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GUIDELINES FOR

ESTABLISHMENT OF BIOREPOSITORIES IN ICMR INSTITUTES

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NEW DELHI, INDIA

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Secretary, Government of India
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FOREWORD

Biological specimens are invaluable assets for advancing biomedical research and strengthening public health systems. Over the years, ICMR institutes have generated and maintained a vast and diverse collection of biospecimens through surveillance activities, clinical studies, and laboratory research. These collections represent a significant national resource with immense potential to support scientific discovery and innovation.

However, the true value of these specimens can only be realized when they are collected, processed, stored, and utilized in a standardized and scientifically robust manner. This underscores the need for clear and harmonized guidelines to ensure their quality, integrity, and responsible use across institutions. Equally important is the systematic capture and maintenance of comprehensive, accurate metadata associated with each sample, which is critical for ensuring traceability, context, and meaningful downstream use. When managed appropriately, well-characterized and high-quality biospecimens can greatly accelerate research, enable development of diagnostics and therapeutics, and drive medical innovations that directly benefit public health. Establishing a consistent framework for their governance and utilization is therefore both timely and essential.

In this context, these guidelines provide a structured approach for standardizing biorepository practices across ICMR institutes with an aim to promote uniformity in processes, strengthen quality systems, and facilitate ethical and responsible access to biospecimens for research.

I am confident that this initiative will enhance the scientific value of existing collections and contribute significantly to advancing research, development, and innovation in the country.

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Dr. Renu Swarup

Former Secretary to the Government of India
Department of Biotechnology
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New Delhi, India

Message

I am pleased that ICMR has brought out the "**Guidelines for establishment of Biorepositories in ICMR Institutes".** The development of these overarching guidelines reflects a collective effort to bring greater coherence and scientific rigour to the best practices across ICMR institutes for establishing Biorepositories . With the growing scale and diversity of biospecimens being generated through research and surveillance activities, it is essential to establish structured systems that ensure their quality, traceability, and responsible use.

It has become evident that while significant capacities exist across institutes, there is a need to ensure that there is no variation in practices related to specimen handling, documentation, and access. There is therefore a need for formulation of a common framework that is both comprehensive and adaptable and ensures a uniform set of practices is followed across Institutes .

These guidelines cover key areas such as governance, infrastructure, biosafety, quality assurance, data management, and ethical compliance. They are intended to support institutes in strengthening their internal systems while enabling alignment with shared standards. A key consideration throughout this process has been to ensure that the framework remains flexible, allowing institutes to tailor implementation based on their specific needs and specimen profiles, without compromising on core principles.

As the Chair of the Committee ,I would like to acknowledge the valuable contributions of all committee members and stakeholders who have provided their expert views and insights in shaping this document. I am confident that these guidelines will facilitate a more coordinated and consistent approach to Biorepository management to support high-quality research across the ICMR network

(Dr. Renu Swarup)

Committee Chairperson,

भारतीय आयुर्विज्ञान अनुसंधान परिषद
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Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India

Dr. Sanghamitra Pati
Additional Director General

As biomedical research becomes increasingly collaborative, data-driven, and translational, the importance of well-organized biorepositories has grown substantially. The scientific value of biospecimens lies not merely in their storage, but in the strength of the systems that ensure their quality, traceability, accessibility, and responsible use. Developing such systems across institutions requires both standardization and sustained coordination.

This is an important initiative towards creating a coordinated framework across ICMR institutes. By linking repositories through common principles and operational standards, it aims to improve consistency in biorepository practices, strengthen institutional capacities, and support efficient access to well-characterized biospecimens for research and innovation.

These overarching guidelines provide a practical and structured foundation for institutes to align their practices in areas like specimen handling, inventory and data management, governance, quality assurance, and ethical oversight. They are intended to serve not as a rigid template, but as a guiding framework that enables harmonization while recognizing institutional diversity.

I hope this document will serve as a useful resource in advancing that collective effort.

Dr. Sanghamitra Pati
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2. ICMR-Centre for Cancer Pathology (ICMR-CCP), New Delhi
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4. ICMR-National Institute for Research in Bacterial Infections (ICMR-NIRBI), Kolkata
5. ICMR-National Institute for Research in Tuberculosis (ICMR-NIRT), Chennai
6. ICMR-National Institute for Research on Blood and Immune Disorders (NIRBID), Mumbai & ICMR-Centre for Research, Management and Control of Haemoglobinopathies (ICMR-CRMCH), Chandrapur
7. ICMR-National Institute for Research on Women's Health (NIRWoH), Mumbai
8. ICMR-National Institute of Child Health Research (NICHR), New Delhi
9. ICMR-National Institute of Epidemiology (ICMR-NIE), Chennai
10. ICMR-National Institute of Malaria Research (ICMR-NIMR), New Delhi
11. ICMR-National Institute of Nutrition (ICMR-NIN), Hyderabad
12. ICMR-National Institute of Occupational Health Research (NIOHR), Ahmedabad
13. ICMR-National Institute of Traditional Medicine (ICMR-NITM), Belagavi
14. ICMR-National Institute of Translational Virology and AIDS Research (ICMR-NITVAR), Pune
15. ICMR-National Institute of Virology (ICMR-NIV), Pune
16. ICMR-National JALMA Institute for Leprosy & Other Mycobacterial Diseases (ICMR-NJIL&OMD), Agra
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18. ICMR-National Institute of Health Research (ICMR-NIHR), Bhubaneswar
19. ICMR-National Institute of Health Research (ICMR-NIHR), Gorakhpur
20. ICMR-National Institute of Health Research (ICMR-NIHR), Dibrugarh
21. ICMR-Regional Medical Research Centre, Sri Vijaya Puram (ICMR-RMRCSVP)
22. ICMR-National Institute for Vector Control Research (ICMR-NIVCR), Puducherry
23. ICMR-National Institute for Research in Digital Health (ICMR-NIRDH), New Delhi

