioethics. Under this, the fellows will get the following which is over and above the Research Grant:
 - a. A support to cover round trip economy class travel expenses from Fellow's

home city to Bethesda, MD as well as living expenses for 2-3 months (Up to a total of USD 12,000 per Fellow)

- b. The Fellows will have the option to apply for USD 3,000 to cover relevant travel in U.S. during their stay at the NIH Clinical Centre.

This amount will be provided to the selected Fellow directly by NIH. No amount shall be claimed by the candidate for this purpose from BIRAC.

- Change of Host Institution is generally discouraged and can be allowed only in exceptional cases. Change of Host Institution shall be undertaken only after obtaining due approval from NBM/BIRAC. The new host institute in any case should not be the institution where the applicant has worked for her/his Ph.D. or obtained the Ph.D. degree.
- If the fellow candidate leaves the Host Institute and joins elsewhere or changes the Host Institute without approval of BIRAC, her/his fellowship will be terminated and the Host Institute shall refund the un-utilized/unspent amount disbursed by BIRAC for that duration. For the purpose of termination, a separate termination clause will be inserted in the relevant tripartite agreement.
- If the Host Institute is a Government entity, then it shall keep the Grant-in-aid assistance in a separate interest-bearing account with a Scheduled Bank (as defined under the RBI Act, 1934), the withdrawals and payments from which account shall be subject to verification by BIRAC. The interest earned on the Grant-in-aid should be reported to BIRAC.
- If the Host Institute is a private entity, then it shall keep the Grant-in-aid assistance in a separate no-lien account in the name of the Institute with a Scheduled Bank (as defined under the RBI Act, 1934), the withdrawals and payments from which account shall be subject to verification by BIRAC. It shall also obtain and furnish to BIRAC a letter from the concerned bank foregoing the right of set off or lien in respect of such account. Further, the interest earned on the Grant-in-aid if any should be reported to BIRAC. The interest thus earned will be adjusted towards further installment of the fund.
- The Global Access of any product or new IP generated through all supported projects shall be governed and regulated as per BIRAC norms.
- The obligations under this fellowship are non-transferrable.
- The Fellowship can be terminated at any stage and time on a month's notice if BIRAC

is convinced that appropriate progress is not being made or the grant has not been utilized properly.

- The Fellowship can also be terminated forthwith if the particulars given in the application form for Fellowship are found to be incorrect or false at any point of time.
- BIRAC reserves the right to terminate fellowship forthwith without assigning any reason.
- In the event of the selected Fellow leaving before completing one year, she/he will be required to refund the stipend drawn by her/him from the date of joining to the date of leaving the fellowship.

PROJECT DURATION & NUMBER OF FELLOWS:

The projects will be supported for a period of **3 years** (starting from signing of Agreement) extendable further based on performance review/evaluation of the project done by respective committee at BIRAC. The duration of the Fellowship will be for a period of up to three years. The number of fellows selected is subject to merit of the applications received and availability of joint funding.

OUTCOMES:

The Host Institute is expected to submit an outcome report along with completion report to BIRAC at the end of the cycle highlighting the achievements of the Fellow in terms of awards won, patents filed, technology transferred, enterprise developed or follow on funding raised.

APPLICATION PROCESS AND INSTRUCTIONS:

1. Application guideline and process:

- The proposals can be submitted online by the Applicants as per the format provided in the website with a detailed user guide to facilitate the submission of the proposal online. Prior to the submission of the application, the applicant should prepare the following:
 - A cover letter describing her/his interest in the program, including a description of current position and conduct of bioethics research; plans for pursuing a career in bioethics; how participation in the NIH mentored bioethics research program might help to advance her/his current bioethics research and the preferred time period for the visit to the NIH.
 - A two-part research proposal in standard format has to clearly define the work to be undertaken in the host institute and at Department of Bioethics, NIH, USA. The proposal must describe how the project fits within current bioethics research projects in the Department of Bioethics, NIH and the proposed research proposal in India. Proposal should mention NIH faculties who might be able to mentor the project; and whether there has been any prior discussion of the proposed bioethics research with a faculty member.
 - An endorsement letter from the Host Institution, duly forwarded by the Competent Authority in favour of the applicant. If employed, a certificate from her/his employer to accept the Fellowship should be submitted. The endorsement should include a statement describing current involvement in bioethics research; how the Fellow will be involved in bioethics research activities after the NIH mentored bioethics research program; and how participation in the NIH mentored bioethics research program will

enhance their involvement in these bioethics research activities. The endorsement letter should be written on an official letterhead which should provide a clear indication of the letter writer's position.

- Curriculum vitae of the applicant
- Description of available clinical trial infrastructure and clinical trials, or active collaboration of the host institution with institutions that support clinical trials.
- Availability of host institutional expertise in relevant fields, such as ethics, law, sociology and public health.
- A description of how the position in clinical research ethics is integrated in the infrastructure for clinical trials at the institution.

