भारत सरकार
विज्ञान एवं प्रौद्योगिकी मंत्रालय
जैव प्रौद्योगिकी विभाग
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

सत्यमेव जयते

स्वच्छ भारत
एक कदम स्वच्छता की ओर

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File No. BT/BS/17/635/2015-PID **Dated 07.06.2021**

OFFICE MEMORANDUM

Subject: "Standard Operating Procedures (SOPs) for exchange of infectious biosamples/ biospecimens from biorepository, 2021"

In India, all activities related to Genetically Engineered organisms (GE organisms) or cells and hazardous microorganisms and products thereof are regulated as per the "Manufacture, Use/Import/Export and Storage of Hazardous Microorganisms/ Genetically Engineered Organisms or Cells, Rules, 1989" (Rules, 1989) notified by the Ministry of Environment, Forest and Climate Change (MoEF&CC), Government of India under the Environment (Protection) Act, 1986 (EPA 1986). The Review Committee on Genetic Manipulation (RCGM) functions in the Department of Biotechnology and monitors the safety related aspect of on-going research projects and activities involving Genetically Engineered (GE) organisms or cells and non-GE hazardous microorganisms and products thereof.

2. With increasing number of COVID-19 related biosamples/biospecimens transactions, the need for a document on regulatory SOPs was required.

3. The "Standard Operating Procedures (SOPs) for exchange of infectious biosamples/ biospecimens from biorepository, 2021" is hereby notified and can be accessed at http://dbtindia.gov.in, http://ibkp.dbtindia.gov.in.

4. It shall be binding for all public and private organizations involved in any biorepository related transaction of the Genetically Engineered (GE) organisms or cells and non-GE hazardous microorganisms and products thereof.

(Nitin Kumar Jain)
Member Secretary, RCGM
Scientist F, DBT

STANDARD OPERATING PROCEDURES (SOPs) FOR EXCHANGE OF INFECTIOUS BIOSAMPLES/ BIOSPECIMENS FROM BIOREPOSITORY

Department of Biotechnology
Ministry of Science and Technology
Government of India
2021

सत्यमेव जयते

डॉ. रेणु स्वरूप
DR. RENU SWARUP

सचिव
भारत सरकार
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MESSAGE

The COVID-19 pandemic accelerated research and development efforts to developing rapid diagnostic and also preventive and therapeutic measures for ensuring public health. Accordingly, the need of organized platforms for rapid access to different kinds of COVID-19 related biosamples and/or biospecimens was felt. In view of this, it is important to establish designated biorepositories for collecting, processing, storing and distributing biosamples/biospecimens, which would serve as resource material catalogue for validated and valuable samples. A biorepository also needs to ensure well-defined organizational structure that encompasses all aspects of biosamples/biospecimens management.

The Department of Biotechnology (DBT) recognises the significance of biosafety and biosecurity and has been at the forefront in ensuring their compliance as notified under "Rules for the development, use / import / export and storage of hazardous microorganisms / genetically engineered organisms or cells, 1989" (Rules, 1989) of the Environment (Protection) Act, 1986. The Review Committee on Genetic Manipulation (RCGM) functions in the Department of Biotechnology and monitors the safety related aspect of on-going research projects and activities involving hazardous microorganisms, GE organisms and cells and products thereof.

In view of large number of COVID-19 related biosamples/biospecimens transactions through the Biorepositories, it is essential to have a "Standard operating Procedures (SOPs) for exchange of infectious biosamples/ biospecimens from biorepository" to address the biosafety and biosecurity concerns involved in such transactions.

The purpose of this document is to provide guidance to stakeholders for standard procedures and regulatory approvals required for sample acquisition from biorepository, while ensuring compliance with biological safety. This guidance document applies to all the biorepository related transactions nationwide.

I Compliment the Team associated with the preparation of this document. I am confident that this will be very valuable to accelerate our Research efforts not just for COVID-19 but other infectious disease also.

(Renu Swarup)

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MINISTRY OF
SCIENCE & TECHNOLOGY

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PREFACE

The COVID-19 pandemic accelerated research and development efforts in developing rapid and efficient diagnostic as well as preventive and therapeutic measures for ensuring public health. Accordingly, the need of organized platforms for rapid access to different kinds of COVID-19 related biosamples and/or biospecimens was felt. In view of this, it is important to establish designated biorepositories for collecting, processing, storing and distributing biosamples/biospecimens, which would serve as resource material catalogue for validated and valuable samples. A biorepository also needs to ensure well-defined organizational structure that encompasses all aspects of biosamples/biospecimens management.