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Abbreviations

BMS	Biorepository Management System
BSL	Biosafety Level
CIOMS	Council for International Organisations of Medical Sciences
DBT	Department of Biotechnology
DNA	Deoxyribonucleic Acid
IATA	International Air Transport Association
IBSC	Institutional Biosafety Committee
ICMR	Indian Council of Medical Research
IEC	Institutional Ethics Committee
IMS	Inventory Management System
IRB	Institutional Review Board
ISBER	International Society for Biological and Environmental Repositories
ISC	Institute-Specific Committee
ISO	International Organization for Standardization
LN_2	Liquid Nitrogen
MTA	Material Transfer Agreement
NABL	National Accreditation Board for Testing and Calibration Laboratories
NIMR	National Institute of Malaria Research
NIV	National Institute of Virology
NIVCR	National Institute for Vector Control Research
NJIL&OMD	National JALMA Institute for Leprosy and Other Mycobacterial Diseases
OECD	Organisation for Economic Co-operation and Development
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RNA	Ribonucleic Acid
SOP	Standard Operating Procedure

Preamble

Biological specimens are critical resources for advancing biomedical research, strengthening public health preparedness, and fostering innovation. Their scientific value depends not only on their intrinsic characteristics but also on the quality systems, governance mechanisms, and ethical safeguards under which they are collected, stored, and shared. A coordinated and standardized approach is therefore essential to ensure integrity, traceability, and responsible utilization of these resources.

In recognition of this need, the Indian Council of Medical Research (ICMR), as the apex body for biomedical research in India, has undertaken the initiative to establish a harmonized framework for biorepository governance, building on the extensive collection and storage of diverse biological specimens across its institutes. To operationalize this initiative in a systematic and consistent manner, comprehensive guidance is required to support institutes in aligning their practices with shared standards and principles.

These overarching guidelines provide a structured foundation for the establishment and functioning of biorepositories within ICMR. They outline key principles relating to organizational governance, operational standards, biosafety and biosecurity, quality management systems, data stewardship, and ethical and regulatory compliance.

This document is intended to serve as a guiding framework for participating institutes, which may adopt and operationalize these provisions in accordance with their specific mandates and specimen profiles, while ensuring alignment with applicable national policies and ethical standards.

1. Background

Indian Council of Medical Research (ICMR) is the apex body of biomedical research involved in coordinating and implementing medical research, translating medical innovations into products, and simultaneously introducing them into the health systems. ICMR has a wide network of Institutes situated across various cities in India which are routinely involved in collection and storage of a diverse array of biological specimens like viruses, bacteria, protozoans, and fungi. They also maintain a diverse collection of human biological specimens including blood, urine, saliva, tissues, and biopsy samples as well as various plant specimens, all obtained from multiple pre-clinical studies, clinical trials, and cohort studies.

Several ICMR institutes already maintain specialized biorepositories. For instance, ICMR-National Institute of Virology (ICMR-NIV), Pune maintains a collection of several viruses belonging to various risk groups. ICMR-National Institute of Malaria Research (ICMR-NIMR), Delhi has preserved various *Plasmodium falciparum* samples in its malaria parasite repository, maintained since 1992. Similarly, ICMR-National Institute for Vector Control Research (ICMR-NIVCR), Puducherry has a state-of-the-art facility housing a wide variety of mosquito species. ICMR-National JALMA Institute for Leprosy and Other Mycobacterial Diseases (ICMR-NJIL&OMD) has been maintaining a Mycobacterial Repository, established in 1997 with the support from Department of Biotechnology (DBT) and ICMR. It currently houses well-characterized mycobacterial isolates. While these biospecimens are occasionally shared with researchers, there is an opportunity to include them into a nationally integrated biorepository system.

Building on these existing capabilities and with an aim to standardize the collection, storage, access, and use of high-quality, well-characterized specimens, ICMR is establishing an integrated system of biorepositories with its Institutes. The participating ICMR institutes are shown in **Figure 1**. This initiative is envisioned as a national platform for advancing biomedical research, facilitating education and training, supporting industry collaborations, accelerating vaccine development,

strengthening medical countermeasures, and promoting public-private innovation to improve health outcomes. To support this vision, there is a need for overarching guidelines for the acquisition, processing, storage, and utilization of biospecimens and associated data, stored at various ICMR Institutes.

