Investigator Initiated Research (IIR) Initiative 2023

ICMR-IAVI Joint Call for Proposal

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Closing Dates: Expression of interest (EOI) - 30th April 2023; Full proposal – 15th July 2023

The Indian Council of Medical Research (ICMR), under the Department of Health Research, Government of India, is the apex body in India for the formulation, coordination and promotion of biomedical research and continues to nurture ecosystems for enabling medical innovations and their introduction into the health systems across the country. Throughout this journey, ICMR has established a number of regional and international collaborations to accelerate health research in India leveraging on complementary strengths and synergies. This includes the successful partnership with IAVI towards joint mandate of developing scientifically robust practical solutions to public health problems.

IAVI, a global non-profit product development partner (PDP) organization, generously supported by U.S. Agency for International Development (USAID), is dedicated to building and strengthening capacity and capability in India and Africa towards accelerated efforts to develop a safe, effective, affordable and globally accessible HIV biomedical prevention tool to serve the unmet global health needs tailored to the most relevant populations.

ICMR and IAVI had undertaken a joint initiative to launch the first Investigator Initiated Research (IIR) Call in 2021 inviting research proposals from young investigators across Indian and African partner institutes on HIV and HIV-COVID-19 research.

To continue the efforts and further strengthen South-South collaboration, ICMR and IAVI are now launching the ***Second Investigator Initiated Research (IIR) Call 2023 inviting applications from young investigators across India and Africa on HIV*** *research under various priority areas towards enhancing indigenous scientific capacity of young investigators and promoting regional collaborations between India and Africa.*

The IIR Call 2023 will grant **Regional Collaboration Awards** to support joint collaborative projects between young Indian and young African investigators towards advancing scientific research and leadership across both regions. Each regional collaboration award will be for an approximate consolidated budget of 400,000 – 500,000 USD for a maximum period of 30 months for all partners across the two regions (at least 1 Indian and 1 African partner).

IIR call 2023 will aim to support ***3-4 Regional Collaboration Awards*** through a competitive selection process.

The Indian PIs will be funded by ICMR whereas the African PIs in a given joint project will be funded by IAVI. Certain activities such as interactive workshops/review meetings etc shall be funded jointly by ICMR and IAVI.

Eligibility

Researchers who have an advanced degree (PhD in life sciences/social sciences or equivalent Medical degree), have some experience of working in the field of HIV or want to pursue research in the field of HIV, and are under 45 years of age will be considered eligible to apply for this call.

For India: All primary applicants (PI) should be a permanent employee of the Institute. The current PhD students can be included as Co-PIs in the proposal. All applicants should preferably have a senior mentor as Co-PI in the proposal.

For Africa: All primary applicants (including current PhD students) should be affiliated to the institute OR be a permanent employee of that institute and must have a senior mentor as Co-PI who is a permanent employee in that institute.

Scope of the projects

Scientifically robust comprehensive proposals are invited in the field of HIV/AIDS prevention research. The proposals for 2023 may be in any of the disciplines of epidemiology, socio-behavioural research, community engagement, immunology, virology and discovery research towards informing vaccine/product development in the field of HIV. The proposals should align with at least one or more of the following four D's for impactful outcomes:

1. *Discovery* research (aimed at finding novel interventions (basic research));
2. *Development* research (aimed at developing innovative interventions related to HIV screening, detection, prevention, awareness, behaviour change);
3. *Delivery* or implementation research (aimed at learning how to overcome barriers in delivering effective interventions to the people who need them);
4. *Descriptive* Research (aimed at generating evidence to enable/facilitate developmental science).

