**POLICY ON**

# Research Infrastructure Sharing Ecosystem (P-RISE)

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स्वास्थ्य अनुसंधान विभाग
DEPARTMENT OF
**HEALTH RESEARCH**

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# Policy on Research Infrastructure Sharing Ecosystem (P-RISE)

## A Document for sharing of DHR-ICMR Research Infrastructure for Integrated Healthcare Approach

**2023**

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# Abbreviations

| | |
|---|---|
| **AMC:** | Annual Maintenance Charge |
| **BSL:** | Biosafety Level |
| **CIF:** | Central Instrumentation Facility |
| **DG:** | Director General |
| **DHR:** | Department of Health Reseach |
| **GFR:** | General Finance Rules |
| **HR:** | Human Resource |
| **ICMR HQ:** | Indian Council of Medical Research Headquarter |
| **MoHFW:** | Ministry of Health and Family Welfare |
| **MoU:** | Memorandum of Understanding |
| **MSME:** | Micro, Small and Medium Enterprises |
| **P-RISE:** | Policy on Research Infrastructure Sharing Ecosystem |

# Contents

# 1. Background

Department of Health Research (DHR) works with a mandate of promotion and coordination of basic, applied clinical, and operational research through infrastructure, manpower, and skill development in cutting edge areas along with the implementation of such researches for better health outcomes and human well-being. Department of Health Research comprises the Indian Council of Medical Research (ICMR), an autonomous body, and its network of institutions across the country.

ICMR, the apex medical research body in India has always made substantial efforts to promote biomedical health research in the country. ICMR recognizes the growing need from the Indian research community for access to cutting-edge state-of-the-art technologies and instruments for medical and scientific research. ICMR, through its institutes, has developed a strong network of biomedical research laboratories in the country. These sophisticated laboratories created and maintained over the years in ICMR can also be effectively and optimally utilized for scientific research and academic growth of the country in the health research sector. The initiative of sharing and effectively utilizing these research laboratories generated through public funds, with researchers across the country will promote health research by ensuring quality research outcomes and facilitating innovative research.

Currently, access to cutting-edge and state-of-art facilities in health research infrastructure has limited access in India, due to the high cost of equipment's and their subsequent maintenance and running cost. A limited pool of trained manpower who handles such sophisticated instruments is another bottleneck. However, the number of researchers in the health sector is increasing day by day, and thereby it is imperative that mechanisms for access to critical scientific infrastructure should be in place to provide support to deserving researchers/ institutions who lack such facilities. The medical/dental/pharmacy colleges/ universities and other research-oriented institutions represent a large pool of researchers whose scientific outcome gets confined or compromised due to limited or no access to the required research infrastructure. This lacuna can be sealed to a maximum extent by making available the existing laboratory resources to all researchers in the country.

Considering the necessity of having a structured research infrastructure sharing and access policy, this document is formulated to provide guidance on appropriate sharing and responsible management of research infrastructure available in ICMR institutes.

# 2. Purpose and Scope

The purpose of the policy is to provide a structured overview for sharing of advanced research facilities in ICMR laboratories (high tech research infrastructure in the country even through institutes in Tier II cities) with researchers from medical colleges/universities and other institutions. This will help:

- Facilitate access to sophisticated instrumentation to researchers working in institutions with limited infrastructure, enabling them to perform good research.
- Encourage research outreach and networking.
- Improve quality data health research.
- Ensure cost-effective research outcomes.
- Avoid duplication of Research Infrastructure.

This policy may be referred by all researchers from Medical Colleges/Universities/R&D facilities/Start-ups/ MSME industries for utilizing the infrastructure facilities of the above given institutions for the purpose of Research and Development.

The overall purpose is to facilitate and encourage biomedical research in India and support research and development of health technologies to improve health of citizens and contribute towards make in India mission for diagnostics, therapeutics and vaccines.

# 3. Objectives

1. To establish access to a centralized network of scientific research infrastructure within ICMR to fulfill the research needs of all researchers across the country thereby ensuring optimal use of available research infrastructure.
2. To develop a provision of incentivization to the host institutes/researchers to support sharing and utilization of ICMR research facilities.

# 4. Benefits of the Research Infrastructure Sharing Policy

1. To ensure optimal use of research instrument/ facility available at ICMR institutes through sharing with Indian research community.

2. To reduce cost involved in procurement and maintenance of research infrastructure by sharing of established state-of-the art equipment/ infrastructure at ICMR institutes, thereby enhancing the efficiency of expenditure made by DHR-ICMR, MoHFW.