S.No.	Participating ICMR Institutes
1	Indian Council of Medical Research, Headquarters
2	ICMR-Bhopal Memorial Hospital & Research Center (ICMR-BMHRC), Bhopal
3	ICMR-Centre for Cancer Pathology (ICMR-CCP), New Delhi
4	ICMR-National Institute for Pre-Clinical Research (NIPCR), Hyderabad
5	ICMR-National Institute for Research in Bacterial Infections (ICMR-NIRBI), Kolkata
6	ICMR-National Institute for Research in Tuberculosis (ICMR-NIRT), Chennai
7	ICMR-National Institute for Research on Blood and Immune Disorders (NIRBID), Mumbai & ICMR-Centre for Research, Management and Control of Haemoglobinopathies (ICMR-CRMCH), Chandrapur
8	ICMR-National Institute for Research on Women's Health (NIRWoH), Mumbai
9	ICMR-National Institute of Child Health Research (NICHR), New Delhi
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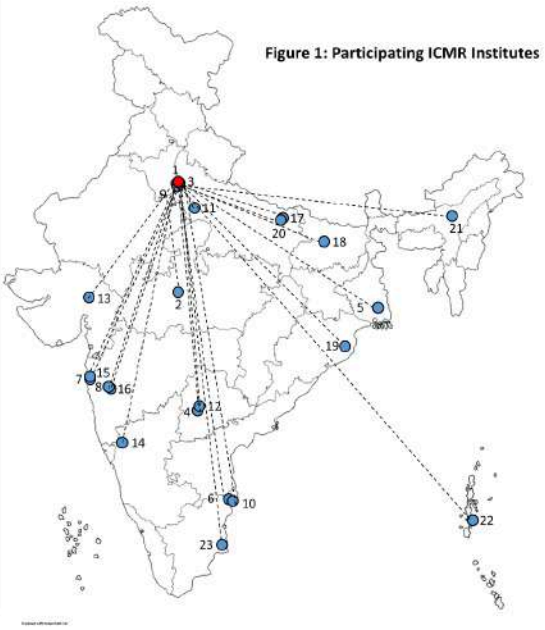

Figure 1: Participating ICMR Institutes participating

Accordingly, the current document has been developed as a set of overarching guidelines encompassing the full spectrum of biorepository operations, including organizational and operational frameworks, infrastructure requirements, biosafety and biosecurity measures, quality management systems (quality assurance/quality control [QA/QC] and standard operating procedures [SOPs]), risk management, ethical and legal compliance and data management. These guidelines are intended to assist participating ICMR institutes in adopting informed and standardized practices while ensuring regulatory and ethical compliance. Each participating Institute is expected to adopt these guidelines as a foundational framework and develop detailed, institute-specific procedures tailored to the type of specimens

maintained at their respective sites alongwith the operational requirements of the biorepository.

1.1. Scope

The current document of overarching guidelines is intended to provide only general guidance to standardized procedures for the collection, transportation, processing, storage, and sharing of biological specimens. It outlines technical, operational, and ethical best practices to promote consistency and standardization across ICMR institutes participating in this initiative. These guidelines will ensure specimen uniformity, quality and integrity and can be used across different ICMR Institutes / medical colleges or industrial partners.

1.2. Mandate

To have a uniform system for the use of biospecimen resources in India to nurture and promote innovations.

1.3. Goals

To establish Biorepositories for biospecimen acquisition and preservation, for long-term research use.

1.4. Objectives

- To establish standardized and harmonized processes including an integrated information management system for the collection, storage, sharing, and utilization of biological materials for research and development across all participating ICMR institutes.
- To have well-characterized, viable biological material available to support research, education, and industry-led product development.
- To build and strengthen national capacity by developing local expertise in biorepository management and operations.

Section 2

Operational Management of Biorepositories

The purpose and operational requirements of a biorepository must be clearly defined during the planning stage to ensure specimen quality and data integrity. A biorepository stores various biological specimens, including DNA, RNA, organoids, along with associated information. These specimens may originate from humans, plants, vectors, or other sources and can be collected either directly from the source or as preserved material that has been stabilized for long-term storage, such as frozen organs, fixed tissues, or lyophilized samples. Effective operation of a biorepository depends on appropriate infrastructure, trained personnel, and reliable support systems. These overarching guidelines provide a structured overview of the components essential for the planning, establishment, and operation of a biorepository while recognizing that each participating site of ICMR may have different specimen types and specific requirements that need to be addressed in detail in their own site-specific guidelines.

2.1 Infrastructure

Infrastructure must provide secure, contamination-free storage and maintain controlled environmental conditions. In order to achieve this:

- Each participating ICMR institute must allocate a designated space for the biorepository facility, equipped for secure and long-term preservation of biological specimens.
- The biorepository facility should include specimen storage units operating at multiple temperature levels (−80°C, −20°C, 2–8°C, liquid nitrogen [LN_2], and vapor-phase freezers) with standby systems.
- The lighting in the biorepository should suit the storage area, the work being done, and the specimen type.

- In areas with the potential for low oxygen levels or the presence of hazardous gases, oxygen and carbon dioxide monitors with audible and visible alarms must be installed in accordance with manufacturer instructions. These systems should be integrated with a dedicated exhaust system that replaces room air in compliance with applicable regulations and without air recirculation. Areas prone to high humidity should also be equipped with appropriate dehumidification systems.
- Reliable electronic monitoring and security systems should continuously track freezer performance and ambient conditions, recording temperature, humidity and oxygen levels. Further, the air quality should be maintained through appropriate biosafety measures [Biosafety level (BSL)-2/3 as per specimen type), with defined alert and response mechanisms. An adequate backup power system must be in place to maintain critical operations, like specimen storage, monitoring, and LN_2 filling cycles.
- Biorepository infrastructure should be tailored to the needs of each specimen type stored at each participating institute.

2.2 Biorepository Personnel

- Participating ICMR institutes must ensure that personnel are appointed based on the nature of activities and type of services provided. Staff may include managerial, technical, administrative, and support personnel, with clearly defined roles and responsibilities aligned with the biorepository's scope and resources. Each participating institute should define its staffing structure in accordance with its operational requirements.
- A documented institutional structure outlining roles, responsibilities, and reporting lines should be maintained. All personnel must be trained, competent in assigned tasks, and compliant with institutional policies and applicable regulations, including data privacy and confidentiality. Refresher training of the personnel and relevant certifications should be conducted periodically.

