

Cohorts of HIV Resistance and Progression in Indian Children and Adults (CoHRPICA) Biospecimen Repository – Guidelines for Access to Biological Specimens

Introduction:

The central biorepository established, under CoHRPICA study, at ICMR National Institute of Translational Virology and AIDS Research (ICMR-NITVAR) houses a collection of high-quality biospecimens collected from individuals under different cohorts, which are now made available to larger scientific community across India to facilitate nationally relevant HIV research.

Eligibility:

All researchers in India are eligible to access the biospecimens.

Responsibilities:

- The researchers must adhere to all relevant policies, procedures and SOPs when accessing and using the biospecimens and/or data from CoHRPICA biorepositories/data management unit.
- The researcher must abide by approved research uses of the requested biospecimens and/or data. Biospecimens and/or data cannot be used for any other research projects unless a new request has been approved by the Repository Access Committee (RAC).
- It will be the responsibility of the researcher /requester to ensure funding and other necessary approvals for the research proposed by him/her.
- The researcher must not seek to identify individuals within the dataset and maintain confidentiality.
- The researcher must not distribute biospecimens in any form to any entity or individual or industry other than his/her research staff or trainees or independent collaborating investigators listed in sample/data access request applications.
- The researcher must ensure that biospecimens disseminated to him/her are secure.
- The researcher must not donate or sell the remnant biospecimen after study closure to any entity or individual or industry.

Application Process:

1. Submission of Application:

- Researchers may submit an initial email (cohrpica.nari@gmail.com) request to check availability of biospecimen as per the study requirement.
- After confirmation of biospecimen availability, a formal Access Request Form must be submitted (Annexure I).

2. Screening and Evaluation

- Applications are screened by the secretariat of Central Biorepository for completeness and each application will be assigned a unique reference number.
- RAC (Repository Access Committee) will evaluate the applications received by the secretariat.
- Researchers may be asked to present the study proposal and provide additional information requested by the RAC.

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- Decision of RAC will be communicated to researcher within 15 working days of the RAC meeting.

3. Special Considerations

- Expedited review may be requested for time-bound funding calls (with justification).
- Large or additional sample requests are reviewed case-by-case with proper justification.
- Additional samples under approved/funded projects require RAC review.

Biospecimen Dissemination:

Upon approval, the researchers must submit:

- Funding approval letter(s)
- IRB/IEC approval(s)
- Signed agreements (MDTA, CDA, etc.)

Once documentation is complete, biospecimens will be released within 15 days.

IMPORTANT:

- Researcher must obtain all necessary funding and regulatory approvals independently.
- Researchers are responsible for the arranging the shipments as per the required temperature at their own cost following IATA guidelines and their institutional SOPs.
- Secretariat will not be responsible for the shipments of the biospecimens.

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Annexure I: Access Request Form

1.	Primary applicant details	
a.	Name of Principal Investigator (PI)	
b.	Institution/Organization (Name and address)	
c.	Telephone	
d.	Email Id	
e.	Category of Institution/Organization	Please specify (√) ▪ Academia ▪ Industry
2.	Co-investigators/collaborators(Name, Institute/Organization) Please add more co-investigators if required	
a.	Co-investigator(1)	
b.	Co-investigator(2)	
c.	Co-investigator(3)	
3.	Area of Research	
4.	Title of research project	
5.	Project summary: Brief description of the research highlighting its strategic importance along with potential outcomes should be provided as a letter of intent (max 500-word count): Title: Rationale/Background/State of Knowledge: Hypothesis: Primary Objectives: Methodology: Outcome: Action Plan (Deliverables and Timelines):	

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6.	Source of funding (<i>attach a copy of funding approval</i>)	Status (<i>Please select an appropriate response</i>): Approved/Applied/Yet to be applied Name of the Funding Agency(s): Expected timeline for funding approval (<i>if applied/yet to be applied</i>):
a.	Total Budget for research project	
b.	Budget for Shipment of samples	
7.	Ethical Approval (<i>If approved attach copy of the approval letters from the respective IRBs</i>)	Status (<i>Please select an appropriate response</i>): Approved/Applied/Yet to be applied Expected timeline for IRB/IEC approval (<i>if applied/yet to be applied</i>):
8.	Institutional Biosafety Committee (IBSC) Approval (<i>If approved attach copy of the approval letters from the respective IBSCs</i>)	Status (<i>Please select an appropriate response</i>): Approved/Applied/Yet to be applied Expected timeline for IBSC approval (<i>if applied/yet to be applied</i>):
9.	Type of resource requested	<i>Please select an appropriate response</i> Biospecimens and associated data/ Data only
a.	For biospecimens and associated data	

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	Type and number of biospecimens (Provide a description of sample type requested including but not limited to: ○ cohort category ○ Type of visit ○ type of sample - serum/plasma/PBMCs; baseline/follow-up ○ number and quantity of sample vials for each sample type ○ Associated data required ○ Other specifications, as required to describe the request	
b.	For data only	
	Type of data (Provide a description of data type requested including but not limited to cohort category, number of participants, type of visit, and any other specifications, as required to describe the request)	
10.	Undertaking for proper use of biospecimens and/or data and forgiving due credit in publications and resultant products (Please sign to confirm all the below mentioned undertakings) I/we undertake that: a. Biospecimens and/or data requested will be used exclusively for purposes of the approved project detailed in the application submitted to the Repository Access Committee. b. The resources shared are for national use only. c. Due credit/ acknowledgement shall be given to the contributors (institutions and their investigators who have contributed to collection, processing of biospecimens and data, funding agencies and partners) as per the CoHRPICA study publication policy, while reporting, presenting or publishing the results of the research/ project in any manner. Name and Signature of Principal Investigator:	

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	Date and Place:
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List of attachments to be submitted along with the Form:

1. CV of the investigators/Co-Investigators.
2. Scanned copies of the Ethics and IBSC Approvals.
3. Copy of the complete proposal submitted to the funding bodies