

Indo-US Clinical Research Ethics Fellowship

Under the aegis of

Indo –US Vaccine Action Programme (VAP)

Request for Proposal

under

National Biopharma Mission

(Program co-funded by World Bank loan)

Biotechnology Industry Research Assistance Council (BIRAC)

**a PSU of Department of Biotechnology,
Ministry of Science & Technology, Government of India**

&

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, 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 Department of Bioethics, National Institutes of Health (NIH) and Department of Biotechnology, GoI. The program has been designed to create leaders in the field of bioethics with the aim to create capacity in the area of clinical research ethics. After completion of the 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. Centre of excellences are expected to serve as resource for guidance and policy related to the ethics of clinical research in India.

APPLICATION TIMELINES: KEY DATES

RFP Publication	01 st July 2022 till 29 th August 2022 (05:30 pm)
Closing of Application	8 weeks (60 days) from date of publication of RFP.

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 annual rate over the next five years. 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 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:

- Ethical aspects of vaccine research and clinical trial
- Research subject recruitment in clinical research
- Informed consent taken during the 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 vulnerable populations such as prisoners, children, or the socioeconomically

WHO CAN APPLY:

Any interested fellow person 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. This fellowship is open to Persons of Indian Origin (PIO) and Overseas Citizen of India (OCI).
- 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.
- The applicant must have obtained PhD in any area of Life sciences/Medical sciences/Pharmaceutical sciences or M.D./M.S./M.D.S or equivalent degree from a recognized university in India. 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.
- The fellows will **NOT** be allowed to work with their Ph.D. 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.
- The applicant should have an excellent track record (i.e., peer reviewed publications or equivalent)
- Applicant cannot have more than one fellowship at a given point of time.
- Applicant should have a valid passport and be eligible for an appropriate U.S. visa.

B. Host Institute:

- Recognized Universities/ Institutes established under statutes/ Academic Research Institutes/ Research Foundation/ Medical 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 in Life Sciences or related streams (Biotechnology/Biosciences/Agriculture/Horticulture/Food technology streams etc.) for technical support and expertise in bioethics field such as but not limited to ethics, law, sociology and public health.
- Age of the Host Institute should be at least 3 years or more.
- Presence of supportive clinical trial infrastructure facility is a must.
- It is desirable for the Host Institute to have Network of experts who can provide technical/business mentorship to fellows.
- Plan to establish a permanent position in clinical research ethics in due course, subject to meeting statutory requirements.
- The Host Institute should endorse a commitment of 40% of the time for tenured candidates of institute and 100% of the time for adhoc/temporary/contractual candidate towards the fellowship.
- Host Institute to provide endorsement letter(s) to the Fellow Applicants.
- Availability of IP, regulatory, business support to the fellows.

EXPECTATION FROM FELLOW APPLICANT:

- The Fellow Applicant must first identify the host institution under which the proposed research objectives will be pursued.
- The fellow should carefully choose the Host Institute, availability of necessary infrastructural and other facilities etc. to carry out his/her research work before applying. Request for transfer of fellowship will not be entertained after completing one year under the fellowship program in a particular institution/organization, except on compelling circumstances for which the fellow & 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 for the same.

- The proposal should be original and have a clearly defined plan with details of proposed activities, specific milestones & timelines, and the budget estimates.
- The Fellow Applicant will identify a host institute in India and a mentor at Department of Bioethics, NIH (<https://www.bioethics.nih.gov/>).
- The selected Fellow Applicant with the Host Institute under 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 in the manner as prescribed by BIRAC.
- Fellowship requires the Fellows to work fulltime and cannot be combined with fellowships from other funding organizations. The Fellow Applicant once selected should not avail any other fellowship/funding or be in receipt of any other type of financial assistance except the salary they are entitled for the position held at the time and during this fellowship program. If employed, a No Objection Certificate from his/her employer must be furnished by the fellow applicant along with the application.
- Fellow Applicant shall not take up other assignments during the period of her/his fellowship.
- A cordial relation with the Host Institute shall be maintained by the Fellow Applicant for the entire duration of this fellowship program. Any future disputes arising between the Host Institute and the Applicant Fellow shall not impact the Clinical Research Ethics under this Program and shall be resolved amicably without BIRAC intervention. An undertaking regarding the same shall be submitted by the selected Fellow Applicant with the Host Institute to BIRAC.
- The Fellow Applicant shall at all times ensure to submit all the necessary documents sought by the Host Institute within the given time period.
- The Fellow Applicant must seek the consent of BIRAC and Host Institute if he/she intends to be away from the institute (except for field work related to the project) continuously for a period more than eight weeks.
- Proper and complete documents with regard to the fellowship project shall be submitted by the Fellow Applicant on completion of the fellowship program without any delay.
- 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 he/she carries his works and will be subject to the Rules and Regulations of the Institute concerned.