- Staff must be skilled in managing biospecimen data, operating biorepository equipment, and following SOPs to maintain specimen integrity, and confidentiality. Dedicated personnel should handle sample processing, storage, and data management, and verify completeness of accompanying documentation and associated data, as well as regulatory and protocol compliance, before approving sample access or deposits. Personnel handling infectious specimens must be vaccinated according to recommended schedules (Hepatitis B, anti-rabies, tetanus, etc.), and their records must be maintained.
- Staff handling infectious specimens must complete mandatory International Air Transport Association (IATA) Dangerous Goods Regulations training (identification, classification, packaging, labelling, documentation) and undergo emergency response and disaster preparedness training.

2.3. Biosecurity Measures

- Biosecurity measures to prevent loss, theft, or misuse of biological materials must be implemented at each Institute. These measures may include restricted access, biocontainment, end-user qualification (ensuring individuals handling materials are trained and authorized), and inspections (internal or external audits of facilities).
- Each participating institute must also have biosecurity policies for unexpected or unidentified materials, covering containment, quarantine, disposal, and escalation procedures. Personnel must be trained in biorisk management and, where relevant, receive appropriate immunizations.

2.4. Biospecimen Collection, Processing, Storage, and Transportation

- Each ICMR institute maintaining a biorepository must ensure proper acquisition, storage, and distribution of specimens and related data to maintain quality, integrity, and traceability.

- There should be well-documented SOPs governing collection, processing, cataloguing, and long-term storage of biospecimens. SOPs should be tailored to each specimen type and associated analytes, covering all stages from collection or extraction to storage, handling, and processing.
- Each participating ICMR institute must establish and follow specimen-specific SOPs tailored to the types of specimens handled, with due consideration to viability status and applicable regulatory, safety, and ethical requirements.
- Specimens should be identifiable and traceable throughout their entire lifecycle within the biorepository, regardless of format or container. Collection, preservation, and storage methods should ensure that any treatments (e.g., preservatives, dehydration) do not compromise the specimen's fitness for its intended purpose. QA and QC measures must be implemented at all stages to ensure consistent specimen handling.
- Each specimen should have a unique identifier catalogued within a centralized system (as mentioned in Section 3) to ensure confidentiality, enable traceability, accurately track usage and link the specimen to all preceding stages and associated data.
- Transport of biospecimens must follow specimen-specific SOPs, using leak-proof, multi-layered containers, wherever required. Hazardous specimens must carry biohazard labels, and non-hazardous specimens must be clearly marked according to the standard regulations.

2.5. Risk Management

- Participating ICMR institutes should establish a comprehensive risk management framework to identify, assess, and alleviate potential internal and external risks affecting biorepository operations.
- External risks may include natural disasters, public health emergencies, or cyber threats, while internal risks may arise from equipment failure, data errors, or personnel-related issues. Each biorepository should maintain a

documented risk log detailing identified risks along with mitigation and contingency measures.

- A formal risk management policy should define procedures for risk assessment, control, monitoring and ensuring operational preparedness. Biorepository personnel must be trained in and familiar with this policy to enable a proactive and coordinated response.

Section 3

Biorepository Inventory and Data Management System

3.1. Inventory Management System (IMS)

An integrated biospecimen inventory system is essential to maintain accurate and comprehensive records of samples and associated data throughout their lifecycle, from entry and tracking to retrieval and controlled sharing. **Figure 2** illustrates the operational flow of an IMS.

3.1.1. Unique Identification of Specimens

- Each biospecimen should be assigned a unique identifier to prevent misidentification and ensure traceability.
- Comprehensive metadata for each sample, including specimen type, source, collection date, processing method, storage conditions, and quality control parameters (e.g., number of freeze–thaw cycles, viability, integrity) must be recorded.
- In case of human specimens, donor or patient data must be coded or deidentified to protect confidentiality. The documentation of consent and regulatory compliance should be maintained for each sample.

3.1.2. Tracking Transportation and Chain of Custody

- The inventory should enable complete traceability of all specimen movements, including transportation to the biorepository, aliquoting, distribution, and release alongwith the remaining volumes. The participating Institutes must ensure accountability and compliance with ethical and operational standards at all stages of specimen handling.

3.1.3. Unique Identification and Tracking of Storage Units

- Each storage unit freezers, refrigerators, room-temperature cabinets, or liquid nitrogen tanks must have a unique identifier**.**
- Components within these units (shelves, racks, boxes, slots) should also be distinctly labelled. Barcodes may be used for accurate and efficient location tracking within the IMS**.**

3.1.4. Environmental Monitoring and Data Management

- Environmental parameters, including temperature, humidity, and container type (e.g. vial, plate, slide, cassette, straw), must be continuously recorded and maintained**.**
- The IMS should link these data to the respective storage locations and specimen identifiers.

3.1.5. Comprehensive Audit Trail

- The IMS must automatically record all data changes, including the original and updated values, user identity, method, date, time, and, where applicable, the reason for modification.
- Each data point must be traceable back to its raw source, ensuring data integrity and transparency**.**
- Audit trails should be conducted at regular intervals and must be read-only, searchable, and capable of generating electronic reports.
- Scheduled audits must verify data accuracy, resolve discrepancies, and ensure completeness.
- Records should be retained according to institutional and regulatory requirements.