The Department of Biotechnology (DBT) recognises the significance of biosafety and biosecurity and has been at the forefront in ensuring their compliance as notified under "Rules for the development, use / import / export and storage of hazardous microorganisms / genetically engineered organisms or cells, 1989" (Rules, 1989) of the Environment (Protection) Act, 1986. The Review Committee on Genetic Manipulation (RCGM) functions in the Department of Biotechnology and monitors the safety related aspect of on-going research projects and activities involving hazardous microorganisms, GE organisms and cells and products thereof.

In view of large number of COVID-19 related biosamples/biospecimens transactions through the Biorepositories, it is essential to have "Standard Operating Procedures (SOPs) for exchange of infectious biosamples/ biospecimens from biorepository" to address the biosafety and biosecurity concerns arising from such transactions. These SOPs are also imperative to ensure that uniform procedures, protocols, standards, and practices are implemented by the biorepository community to ensure their well coordinated networking and functioning, while adhering to biosafety principles and practices.

We are sincerely grateful to RCGM members and Experts from the existing Biorepositories, for providing their critical inputs. We also acknowledge the contribution of Biosafety Support Unit, Regional Centre for Biotechnology, in preparation of this document.

This guidance document is applicable to all biorepository related transactions across both public and private organisations engaged in research and development activities and handling of GE organisms and non-GE HMOs nationwide.

Dr. Alka Sharma
Head, Regulation &
Adviser

Dr. Nitin Kumar Jain
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CONTENTS

ABBREVIATIONS

BSL	Biosafety Level
CSIR	Council of Scientific and Industrial Research
DBT	Department of Biotechnology
EPA	Environment (Protection) Act
GE	Genetically Engineered
HMO	Hazardous Microorganisms
IBKP	Indian Biosafety Knowledge Portal
IBSC	Institutional Biosafety Committee
ICMR	Indian Council of Medical Research
MoEF&CC	Ministry of Environment, Forest and Climate Change
NITI	National Institution for Transforming India
RCGM	Review Committee on Genetic Manipulation
rDNA	Recombinant DNA
RG	Risk Group
SOPs	Standard Operating Procedures

I. BACKGROUND

A biorepository is a facility that collects, processes, stores and distributes biosamples and/or biospecimens that are derived from humans, animals, plants and other living organisms. Biosamples/biospecimens refer to any material sample taken from a biological entity for testing, diagnostic, propagation, treatment or research purposes. Biosamples/biospecimens referred in this document are the infectious biological samples which require BSL-2 or higher containment facility. Biosamples/biospecimens can contain one or more components including but not limited to cellular molecules (like DNA, RNA or protein), cells, tissues, cell cultures, organs, clinical samples (like body fluids, blood, plasma, sera, body excretory products, naso-oro-pharyngeal swabs, saliva), microorganisms including hazardous microorganisms. Biosamples/biospecimens are collected and stored as a resource material to support research and development activities. The availability of high-quality biosamples/biospecimens requires the development of standardized methods for collecting, processing, storing, retrieving, and distributing through Biorepositories.

The integrity of a biorepository relies on the implementation of stringent study specific Standard Operating Procedures (SOPs) during collection, processing, storage, and distribution of biosamples/biospecimens. Although these SOPs differ to some degree according to the biosample/biospecimen, these procedures are an integral component of any biorepository. In order to ensure the health and safety of workers, safety protocols must be implemented in a biorepository in compliance with national and international regulations. The Department of Biotechnology (DBT) recognises significance of biosafety and biosecurity and has been at the forefront in ensuring their compliance as notified under "Rules for the development, use / import / export and storage of hazardous microorganisms / genetically engineered organisms or cells, 1989" (Rules, 1989) under the Environment (Protection) Act, 1986. The Review Committee on Genetic Manipulation (RCGM) functioning in the Department of Biotechnology, monitors the safety related aspect of on-going research projects and activities involving hazardous microorganisms, GE organisms and cells and products thereof.