ROLE & RESPONSIBILITIES OF HOST INSTITUTE:

- The Host Institute with the selected Fellow Applicant shall enter into an agreement with 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 Applicant as a point of contact/as a project investigator for BIRAC.
- The Head of the Institution, where research work will be carried out, must certify that full equipments, 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.
- Annual Progress Report and financial statements at the end of each financial year shall be submitted by the Host Institute to BIRAC.
- The host institution should provide necessary administrative and infrastructural support to the fellow applicant throughout the fellowship program.
- Host Institute shall be solely responsible for further processing the BIRAC grant to the fellow candidate for the project.
- The following documents should to 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. Selected candidate 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 end or early closure of the project.

NATURE OF SUPPORT AND FUNDING BY BIRAC:

- The research projects will be funded at recognised academic 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 candidates directly by BIRAC.
- BIRAC shall not be responsible for any delay in disbursement of grant caused by the selected fellow applicant and host institute in submitting the required documents sought by BIRAC from time to time.
- The grant carries a fellowship of **Rs.2.00 lakh per annum** for candidates who have a permanent position in the host institute or is not availing the monthly fellowship and of **Rs.85000/- per month** for those candidates working on temporary/contractual/adhoc position (*refer Table 1 below*) hereinafter referred to as Fellowship Grant. The selected fellows on temporary/contractual/adhoc position to avail only one salary either from the fellowship or 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 Applicant 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 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 Applicant 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 candidate 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 from which the applicant has worked for his Ph.D. or obtained his Ph.D. degree.

- If the fellow candidate leaves the Host Institute and joins elsewhere or changes the Host Institute without approval of BIRAC, his/her fellowship will be terminated and the Host Institute shall refund the un-utilized/unspent amount disbursed by BIRAC for that duration.
- The Host Institute 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.
- 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.
- BIRAC reserves the right to terminate fellowship forthwith without assigning any reason.
- In the event of the selected fellow applicant leaving before completing one year, he/she will be required to refund the stipend drawn by him/her 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 and up to **2 fellows** for this call will be awarded.

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 fellows 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 Fellow Applicants as per the format. The website will provide a detailed user guide to facilitate the online proposal submission. Prior to application, applicant should prepare the following:
 - A cover letter describing his/her interest in the program, including a description of current position and bioethics research conducted; plans for pursuing a career in bioethics; how participation in the NIH mentored bioethics research program might help to advance his/ her current bioethics research and the preferred time period for your visit at the NIH.
 - A research proposal clearly defining 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 fellow applicant. If employed, a certificate from his/her 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 your involvement in these bioethics research activities. The

endorsement letter should be written on an official letterhead and 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 with institutions that support clinical trials at the host institution.
- 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 call detailed description.
- Click on the active call against Indo-US Clinical Research Ethics Fellowship.
- If you are already a registered user, then kindly enter your login credential at the below link in order to submit proposal: <https://birac.nic.in/login.php>
- If you are a new user then you need to register by clicking on link: https://birac.nic.in/birac_registration_page.php
- Once you register the account will be activated, login by using login credentials then kindly click on "Indo-US Clinical Research Ethics Fellowship" 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 contingencies. The system stops accepting applications automatically after 5:30 PM of the last date of submission.
- Applicants are advised to provide sufficient details in their applications to allow for an informed and fair evaluation/review.
- Applicants are advised to provide self-contained proposals with essential supporting materials provided as uploads.
- Requests for changes in the proposal once submitted will not be entertained.

- Please read through the proposal in its entirety and ensure that your technical details, budget, and organization details are in compliance with the eligibility criteria provided. The Applicants should read the guidelines for clear instruction and other details for comprehensive preparation of the proposal. Proposals for projects that do not meet the eligibility criteria and/or do not directly respond to the call area will not be reviewed, regardless other parameters.
- The proposed budget shall be made INCLUSIVE of all applicable taxes and shall be considered accordingly. The commitment of the applicant to put in its resources as part of the Project will be specified distinctly.

2. Selection process:

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

- Primary eligibility check 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 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.

3. 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 legally 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 has relevant capabilities and appropriate experience for the same?
 - Does the applicant has 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:**
 - Has the implementation methodology and work plan adequately detailed and realistic?
 - Has the applicant provided clear metrics for monitoring project progress, including milestones and outputs 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 in light of 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 fellow applicant be sanctioned as per BIRAC norms and mandates?
 - Does the Fellow Applicant and Host Institute agree to submission of proper Utilization Certificate and Statement of Expenditure 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 applicant (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.

4. 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 will 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.

5. Process of sanction of funding:

- Site visits for Technical Due Diligence may be conducted (Physical/Virtual) however certified infrastructure pictures and details to 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, application will be proceeded 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 initiated by NBM/BIRAC/DBT.

6. 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.

7. 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:

Mission Director,

PMU- National Biopharma Mission

Email- technical@birac.nic.in, mdpmubmgf@birac.nic.in