The scope of this call will include the following research areas in the field of HIV:

- *Immunology, Virology and Discovery Research*
    - Study viral factors and their role in HIV replication dynamics /pathogenesis/transmission - genotypic (sequencing and phylogenetics), phenotypic (sensitivity & resistance to bNAbs) characterization, diversity and impact on susceptibility to neutralization;

- Predictive analysis for identification of new and recent infections and use of bioinformatics to study viral evolutionary patterns in Indian and African populations;
- Use of functional genomic approaches to dissect effective immune responses and host responses to HIV-1 acquisition and pathogenesis (in adults, adolescents and pediatric population);
- Study B-cell repertoire (diversity/frequency) and T-cell receptor diversity in healthy individuals to inform HIV vaccine design;
- Isolation, functional characterization and suitability assessment of broadly neutralizing antibodies relevant to circulating HIV-1 strains (in adult, adolescent & pediatric populations) in India and Africa and preclinical evaluation of novel antibodies;
- Understanding emerging trends of drug resistance in circulating HIV strains and their functional assessment;
- Design and characterization of immunogens that can elicit potent and broadly neutralizing antibodies for HIV-1.

- *Epidemiology*
  - Identifying most relevant target populations and emerging pockets of risk towards informing targeted intervention development – With a focus on physical and virtual network dynamics in diverse (including hard-to-reach) populations (including at-risk key populations, adolescents and young adults) across India and Africa;
  - Studying diversity and evolution of circulating viruses across different risk groups (including high risk key populations, adolescents and young adults, pregnant mothers and children below 2 years) and geographical regions (including urban/ rural) in India and Africa;
  - Understanding cost-effective approaches to identify acute/early HIV infections towards sustainable surveillance;
  - Identifying the unmet needs and translational gaps in prevention of mother to child transmission and addressing ways to address them in India and Africa;
- *Socio-behavioral research and Community Engagement*
  - Understanding population needs and factors (individual, social and structural) influencing a) uptake of preventive health services; and b) research participation (recruitment, retention, care) and innovative interventions and strategies to ensure participant-centric engagement;
  - Understanding the social, contextual and behavioral needs of adolescents and young adults (girls and boys), particularly related to their sexual and reproductive health and identifying adolescent-responsive strategies to engage them in HIV prevention research and product uptake;

- Developing and piloting innovative interventions/behaviour change strategies among at-risk populations (including at-risk key populations, adolescents and young adults, pregnant women, and children) towards improving prevention outcomes and ensuring meaningful engagement in India and Africa;
- End-user acceptability & health system feasibility studies for HIV prevention products in the pipeline to inform their development, introduction and uptake in India and Africa;

The proposed work may also include research questions utilizing data and samples from ongoing and prior trials and other studies as may be available to applying investigators.

Structure and selection process of the Applications

The application submission will be in 2 stages:

1. *Expression of Interest (EOI)*

- *T*he applicant will be required to submit a concise Expression of Interest (EOI) which should briefly describe the scientific rationale, objectives, study plan and intended impact (**detailed format for EOI attached as annexure 1**). The EOI submitted will be evaluated on the basis of defined selection criteria (**evaluation criteria for the EOI provided in the section below**).

- The shortlisted EOIs will be invited for an in-person pre-submission workshop towards enabling robust proposals and facilitated alignment among the identified collaborating partners.

2. *Full proposal*

- The shortlisted EOI applicants will be required to submit detailed proposals which will be evaluated and again scored **(evaluation criteria for the full proposals provided in the section below).**

The applicants must also submit the following:

- CVs of all collaborators (at the time of EOI submission)
- Detailed Budget (at the time of Full proposal submission)

The onus is on the applicants to find their own research collaborator(s) in the partner country(ies). Only a joint proposal with **atleast** 1 Indian and 1 African partner will be considered.

Evaluation criteria

1) **Expression of Interest (EOI)**

a) Scientific Relevance:

- Does the project align with the call's objective?