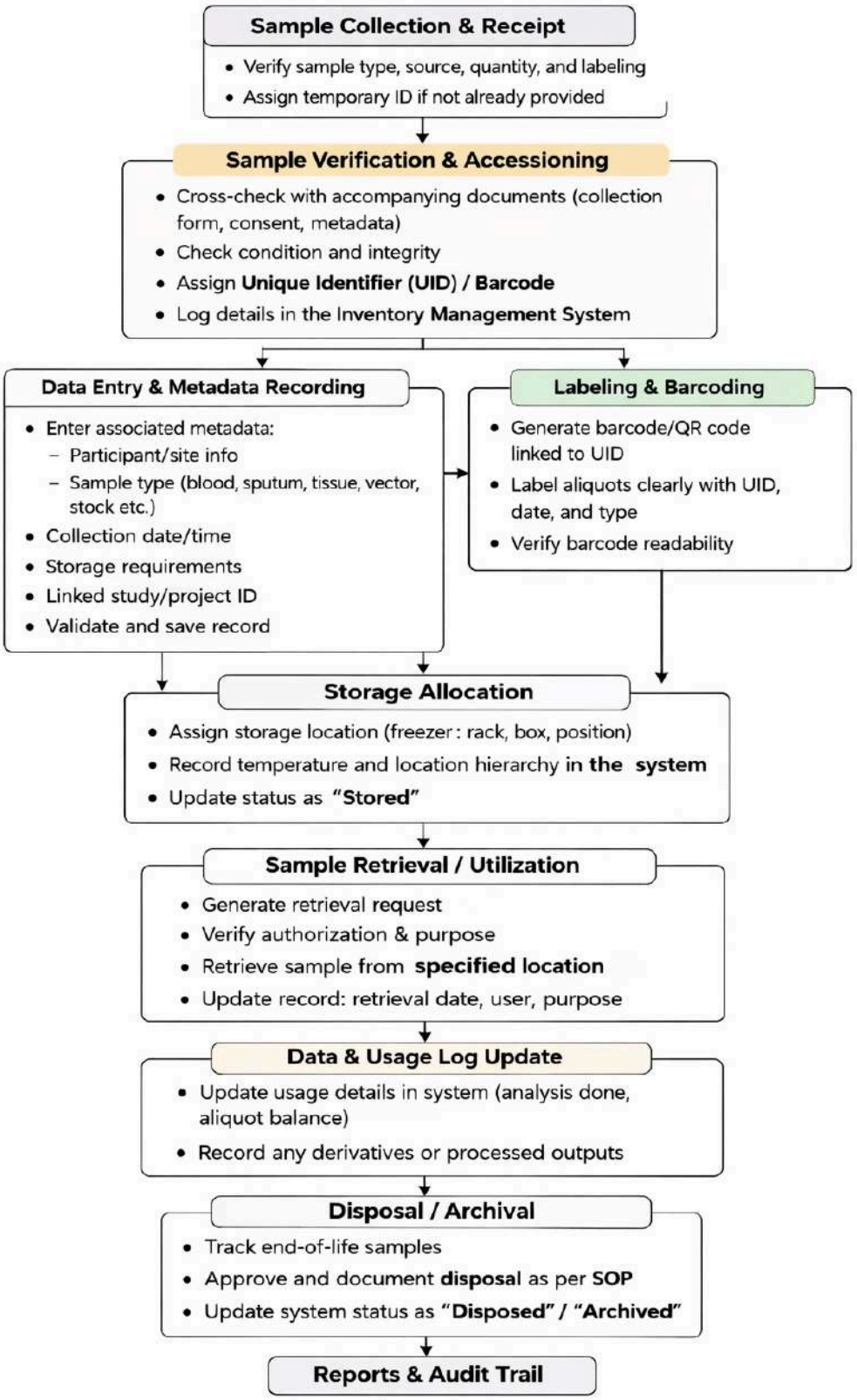

Figure 2: Operational Flow of Inventory Management System (IMS) at the participating ICMR institutes.

3.2. Biorepository Management System

The Biorepository Management System (BMS) should act as a centralized digital backbone that scales up from individual site-level inventory systems. By harmonizing data flow and ensuring seamless interoperability, the BMS should strengthen governance and standardize operations across ICMR biorepositories.

3.2.1. Centralized and Linked Infrastructure

Each site-specific inventory should be digitally linked to this central BMS system, hosted either at ICMR Headquarters or one of the designated ICMR institutes. The system should facilitate seamless coordination, real-time data access for authorized users, and transparency in operations.

3.2.2. Metadata and Privacy Protection

The BMS should maintain a secure backend repository containing detailed metadata for each specimen classification, collection details, processing method, storage conditions, and consent status. Personal identifiers must be replaced with unique alphanumeric codes to preserve privacy, with a secure key maintained under restricted access for ethically approved re-identification. These measures should align with ISO 20387:2018 standards and UK Biobank data governance principles**.**

3.2.3. User Interface and Access Management

The BMS should feature an intuitive, user-friendly dashboard displaying real-time, site-wise summaries of biospecimen availability categorized by type and subtype. Automated sample or data access requests should only be generated once all mandatory fields are completed. Access must be role-based**,** ensuring that permissions align with user responsibilities, while data sharing and approvals are managed centrally.