3. To resolve the unmet needs of researchers/ scholars/ academicians/ private organizations towards access to state of the art research infrastructure thereby promoting research activities and improving scientific output of the country.

# 5. General Terms and Conditions for Sharing Research Infrastructure

1. The host institute will list all the sharable instrument/ facility available at respective institute in the P-RISE portal. Basic general instruments may be included in Central Instrumentation Facility (CIF). It is mandatory that all equipment costing above 10 lakhs to be included in CIF and listed in portal.

2. Only those institutes listed in P-RISE portal will come under the purview of this policy.

3. Host institute should ensure that at least 20% of the user time of each equipment be allocated to external users.

4. Centralized instrumentation facility shall be responsible for maintaining the online log regarding the availability, usage and maintenance of instrument/ facility at each institute.

5. Only trained and skilled /certified operators of the host institutes will be allowed to operate the facilities of ICMR.

6. The services shall be availed by the external user under supervision of host institute only, as per the time slot assigned.

7. Liabilities of the host institute include ensuring the availability of equipment in the portal, maintenance of equipment at laboratories as per the terms of procurement, AMC and timely disposal of equipment as per GFR 2017.

8. Charges for maintenance and running costs of the instruments may be taken from requesters. For utilization of instrument/ facility at ICMR institutes, charges shall be proposed uniformly by a central committee on the user, based on the type of equipment utilized, number of samples to be processed and reagents utilized, factoring time etc. The pricing may be tiered for government & private institutions /universities/ industries / MSMEs.

9. The applicants with fund limitation will have provisions to request for subsidization, which will be decided by the respective institution based on the quality of research proposal on case-to-case basis. Such request may be submitted by the requester through portal in advance to the respective institute. There is provision of incentivization to the host institutes /researchers through a scheme to encourage the process of sharing/effective utilization of the instrument/ facility by the research community.

# 6. Procedure for Research Infrastructure Sharing

1. Each ICMR institute will set up a central instrumentation facility (CIF) to which all sharable equipment will be linked. Till the CIF is established, existing facilities may be open for utilization.

2. Research Infrastructure sharing will be promoted through an online system where all shareable instruments/facilities of ICMR institutes will be listed with trained manpower.

3. Researchers will be allowed to raise a request for booking through the portal, which will be confirmed by the institute.

4. The portal must clearly maintain an update of facilities which are non-utilized, optimally utilized or over-utilized, for optimal distribution of resources.

5. All ICMR intra-institutional booking will also have to be done through the portal.

6. There will be a 4-level hierarchy implemented while accessing the CIF of ICMR institutes through the online portal with individual responsibilities as detailed in section 7.

7. CIF nodal officer will be the nodal contact for booking and processing who will further confirm the booking and communicate back after confirmation of slot availability from technical contact. Reports issued will be released with approval of Instrument in charge.

8. Data retention and disposal: Research data and related records must be retained only for the minimum period that will not exceed one month from generation of the report.

9. Ownership and Copyright: No ICMR institute/CIF facility members will have ownership/copyright on any of the tests done or result generated unless agreed before the test is conducted, in case of instances like collaboration, mutual agreement etc. However, the efforts of ICMR may be acknowledged by the user writing any manuscript/ research paper/ report.

# 7. Responsibility of the Stakeholders

## A. Office of P-RISE at ICMR Headquarters

a. A unit will be set up at the ICMR Head Quarter to centrally monitor and facilitate the research infrastructure sharing mechanism of DHR-ICMR. The unit will co-ordinate with the nodal officer of individual institutes for facilitation.

b. ICMR-HQ shall develop user-friendly and interactive portal with public access and simple dashboard display with a single window approval process and maintained centrally at ICMR HQ.

c. The Central Committee will be responsible for deciding on the charges for usage of instruments subjected to approval of DG, ICMR to maintain the uniformity of pricing across all ICMR institutes.

d. An independent committee to review the appropriate implementation and utilization of facilities needs to be put in place.

e. Any complaints may be addressed to the in-charge of P-RISE unit at ICMR HQ (whose details will be displayed in the portal). Complaint redressal mechanisms are also inbuilt in the portal.

f. DHR/ICMR funded labs and other institutions will be encouraged to join this policy to share their research infrastructure with needy researchers. Provisions will be available in the portal once a request is made to ICMR HQ to add such institutes voluntarily willing to share their facilities through an MoU, as approved by the oversight committee at ICMR-HQ.