- Is the proposed project relevant to and important for the HIV prevention landscape including vaccine and/or antibody design/development?
- Is there a strong scientific rationale for the project?
- How significant is the impact that the proposed work will bring about in the field?

b) Innovation & Approach:

- Are the concepts, approaches or methodologies, instrumentation, or interventions novel to the field of research?
- Are the overall strategy and methodology well-reasoned and appropriate to accomplish the specific aims of the project?
- Are the plans for exchange visits, training, knowledge and tech transfer well-articulated and planned?

c) Investigators/Collaborations:

- Are the investigators well suited to achieve the aims of the proposal?
- Do the applications leverage on complementary expertise across partners to deliver in impactful outcomes?

2) <u>Full proposal</u>

Funding under this mechanism is only to support the realization of not-for-profit scientific work towards acquiring new knowledge, promoting scientific exchange within and across regions, and to foster the development of integration and cooperation between scientific organizations in India and Africa. Proposals will undergo a quality evaluation taking into account the following criteria:

- **Scientific Merit** - Does the project align with the call's objective? Is the proposed project relevant to and important for the HIV prevention landscape including vaccine and/or antibody design/development? Is there a strong scientific rationale for the project? What is the state of readiness for the proposed work based on the background information and scientific work in the relevant field? How significant is the impact that the proposed work will bring about in the field? How well does the project align with in-country programmatic priorities, does it support or provide additional value to programmatic needs? How relevant are the proposed outcomes of the project to the needs and constraints of the country(ies)/regions and target groups/final beneficiaries and does it have any policy impact?
- **Implementation Plan** - Are the objectives and endpoints/outcomes clear? Does the proposal have a justified study design, appropriate methodology and detailed analysis plan to achieve the stated objectives within feasible timeline? Is the implementation work plan adequately detailed and realistic? Is there clear metrics for monitoring project progress including milestones, and outputs expected timelines?
- **Investigator** - Is the investigator and other researchers well suited to the project? Do they have appropriate experience and training? Will the project allow career development for a young

investigator? If appropriate, is a suitable mentor identified? Is the investigator likely to make significant contributions to scientific capacity at the institute over time?

- **Operational Feasibility** - Does the applicant have access to adequate resources (samples, data, local linkages with relevant partners, infrastructure) to conduct the proposed work? Does the researcher consider/integrate other national collaborators, expertise and other ongoing work to strengthen the value or impact of this work? Has the applicant anticipated difficulties/risks that may be encountered? Have alternative tactics and mitigation plans been considered in case of failure?
- **Cost Effectiveness and Sustainability** - Is the ratio between the estimated costs and expected results satisfactory? Have the budgets required over the time frame been comprehensively mapped to highlight justified needs towards the proposed objectives? Are sustainability plans (based on results from current study) identified and linkages to broader national/international programs/sustainable funding mentioned?
- **Value of Partnership** - Does this collaboration provide significant value addition for the work proposed? Do the investigators have complementary and integrated expertise? Is there any additional future work expected through this partnership? Are the plans for capacity building (cross learning, knowledge sharing and tech transfer) between the collaborators across two regions well-articulated and planned? Are the team roles and responsibilities (including project management and coordination, governance and organizational structure) clearly defined?

- *Collaborative projects across institutes and across disciplines are highly encouraged to increase generalizability of data*
- *Innovative research in partnership with senior researchers or external collaborators where the work significantly focuses on building scientific capacity of mid-early career investigators is also encouraged.*
- *In order to provide equal opportunities to the widest number of eligible applicants to participate in this Call for Proposals, a primary applicant may submit only one proposal with the same partner institution(s). A primary applicant can only be awarded one grant under this Call for Proposals. An applicant may at the same time be partner in another application.*
- *All short-listed projects will be subject to consideration and due approval by Health Ministry's Screening Committee (HMSC) before initiation.*

Application Procedure

The EOI should be a concise concept of the proposed idea. The complete proposal should be a detailed description of the intended research, including the scientific principles upon which it is founded. The EOI and full proposal should be written to consider each of the review criteria outlined above.

We recommend that all co-investigators and collaborators mentioned in the proposal be aware of the proposed work at the time of EOI submission and have granted written permission at the time of full proposal submission.