The "Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment, 2017" details the principles and facility for handling of genetically engineered (GE) organisms (organism includes microorganisms, animals, plants, arthropods, aquatic animals, etc.) and non-genetically engineered (non-GE) hazardous microorganisms (microorganism includes parasites, protozoa, algae, fungi, bacteria, virus, prions, etc.). The Guidelines identify the levels of risk(s) associated with GE organisms and non-GE hazardous microorganisms (HMO) and classification of those organisms into their respective risk groups to select appropriate containment facilities. In addition, the criteria for Manufacture, Use, Import, Export, Exchange and Storage of any hazardous microorganisms, GE organisms or cells and product(s) produce through exploration of such organisms has also been detailed in these Guidelines. Research and development activities of GE organisms and non-GE hazardous microorganisms mandate adoption of stringent biosafety measures facilitating their safe use and handling. This is crucial for ensuring safety of public health and environment.

Designated biorepositories serve as integral component of an important structured mechanism for collecting and storing biological material, for facilitating research and

development activities across the Nation. Accordingly, biological materials must be properly collected, processed, preserved, stored, retrieved, transferred, and disposed of or decontaminated, in compliance with the Biosafety regulations.

ICMR has designated several Biorepositories for COVID-19. These biorepositories are responsible for collecting, storing and maintaining clinical samples (oropharyngeal / nasopharyngeal swabs, bronchoalveolar lavage, sputum, blood, urine and stool) of COVID-19 patients. Such samples may be used to develop validated diagnostics, therapeutics, vaccines etc. Additionally, the samples may prove to be a valuable resource for research & development related activities. The current list of ICMR Designated Biorepositories for COVID-19 is provided in **Annexure I**.

The Handbook for Institutional Biosafety Committees (IBSCs), Third Revised Edition, 2020 describes the role and function of Institutional Biosafety Committee (IBSC). IBSC is to be constituted by every organisation engaged in research, use & application activities related to GE organisms (organisms include microorganisms, animals, plants, arthropods, aquatic animals, etc.) and hazardous microorganisms ("microorganisms" shall include all the bacteria, viruses, fungi, mycoplasma, cells lines, algae, protozoans and nematodes). IBSC is the nodal agency within an organization for implementation of the biosafety regulatory framework. Accordingly, the IBSCs are also mandated for proper functioning of biorepositories, keeping a record of all transactions mediated through it and submitting annual transaction reports for consideration by the RCGM.

II. SCOPE

The present document lays down the standard procedures to ensure biosafety during the collection, processing, storage and transaction of biosamples/biospecimens which require BSL-2 or above containment facility for undertaking research and development activities; and is applicable for both public and private organisations engaged in research and development activities and handling of GE organisms and non-GE HMOs.

III. STANDARD PROCEDURES FOR SAMPLE ACQUISITION FROM BIOREPOSITORY

The concerned authority of the biorepository and the receiving organization shall strictly adhere to the principles and practices as per the Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment, 2017 for ensuring biosafety during the biosample/biospecimen transfer and on site handling, as set out below:

A. For setting up of Biorepository facility:

1. The institute/organization proposing to establish a Biorepository should have a registered IBSC.
2. The facility has to be duly inspected and approved by the IBSC constituted by the institute/organization where the Biorepository is situated.
3. Depending on the type of biosamples/biospecimens being handled in the facility, the availability of appropriate containment facility, that is, Biosafety level 2 (BSL-2) or above needs to be ensured by the organisation.

B. Sample Acquisition procedures:

1. A Template Declaration Form by the Biorepository authority is enclosed at **Annexure II**. Additionally, templates for Requisition Form and Declaration Form by the applicant are enclosed at **Annexures III** and **Annexure IV** respectively.

2. For receiving biosamples/biospecimens for research and development, the receiving organization needs to ensure that, it has a registered IBSC, an appropriate containment facility is available and duly used and submit the filled in application. The IBSC of receiving organization also needs to ensure the availability of trained manpower to handle the organisms received. It is also the responsibility of the IBSC for implementation of the biosafety regulatory framework in an Organization (Handbook for Institutional Biosafety Committee, Third Revised Edition, 2020).

3. The IBSC of receiving organisation needs to ensure that in the event of transfer of biosamples/biospecimens, appropriate approval to perform R&D on the samples received from the Biorepository is available. For R&D projects that involve handling of samples in Biosafety level 2, the IBSC approval from the institute/organization from where the samples are being requested is required. However, R&D projects that necessitate the handling of samples in a Biosafety level 3 and above facilities;require IBSC approval. The IBSC needs to ensure that necessary RCGM permission has been obtained (Revised Simplified Procedures/ Guidelines on Import, Export and Exchange of GE organisms and products thereof for R&D purpose, 2020). An Annual Transaction report of all the samples exchanged between Biorepository and receiving Organization(s) need to be submitted to the RCGM through IBKP Portal (https://ibkp.dbtindia.gov.in/) as part of the Annual compliance report.