3.2.4. Lifecycle Event Tracking and Audit Trails

The BMS should be equipped to log and monitor all critical lifecycle events**,** including receipt, thawing, processing delays, internal transfers, destruction, and distribution or return of specimens. Automated audit trails must capture each data modification with the user, date, time, and reason, ensuring traceability and regulatory compliance. Audit logs must remain searchable and retained as per institutional policy.

3.2.5. Quality Assurance and Data Security

Routine database audits should be conducted to verify data accuracy, identify inconsistencies, and ensure completeness. The BMS should incorporate data validation, encryption, and privacy-preserving mechanisms to maintain data integrity and security. All processes should comply with ISBER (2018), OECD (2017), ISO 20387:2018, and UK Biobank (2023) standards, thereby promoting quality, accountability, and interoperability across ICMR biorepositories.

Section 4

Governance Framework

The biorepository must operate under a well-defined governance structure to ensure accountability, ethical conduct, regulatory compliance, and efficient resource management. The governance framework for ICMR's Biorepositories is illustrated in **Figure 3**, organized into two tiers: the Apex Committee and Institute-specific Committees. The components and functions of these committees are given below.

4.1. Apex Committee or National Group

This committee/ group will be formed centrally and shall comprise 3-4 experts with varied experience in the implementation and maintenance of biorepositories. This committee may be chaired by the Director General of ICMR. This committee shall be responsible for:

- Overseeing the technical, scientific and financial functioning of the biorepositories of ICMR.
- Monitoring the activities of the institutes associated with the biorepository.
- Undertaking annual reviews of the Institute-specific committees.
- Evaluation of the requests placed by the Institute-specific committee.
- Evaluating whether the sites have the infrastructure required to sustain a biorepository.

4.2. Institute-specific committee (ISC)

These committees will be constituted at the level of each ICMR Institute participating in the biorepositories and will comprise 3-4 members. The Director of the Institute will be the Chairperson of the committee, along with other relevant

scientists having the requisite experience in biorepository. These Institute-specific committees shall:

- Provide oversight of all institute-specific biorepository activities, including ethical, legal, scientific, and regulatory compliance.
- Review and approve proposals submitted by internal (ICMR) and external investigators (Medical colleges/ research institutions/ industrial partners).
- Oversee implementation of SOPs and ensure appropriate documentation and archival practices are in place.
- Review quality control mechanisms for different specimen types and ensure adherence to specimen access and deposit policies.
- Ensure submission of final study reports by researchers, industry partners, or collaborating institutions to maintain accountability and appropriate documentation of sample utilization.
- Ensure that ICMR is properly acknowledged in publications, patents, or other outputs arising from the use of biorepository specimens. Maintain copies of resulting publications/patents for repository records.
- Coordinate with the Apex Committee on operational or strategic matters, as and when required.

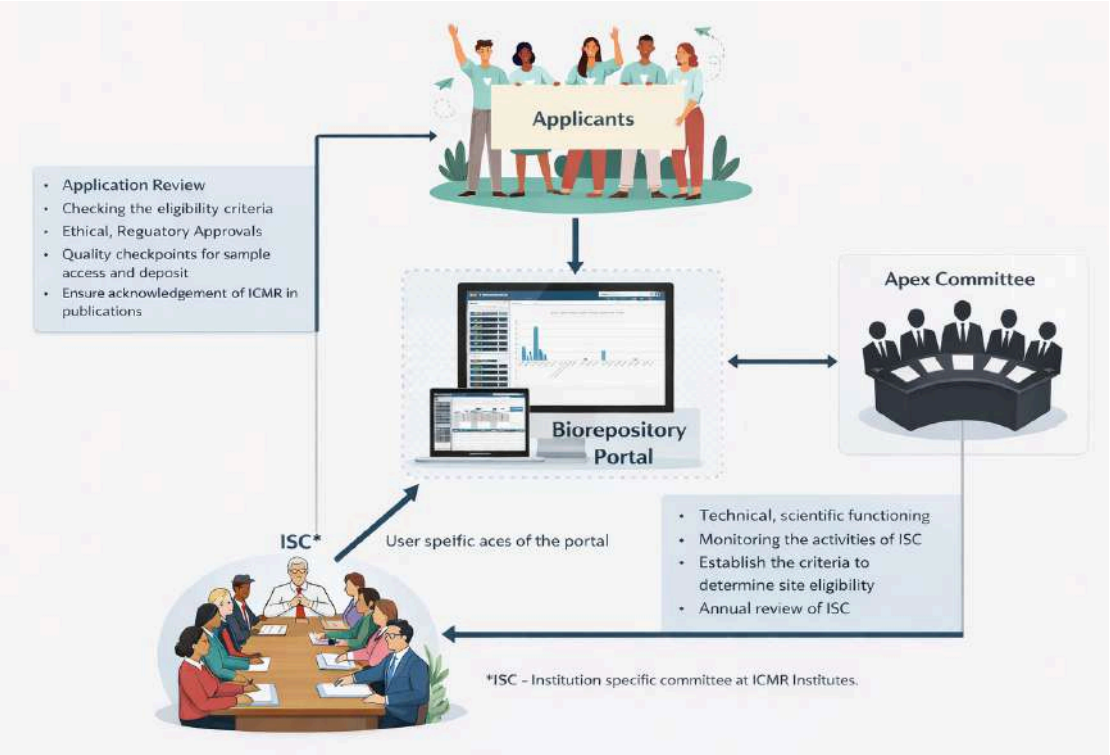

Figure 3: Conceptual Framework of ICMR's Biorepositories

Section 5

Ethical Implications

Biorepositories must uphold the highest standards of research integrity through transparency, accountability, and strict adherence to statutory regulations and the responsible stewardship of resources. Ethical considerations are foundational to all biorepository operations, encompassing critical issues such as obtaining informed consent, the safeguarding of donor confidentiality, and the rigorous regulation of secondary use for samples and data over time. To ensure that these ethical norms are met alongside the responsible utilization of biospecimens, the ICMR's Biorepositories will:

- Adhere to ICMR's Ethical Guidelines (2017, 2023) on health data and biorepository governance.
- Ensure that all biospecimens stored for future research use are collected with informed consent explicitly covering long-term storage and biorepository use, like:
    - broad future research applications
    - potential commercial use
    - possibilities for data sharing, including with third-party/international agencies, in accordance with the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines (2016), and
    - any other use approved by the relevant experts/ethics committee.
- Ensure that investigators clearly address the potential use of biospecimens stored in the biorepository during the initial consent process.
- Establish procedures for storing signed consent forms, where retained, including the storage format (paper or electronic) and appropriate backup mechanisms.

- Permit waivers of consent only when all criteria prescribed by ICMR or the relevant Ethics Committee/Institutional Review Board (IRB) are fully satisfied.
- Ensure that any end-user protocol for the use of specimens or data has received ethics review committee approval, where applicable, before granting access. Institutional Biosafety Committee (IBSC) clearance may be sought from the respective institute/centres requesting samples for research use.
- Recognize the potential risks associated with the handling and distribution of biological agents and toxins.
- Conduct routine biorisk assessments and implement appropriate biosafety and biosecurity measures based on the type and nature of specimens maintained at each Institute.
- Ensure fitness for purpose in biorepositories involved in plant collections, including frozen or fluid-preserved plant tissues, seeds, extracted nucleic acids, and associated data, while monitoring restrictions on collecting threatened, endangered, sensitive, or special concern species.
- Establish protocols for secondary use when applicants/end-users intend to use specimens or data for secondary research.

Section 6

Quality Management

Quality assurance (QA), quality control (QC), and quality management systems (QMS) are essential components of biorepository operations to ensure the integrity and reliability of biospecimens and associated data. QA encompasses the systematic planning, documentation, and monitoring of all the processes of biorepository to prevent errors and maintain compliance with established standards. QC involves the evaluation of biospecimens and associated data detecting deviations and ensuring that samples meet predefined quality criteria. A comprehensive QMS integrates QA and QC activities within a structured framework that includes standard operating procedures, personnel training, equipment calibration, data management, and internal audits. These elements are documented to provide clear guidance for repository personnel.

- Each ICMR biorepository must define what constitutes quality for different specimen types, and should specify acceptable limits, beyond which specimens or associated data would be deemed unfit for use.
- A biorepository should maintain a Quality Manual (QM) outlining the Institute's quality policies, roles, and responsibilities of personnel involved in quality management. The QM should also reference all relevant SOPs necessary to meet QA/QC goals in accordance with applicable regulatory, health, and safety requirements.
- Each ICMR institute participating in the biorepository initiative should establish SOPs clearly outlining methods for performing all critical operational tasks across the biospecimen life cycle. These SOPs should be periodically reviewed and updated whenever there are changes in policies, procedures, or methodologies.
- Competent personnel should be designated at each participating biorepository to oversee quality compliance activities.

- ICMR biorepositories should implement specimen QA protocols including comprehensive documentation and validation of specimen collection, processing, and storage activities, along with regular audits and other measures to ensure adherence to the predefined quality requirements.
- All staff involved in biorepository operations must receive regular training and guidance to ensure adherence to SOPs, internal policies, and applicable regulatory standards.
- Internal audits must be regularly scheduled and conducted to assess compliance with quality protocols. The frequency of audits should be defined by each participating institute. Audits should be conducted by qualified personnel independent of the activities being reviewed and reporting to a separate unit, such as quality assurance.
- Audits should also be initiated in response to incidents, non-conformities, or procedural deviations to facilitate timely corrective actions and continuous quality improvement.
- Biorepositories may seek alignment with, or accreditation from, internationally recognized standards organizations such as the International Organization for Standardization (ISO), including ISO 20387 (Biobanking), NABL ISO 15189 (for clinical testing laboratories), or ISO 9001 (Quality Management Systems). Such accreditation may provide external validation of the biorepository's quality systems.

Section 7

Access, Distribution and Use

Clear policies governing the access, distribution, and use of biospecimens must be established by each participating institute across its biorepository activities. These policies should define eligibility criteria for applicants, prioritize requests for rare or limited specimens, and incorporate safeguards to ensure ethical, legal, and biosafety compliance.

7.1. Access

Access to biospecimens should be governed by transparent, equitable, and scientifically justified procedures. Appropriate procedures must be followed for sharing of biospecimens to prevent unauthorized access, misuse, or inappropriate transfer.

- Each biorepository should have comprehensive policies and procedures governing the sharing of biospecimens and associated data. These must define permissible uses, establish prioritization criteria especially for rare or irreplaceable specimens and specify how access requests will be reviewed. All such details should be a part of the biorepository's access, distribution, and use policy.
- The ISC shall review all new requests for biospecimens at defined intervals on:
    - Scientific merit of the proposal
    - Credentials of the applicant and institution based on past publications, grants, and infrastructure
    - Availability of necessary ethical, biosafety, and regulatory approvals [Institutional Ethics Committee (IEC/IRB), Department of

Biotechnology (DBT), ICMR, etc.] specifying the intended use of samples.