The formats for EOI and full application are attached as Annexure 1 & 2 respectively.

The EOIs with relevant attachments should be uploaded on the ICMR portal (http://iircall.icmr.org.in/home.php) as per the deadline mentioned below. Subsequently, the shortlisted EOI applicants will need to submit full proposals post the pre-submission workshop again on the ICMR portal as per the dates mentioned below.

Important deadlines	
Launch of the Call	March 2023
EOI submission deadline	April 30, 2023
Full proposal submission deadline	July 2023
Final selection	September 2023

Contact Information

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Annexure – 1

Expression of Interest (EOI) Application Format

The application should be written in English. Please use a standard font (such as Arial 11 point, 1 spacing) and one-inch margins in completing the application. In addition to uploading the EOI, please upload an abbreviated CV (2 pages) of submitting investigators.

The components of the EOI should include the following:

A. General Information

Heading	*Instructions for applicants*
1. Title of the Joint Project	*Should be concise and yet sufficiently descriptive and informative*
2. Composition of the Consortium	*Specify all participating investigators from India and Africa with affiliation and contact details – email, phone number. Also indicate the identified project co-ordinator from among them from India and Africa. Add as many rows as required.*
India 1. Principal Investigator & project co-ordinator Name Designation Affiliation Email id Contact Number 2. Co-investigator 1 Name Designation Affiliation Email id Contact Number 3. Add more as required	
Africa 1. Principal Investigator & project co-ordinator Name Designation Affiliation Email id Contact Number 2. Co-investigator 1 Name Designation Affiliation Email id Contact Number	

3. Add more as required	
3. Location of the joint project	*Specify country(ies), region(s) where the activities specified within the project will be conducted*
4. Total duration of the joint project	*Specify in total number of months*
5. Total budget requested for the joint project	*Specify the per partner budget for both India and Africa partners and an overall consolidated budget for the total duration of the joint project*

B. Research Plan

Background and rationale (250 words)

Specify the background information including the current global scientific landscape and state of the art in the relevant field to justify the context of the project. The following should be specified in the rationale:

- If the project addresses an important problem or a critical gap in the field;
- Uniqueness/ novelty of proposed work in addressing the above problem/ gap;
- Where the project is a continuation of previous work how it builds on results of the previous work

Objectives of the Joint project (150 words)

Specify the (a) Overall Objectives of the proposal and (b) Specific objectives with investigators responsible.

Study Plan (500 words)

Provide the following:

- A brief description of the study design (including specifics on study populations, study site, expected sample size and experimental technics);
- Implementation methodologies with approximate timelines;
- Involvement of any stakeholders/ implementation partners including their roles and responsibilities;
- Specify plans for exchange visits and capacity building.

Impact (250 words)

Brief description of short-term and long-term impacts of the proposed outcomes of this project:

- Impact on scientific knowledge;
- Impact on target populations/ final beneficiaries;
- Impact at policy level in the relevant country/region;
- Impact on regional capacity and capability.

Annexure – 2

Full Proposal Application Format

The application should be written in English. Please use a standard font (such as Arial 11 point, 1 spacing) and one-inch margins in completing the application. In addition to full proposal, a copy of any key or important literature that is cited and supporting letters from co-investigators or collaborators if applicable. Do not attach any additional appendices.

The components of the research proposal should include the following:

A. General Information

Heading	*Instructions for applicants*
1. Title of the Joint Project	*Should be concise and yet sufficiently descriptive and informative*
2. Composition of the Consortium	*Specify all participating investigators from India and Africa with affiliation and contact details – email, phone number. Also indicate the identified project co-ordinator from among them from India and Africa. Add as many rows as required.*
India 1. Principal Investigator & project co-ordinator Name Designation Affiliation Email id Contact Number 2. Co-investigator 1 Name Designation Affiliation Email id Contact Number 3. Add more as required	
Africa 4. Principal Investigator & project co-ordinator Name Designation Affiliation Email id Contact Number 5. Co-investigator 1 Name Designation Affiliation	