## B. ICMR Institutes

a. The institute will be responsible for purchase, maintenance and providing HR support for the instrument listed in P-RISE.

b. The institute will maintain usage log for each equipment/ facility listed in P-RISE.

c. The following hierarchy will be responsible maintaining the activities of CIF.

- Head of the institute: Governance and Monitoring of CIF facility.
- CIF Nodal officer: Will be in charge of CIF facility and routing of test requests received, confidentiality of the data/information generated and coordinate redressal of complaints. The Director of the institute will identify nodal officer.
- Instrument in charge: The person in charge of the Department /Division in which the instrument is placed.
- Technical Contact: Person in charge of handling or using the instrument. Dedicated technical staff may be assigned for instrument.

d. All samples should be received along with the form signed by authorized personnel (requester).

e. Upon receiving the sample sent/handed over by a requester, the technical person/staff should assess the quality of processing and note the comments on the same in the portal.

f. In case of samples with compromised processing quality, the technical person/staff with approval of the instrument in charge can reject the sample from accepting and modify the booking.

g. In case, the samples are of unknown/known infectious material (of high risk), the bio safety level can be requested by the user and the central committee or the nodal officer may look into the suitability of BSL space to be provided for working to the requester.

h. Samples once tested will not be retained/ stored by the host institute.

i. Appropriate training to be imparted to users/custodians at regular intervals to ensure quality optimal use of the instrument.

j. Robust referral mechanisms for sending requests from one lab to another.

k. The Technical contact will advise/suggest the requester the quality of reagents, chemicals, supplies etc to be brought or carrying out the work.

l. A 'Quality Control' system is mandatory at the institute level.

m. Complaint redressal system may be developed at institute level to resolve issues that comes under the purview of this document.

n. Revenue generated would be utilized for maintenance of CIF instruments.

## C. Researchers

a. Requesters should belong to a registered medical / research academic organization /MSMEs /industry.

b. Requests should be submitted and received through proper channel via the online portal.

c. Requester should make sure for submission of samples without compromising quality. In case of temperature/light sensitive samples, requester should take additional precaution to maintain the same.

d. The Data/result generated will be transferred only to requester through the portal or in originals as requested by the requester.

e. Requesters are encouraged to approach the CIF nodal officer before generating booking request for information regarding sample preparation, quality requirements, biosafety precautions and analysis parameters before the actual use takes place.

f. It is encouraged that users should provide pre-processed samples depending on the experimental requirement and the equipment to be used thereof. The ICMR institutes will not be responsible for processing or analysis of the data generated from the equipment.

g. Only samples for research purposes are entertained. Routine samples from hospitals/ patient care shall not be entertained through this facility.

h. Sample processing and submission may be done according to the instructions either available in the portal or as instructed by the CIF nodal officer.

i. In case of unsatisfactory data obtained, the complaint may be raised according to the Complaint Redressal mechanism mentioned in section 8.

# 8. Complaint Redressal

In case of any complaint, the researcher may approach the Head of the respective ICMR institute where the test was conducted. Also, the portal will have inbuilt complaint redressal mechanisms for transparency.

# 9. Dissemination of P-RISE and CIF of ICMR Institutes

1. All information related to P-RISE and CIF facility of Individual ICMR institutes will be available on the portal.
2. All ICMR institutional website will be integrated with the ICMR P-RISE portal.

# 10. Ethical Requirements

1. The CIF nodal officer will have all rights to ask the requester to submit a copy of the ethics committee or any other regulatory approvals as appropriate at any time point for processing the sample/ releasing the reports.
2. ICMR will have no ownership on the data derived unless previously committed by the user as in case of a collaboration or agreement.
3. User is bound to reveal the character, behavior and properties of all types of samples submitted through the portal to the CIF nodal officer and technical officer in view of the potential harm such samples may cause and precautions to be taken.

# 11. Legal Responsibility

1. It is the responsibility of all researchers and staff of ICMR institutes to ascertain and comply with any legal, ethical, or contractual confidentiality conditions relating to execution of the commitment made vide this policy.

2. Steps may be taken to ensure the confidentiality of data /test report generated for the requester.

3. ICMR CIF will not be responsible for any discrepancies/malpractices performed or happened on the sample submitted by the requester before it is brought to CIF facility and after being taken from CIF facility.

4. The ICMR institute will not be responsible for any failure in data acquisition due to machine failure/ loss of sample.

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