4. Biorepositories need to ensure that in the event of transfer of biosamples/ biospecimens, the receiving organization should have their IBSC approval followed by RCGM permission, as applicable, to receive sample from Biorepository. Based on the approval of IBSC/ RCGM, the Biorepository can permit transfer of biosample/biospecimen to the receiving Organization. IBSCs of the institute where the Biorepositories are situated, should maintain the record of all the transactions. An Annual Transaction report of all the samples provided by the Biorepository to receiving Organization(s) need to be submitted to the RCGM through IBKP Portal (https://ibkp.dbtindia.gov.in/), as part of the Annual compliance report.

5. All the components of containment/storage of GE organisms and non-GE hazardous microorganisms, including storage facility, safety equipment, health and medical surveillance, decontamination and disposal, and emergency procedures must be strictly complied with the guidelines as per "Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment, 2017" and "Handbook for Institutional Biosafety Committee, Third Revised Edition, 2020".
6. To ensure the safety during the transport of the potentially infectious biosamples/biospecimens, care should be taken to transfer/transport the material as per the guidelines laid down for the transport of perishable and infectious agents, in "Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment, 2017".
7. The standard principles and practices for containment facilities must be complied with the "Guidelines for the Establishment of containment facilities: Biosafety Level 2 (BSL-2) & 3 (BSL-3) and Certification of BSL-3 facility, 2020".
8. Emergency contingency plans to be formulated in consideration of any possible breach in containment of the biosamples/biospecimens, as mentioned in "Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment, 2017". In case of any incident, it should be recorded and immediately reported to facility In-charge, IBSC and RCGM.

ANNEXURE I

DESIGNATED BIOREPOSITORIES FOR COVID-19

Following is the list of Designated Biorepositories for COVID-19:

ICMR Institutes:

1. ICMR-NIV, Pune
2. ICMR-NIV Field Unit, Bangalore
3. ICMR-NIV Field Unit, Allapuzha
4. ICMR-NICED, Kolkata
5. ICMR NIOH, Ahmedabad
6. ICMR- NIIRNCD, Jodhpur
7. ICMR-NIMR, New Delhi
8. ICMR-NIE, Chennai
9. ICMR-NIRRH, Mumbai

DBT Institutes:

10. DBT-NCR Biotech Cluster

(a) Clinical Sample – THSTI, Faridabad

(b) Viral Sample – RCB, Faridabad

11. DBT-ILS, Bhubaneswar
12. DBT - InSTEM, Bangalore
13. DBT funded Biorepository - ILBS, New Delhi
14. DBT- National Centre for Cell Science, Pune

CSIR Institutes:

15. CSIR - IGIB, New Delhi
16. CSIR - CCMB, Hyderabad
17. CSIR - IMTECH, Chandigarh

ANNEXURE II

TEMPLATE FOR DECLARATION FORM BY THE BIOREPOSITORY AUTHORITY

I…….certify that the exchange of biosamples/biospecimens with the applicant is in strict compliance with the DBT "Standard Operating Procedures (SOPs) for exchange of infectious biosamples/ biospecimens from biorepository, 2021". The applicant has submitted the duly signed IBSC approval letter and/or RCGM permit letter attached along with the Requisition Form (**Annexure III**) and Declaration Form (**Annexure IV**). The information as submitted by the applicant has been verified and found to be satisfactory.

Name of the authorised signatory:

Signature:

Biorepository Name and Address:

Date:

ANNEXURE III

TEMPLATE FOR REQUISITION FORM FOR BIOSAMPLE/BIOSPECIMEN

Request Details: Date:

1. Biorepository:
Name:
Address:
Contact Tel. No and Email ID.:

2. Competent Authority/Principal Investigator of the receiving Organization:
Name:
Place of Work:
Address:
Contact Tel. No and Email ID.:

3. Project Collaborators, if applicable:
Name Designation

4. Title of the Project / Research Proposal:
(Please provide a brief summary of the project)

5. IBSC Approval Date and No. (attach copy of approval):

6. RCGM Permit Letter Date and No. (attach copy of permit letter), if applicable:

7. Biosample/biospecimen requested:
a) Type of Biosample/biospecimen:
b) Quantity of samples required (provide concentration, if applicable):
c) Purpose for which samples required (provide break-up, as applicable):
d) Duration of the project:

8. Category to which biosample/biospecimen belongs to (GE organism/Non-GE HMO):

9. Appropriate containment facility to handle biosample/biospecimen available at the Organization as per DBT Guidelines:

10. Details of containment procedures:

11. Details of decontamination and disposal procedures:

12. Details of the trained personnel:

13. Details of Emergency plans:

Conditions for the use of Biosamples/biospecimen:

We the undersigned hereby accept and take control of the biosample/biospecimen released from the Biorepository upon the following terms and conditions:

1. Materials will be handled as potentially infectious.
2. The Competent Authority/Principal Investigator holds the responsibility for the release of biosample/biospecimen from the biorepository.
3. The released biosample/biospecimen will only be used by the concerned research team & it shall be used exclusively for the project approved. Any unutilized biosample/biospecimen will be returned to the biorepository or disposed off as per DBT guidelines.
4. No biosample/biospecimen should be given to Third party without prior written permission by IBSC and Biorepository. In case of any such transaction, it should be duly recorded by IBSC and subsequently, reported to RCGM.
5. Publications / presentations should acknowledge the Biorepository as the source of biosamples/biospecimens and DBT Guidelines as source of standard practices and safety measures.
6. Researchers requesting additional samples for the same project are requested to submit a fresh application with justification for additional samples. The application is subject to approval by the IBSC/RCGM depending on the risk category of the biosample/biospecimen.
7. A copy of the annual progress report on the study/project should be submitted to the IBSC.
8. All the standard practices, including transfer and storage of biosamples/biospecimens, safety equipment, biosafety facility, decontamination and disposal, emergency plans, training of workers must comply with the "Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment, 2017" and "Guidelines for the Establishment of containment facilities: Biosafety Level 2 (BSL-2) & 3 (BSL-3) and Certification of BSL-3 facility, 2020"notified by the Department of Biotechnology.
9. The details pertaining to the samples received and its usage will be updated to the RCGM in the Annual Transaction Record.

Signature of Competent Authority/PI(s) with stamp:

Organization:

Date:

Reviewed and approved by IBSC Chairman

Date of approval

ANNEXURE IV

TEMPLATE FOR DECLARATION FORM BY THE APPLICANT

I…….. hereby declare that the biosample/biospecimen collected from ……. Biorepository will be solely used for R&D purpose. The standard practices including transfer and storage of biosamples/biospecimens, decontamination and disposal, biosafety facility, emergency plans, training of workers, and safety measures on the on-site operations will be strictly complied with the DBT guidelines; "Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment, 2017" and "Guidelines for the Establishment of containment facilities: Biosafety Level 2 (BSL-2) & 3 (BSL-3)" and Certification of BSL-3 facility, 2020".

Signature of Competent Authority/PI(s) with stamp:

Organization:

Date:

Signature of IBSC Chairman

Date

REFERENCES:

- ✓ Establishment of a network of biorepositories in India, Indian Council of Medical Research, 2020.
- ✓ Guidelines for sharing of biospecimens and data for research related to COVID-19. National Institution for Transforming India (NITI) Aayog, H&FW Division, 2020.
- ✓ Guidelines for the Establishment of containment facilities: Biosafety Level 2 (BSL-2) & 3 (BSL-3)" and Certification of BSL-3 facility, Department of Biotechnology, 2020.
- ✓ Handbook for Institutional Biosafety Committee, Third Revised Edition, Department of Biotechnology, 2020.
- ✓ Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment, Department of Biotechnology, 2017.
- ✓ Revised Simplified Procedures/ Guidelines on Import, Export and Exchange of GE organisms and products thereof for R&D purpose, Department of Biotechnology, 2020.

ACKNOWLEDGEMENTS

- ✓ **Review Committee of Genetic Manipulation (RCGM)**
- ✓ **Existing biorepositories for their feedback**
- ✓ **Biosafety Support Unit**, Regional Centre for Biotechnology, Faridabad:
  - Dr. Sangeeta Agarrwal, Chief Scientific Officer
  - Dr. Manpreet Kaur, Scientist (Biosafety & Bio-containment)
  - Dr. Poonam Vishwakarma, Scientist (Veterinary Sciences)
  - Dr. Renu Arora, Scientist (Pharma Biotech)

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