Email id Contact Number 6. Add more as required	
3. Location of the joint project	*Specify country(ies), region(s) where the activities specified within the project will be conducted*
4. Total duration of the joint project	*Specify in total number of months*
5. Total budget requested for the joint project	*Specify the per partner budget for both India and Africa partners and an overall consolidated budget for the total duration of the joint project*

Abstract (up to 500 words)

A concise description of the scientific program, and its expected outcome(s). Following questions should be addressed in the description:

- What major discoveries do you anticipate by undertaking this work?
- What scientific advancement(s) is anticipated and how it leads to advancements in product development or science?
- What key methodologies/ technologies will be employed to achieve the stated objectives.

Objectives/specific aims (up to 200 words)

Describes the major objectives/aims along with specific subobjectives.

Background and rationale (up to 700 words)

The applicants are asked to address the following:

- Describe the scientific foundation/ principles upon which your planned research rests;
- Provide a concise description of any scientific information/ data, novel discoveries, or guiding scientific doctrine that underpins, legitimizes, and substantiates your planned research; also highlight relevance of the work under the scope of this call;
- Describe the anticipated scientific and programmatic impact or value of the proposed work;
- A brief outline of the team's experience and ability to conduct the study should be provided as well as providing preliminary supporting data if applicable. Please include information of co-investigators and or collaborators where possible and their expected contribution to the work.

Brief description of methodology or study procedures (up to 1500 words)

Applicants are asked to provide a brief description of how they will achieve the objectives/specific aims along with the following:

- Describe the study population, number of participants and their desired characteristics including inclusion and exclusion criteria;
- Describe the nature of the data/samples collected (DNA, RNA, serum, plasma, cells or other) and the volume of blood/ sample. The specific study objective must be matched to the cohort/ sample type and any plans to store remaining samples must be clearly specified.
- Describe the scientific methodology and all experimental/data collection steps.

Brief description of analysis plan (up to 500 words)

Applicant should describe the analysis plan as relevant to the proposed work. It may include a list of pertinent variables to be used in the analyses, hypothesis testing and p value criteria, followed by a description of the different analyses to be done. Elaborate on analytical frameworks wherever applicable. Applicants are also encouraged to indicate available biostatistics support/ tools that will be integrated in the proposed work.

Brief description of the collaboration (up to 500 words)

A brief description of the collaborators and their role including any specific areas of expertise or resources they may bring. Collaborators may be part of the whole project or may be part of specific components e.g. the writing or data analysis, or earlier in the data collection phase if there are multiple sites that could participate.

Brief description on the mentorship (up to 350 words)

The capacity building component of mid-early investigators by senior experts. The proposed area of capacity building/ mentorship, why it was selected and the anticipated impact.

Milestones (up to 350 words)

Enumeration of the planned critical activities for the study and indicative timelines (e.g., draft protocol, submit to ethics, start research and/or analysis, write up results). Applicants are requested to provide a detailed workplan with clearly defined milestones/ deliverables along with the anticipated time for completion (measured in months following initiation of the program) for each of the milestones.

Budget (up to 500 words)

Applicants should provide a table that summarizes the budget for this project including adequate detail to allow an informed decision to be made about the request. Justification for each ask should be provided in a narrative following the table. In addition, the following should be addressed:

- Brief details on the source of additional/initial funding for work if appropriate (prior or current funding is not a requirement for this proposal and will not be counted for or against this submission).
- Details of sample shipments or of travel where necessary e.g. tech transfer training. Details of the budget should be explicit, particularly if aspects of the study are to be funded by other collaborators. Applicants may provide local currency amounts for budget but must include a column to show budget in US$.

Sustainability plans (up to 350 words)

Applicants are encouraged to identify potential opportunities to indicate plans for sustaining the work beyond the duration of this project through linkages to broader national/international programs/sustainable funding.