- All transfers of biological specimens and associated data between biorepositories and end-users should be governed by a formal transfer agreement to ensure transparency, accountability, and compliance with ethical, legal, and institutional requirements.
- In this context, a Material Transfer Agreement (MTA) is a legally binding document executed before the transfer of biological specimens and/or associated data specifying the purpose of the transfer, including a description of the materials or data being shared, their intended use, and any relevant annexed documentation. The MTA must outline the ownership and rights related to the specimens and data, provisions for benefit sharing**,** and restrictions on use**,** such as prohibiting, resale, commercial exploitation, redistribution, or any use beyond the approved research scope. It should also clearly define intellectual property and publication rights**,** including proper acknowledgment of both parties and timelines for reviewing publications or patent applications arising from the work. The agreement should state the final disposition of unused specimens or data whether they are to be returned or securely disposed of, and include biosafety provisions, ensuring recipients handle materials safely and assume responsibility for any associated risks. Finally, the repository should ensure that any data-sharing restrictions specified in the MTA are upheld, including limitations on combining data from unrelated studies or sharing with third-party service providers.
- The MTA must also define rules for custodianship, access, and control of transferred data; protection against unauthorized access; restrictions on re-identification of participants (especially for de-identified specimens) and requirements for maintaining traceability, donor/participant privacy, and proper shipping and storage conditions.

- All requests for biospecimen access should be authorized by the Director of the respective Institute, accompanied by necessary ethical and regulatory clearances from the requesting institution.
- Specimen access must be regulated through a centralized IMS using a standardized cataloguing template across all participating ICMR institutes to ensure consistency, traceability, and oversight.
- Each participating institute must maintain comprehensive audit trails for specimens, including access logs, transfer records, approvals, and residual sample inventories, to ensure accountability and traceability of specimen use.
- ISC should ensure adherence to applicable biosafety and biosecurity standards, including measures against potential bioterrorism risks.
- Residual specimens remaining after approved use must not be utilized for new projects without fresh approval.
- Investigators seeking to access their own previously deposited samples, especially where such use may deplete remaining aliquots, must submit a request for review.
- Turnaround timelines for review and approval of access requests should be predefined at each participating site.
- All transfers and disposals of samples should be documented in site-specific SOPs, with procedures modelled on best laboratory governance practices (e.g., handling of controlled or hazardous substances). Before transferring biohazardous material, it should be ensured that the receiving institute has the required biosafety infrastructure and trained personnel.
- Prior to releasing any infectious specimens, an appropriate safety advisory should accompany the samples, highlighting potential infection or hazard risks.

7.2. Deposit

Biological specimen deposits in ICMR biorepositories may fall into three categories: General deposits accessible to researchers across India; Safe deposits for future

use submitted by researchers or industry partners, typically for pathogen storage; Regulatory deposits submitted specifically for regulatory compliance or reference purposes.

- The ISC must ensure that the origin, chain of custody, and documentation for all incoming materials are clear, complete and verifiable.
- Depositors are responsible for ensuring sample quality and providing complete metadata accompanying the biological material.
- Uncharacterized or unverified materials shall not be accepted for deposit.
- Before deposition, appropriate risk assessments and biosafety warnings must be conducted, especially for hazardous or high-risk specimens. High-hazard samples must follow dedicated transport and security protocols incorporating appropriate safety measures.
- Depositors should approach the nearest regional or specialized biorepository for their sample type to optimize logistics and ensure proper handling.
- Each site must define minimum and maximum deposit limits to prevent overburdening of biorepositories and ensure equitable access to resources.
- The depositor should retain the first right of refusal for future use of deposited samples during the approved “future use” period defined by the IEC. Deposits should not occur until that period has expired, unless explicitly permitted.

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Annexure I

List of SOPs – To be developed by each participating site based on the available sample type

- **Governance & Compliance**
  Ethical and Legal Compliance (consent management, privacy, confidentiality)
  Material Transfer Agreement (MTA) and Data Use Agreement (DUA) procedures
  Incident Reporting and Corrective Action/preventive action (deviations, non-conformities, accidents)
  Audit and Review Procedures (internal/external audits, corrective & preventive actions – CAPA)

- **Sample Handling & Processing**
  Sample Collection Procedures (site-level harmonization and labelling standards)
  Sample Processing and Aliquoting (plasma, serum, DNA, RNA, PBMCs, tissue protocols)
  Cryopreservation and thawing procedures
  Sample Disposal and Destruction (after study completion/expiry/withdrawal of consent)

- **Equipment & Infrastructure**
  Equipment Qualification, Calibration, and Preventive Maintenance
  Backup Power Management (UPS, generators, alarm response)
  Freezer/Liquid Nitrogen Tank Failure & Emergency Response
  Pest Control and Environmental Monitoring; Temperature monitoring

- **Data & IT**
  Laboratory Information Management System (LIMS) operation and backup
  Data Security and Confidentiality (access control, encryption, backups)
  Data Sharing and Reporting Procedures

- **Personnel & Safety**
  Personnel Competency Assessment and Requalification
  Personal Protective Equipment (PPE) Use and Biosafety Practices
  Emergency Response Procedures (spill management, fire, medical emergency)
  Health Surveillance and Immunization of Staff (e.g., Hepatitis B vaccination)

- **Sustainability & Oversight**
  Disaster Recovery Plan
  Periodic Risk Assessment and Mitigation Strategy

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