The process of submitting the proposal online is detailed below:

- Go to BIRAC's website <https://www.birac.nic.in>
- Click on the Call for Proposal and then-current call tab in order to view the detailed description the call.
- Click on the active call (active link) against which you wish to submit the Proposal.
- Further details on 'How to Submit a Proposal' would also be available on BIRAC Portal.
- If you are a new user then you need to register your institute/organization by clicking on link: https://birac.nic.in/desc_new.php?id=327
- Once you register the account will be activated within 24 hrs. After activation, please create your login credential by browsing the same link: https://birac.nic.in/desc_new.php?id=327 . After registration, you will receive an auto-generated link on the registered email id entered at the time of registration.
- If you are already a registered user, then kindly enter your login credential on the given link in order to submit proposal: <https://birac.nic.in/login.php>
- Once you login into <https://birac.nic.in> by using login credentials, then kindly click on "National Biopharma Mission" on the dashboard to submit the proposal.
- Applicants are advised to fill-up and submit their applications early without waiting for the last date in order to avoid any last-minute difficulties. The system stops accepting applications automatically after 5:00 PM of the last date of submission.
- Applicants are advised to provide sufficient details in their applications to allow an informed and fair evaluation/review.

Selection process:

Proposals will be selected based on a three-tier selection process:

- Primary eligibility checks by BIRAC.
- Peer review and shortlisting of proposals by Evaluation Committee.
- Presentation of research proposal before the Evaluation Committee and final selection.
- Fellows will be selected based on evaluation of their individual qualifications and the institutional commitment and other ancillary documents submitted by the Applicant and Applicant's Institute.
- BIRAC reserves the right to accept or reject any application for this Fellowship without assigning any reason.
- Successful submission of an application form does not guarantee admission to this Fellowship program.

2. Evaluation and Decision-Making Criteria

- **Proposal Merit:**
 - Does the Proposal's approach align with the objective of RFP?
 - Does the Proposal demonstrate preliminary work useful for the proposed scope of work?
 - Has the Applicant provided an adequate description of the existing facility to understand their present capabilities?
 - Are the objectives, activities and milestones well defined?
- **Applicant:**
 - Is the applicant competent to ensure the effective conduct of the proposed work?
 - Does the applicant qualify the basic eligibility criteria mentioned in the guidelines?
 - Does the applicant have relevant capabilities and appropriate experience for the same?
 - Does the applicant have any prior experience in the field of bioethics?
 - Has the applicant provided letters of support/agreements with any third party they would like to engage with during the different stages of the project?

- **Implementation:**

- Is the implementation methodology and work plan adequately detailed and realistic?
- Has the applicant provided clear metrics for monitoring project progress, including milestones and output expected timelines, budget?
- Has the applicant anticipated difficulties/risks that may be encountered? Have mitigation plans been considered in case of failure?

- **Budget Estimates:**

- Is the proposed budget reasonable considering the defined scope of work? Have reliable references been provided for justification?
- Is the resource allocation across various stages, sufficient and appropriate?
- Is the proposed budget clearly demarcated under proper heads specified in this RFP?
- Can the estimated budget proposed by the applicant be sanctioned as per BIRAC norms and mandates?
- Do the Applicant and Host Institute agree to submission of proper Utilization Certificate (UC) and Statement of Expenditure (SoE) in BIRAC format in the time period provided?

- **Intellectual Property:**

- The applicant team should have the legal interests and the freedom to operate as related to IP, including consent from others where applicable.
- IP developed through this grant will be owned by and will be the responsibility of the Fellow (unless stated otherwise) subject to pre-existing legal arrangements.

- **Requisites for Funding:**

- Successful proponents shall enter into necessary funding agreements. The fund disbursement will be subject to completion of required formalities by way of Grant-in-aid assistance and associated documentation. The fund recipient shall be accountable for fund utilization as per the sanction.

3. Fund disbursement per Fellow to Host Institute:

The disbursement of funds for the research project as well as the Fellowship will be carried out upon successful achievement of milestones. Disbursement may be done in four instalments as follows:

a. Signing of Agreement: (First Release)

30% of Research Grant (INR 12 Lakhs) + 2 Years of Fellowship Grant

b. 1st technical milestone: (Second Release)

30% of Research Grant (INR 12 Lakhs) after submitting Audited UC & SoE for First release.

c. 2nd technical milestone: (Third Release)

30% of Research Grant (INR 12 Lakhs) + final year of Fellowship Grant after submitting Audited UC & SoE till Second release.

d. Submission of final report: (Fourth & final Release)

10% of Research Grant (INR 4.00 Lakhs) amount after submitting Completion Report, Final Audited UC & SoE.

4. Process of sanction of funding:

- Site visits for Technical Due Diligence may be conducted (Physical/Virtual) however certified infrastructure pictures and details should be provided by the Applicant to BIRAC as and when required.
- Financial Due Diligence (FDD) may be done on case-specific requirements as per BIRAC norms.
- After, the final recommendation of the respective evaluating committee proposal will be processed further for financial concurrence, legal concurrence and issuance of Agreement as per BIRAC/DBT/Government norms.
- After successful execution of the agreement and submission of ancillary documents sought by BIRAC and fulfilment of other formalities, fund disbursement will be considered by NBM/BIRAC/DBT.

5. Post Approval review and Monitoring

The projects will be monitored and mentored regularly by a Project Review and Monitoring Committee (PRMC) constituted by NBM/BIRAC/DBT for each project. On Successful completion of each Milestone, the applicant will be required to submit a detailed Milestone Completion Report (MCR) as per the prescribed format.

6. Definitions

Indian Citizen: An Indian citizen is defined as one who is in possession of a government approved proof of nationality such as a valid passport. NRIs are Indian citizens. OCI/PIO cardholders are not eligible for this scheme. As per Article 9 of the Constitution of India 1949, people voluntarily acquiring citizenship of a foreign state are not deemed to be citizens.

Contact details:

For queries about the application and submission of the completed application form:

PMU- National Biopharma Mission

Dr Madhvi Rao - nbm1.birac@nic.in

Or

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