Biorepository Facility **Translational Health Science and Technology Institute** **Faridabad, Haryana, India** **Standard Operating Procedure** (Understanding human COVID-19 infections: a DBT India consortium) **Title: Biospecimen/ metadata/ data access and sharing procedure for COVID-19 Bioresource.**	**SOP No: BRF/COV/SOP/001** **Version No: 2.0** **Issue date: 13 APR 2021** **Effective date: 20 APR 2021** **Next review date: 06 APR 2023** **Page 1 of 23**

Amendment sheet

Sl. No.	Page No.	Section/ Clause No.	Date	Nature of amendment	Authorization

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1. Introduction

The COVID-19 Bioresource Repository comprises of biospecimen collected from participants who are either suspected cases of COVID-19 or positive for COVID-19 infections. Relevant biospecimens are being collected during the acute and convalescent phase of the illness across district and tertiary hospitals situated in and around the NCR as per biosafety and biosecurity guidelines of DBT, WHO and ICMR. The COVID-19 biorepository at THSTI hosts these high qualities, well phenotyped biospecimen along with associated anonymized donor information including COVID-19 testing reports and the methods used for hospital diagnosis. Data on clinical variables and biospecimen availability is stored with unique identifiers as CRFs/ electronic records.

2. Purpose

The overall aim of this SOP is to create a COVID-19 resource that can be optimally used by scientists from academia and industry, for:

2.1. Discovery of new and better methods of diagnosis

2.2. For investigation of the immune response

2.3. Measurement of viral shedding

2.4. Novel algorithms of risk prediction

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2.5. Development/ validation and testing of antigen and antibody immunoassay kits under the COVID-19 R&D.

3. Scope

3.1. To establish biospecimen/data sharing principles, policies and procedures according to which biospecimen and data sharing will be enabled.

3.2. This document aims to:

3.2.1. Outline the procedures for biospecimen/ data request and sharing

3.2.2. Define the governance of the biospecimen/ metadata Access Control Committee (ACC)

3.2.3. Define the roles and responsibilities involved in this process

4. Definitions

4.1. **Biospecimen -** which may be a:

4.1.1. **Primary sample and its simple derivatives:** Clinical specimen directly collected from the donor (e.g., whole blood and its derivatives: sera, plasma, primary blood mononuclear cells, nasopharyngeal and oropharyngeal swabs, sputum, saliva, urine, tissue) presenting to screening centers with suspected COVID-19 infection, patients diagnosed with COVID-19 infection being kept under home quarantine or

hospital isolation, patients with moderate and severe COVID-19 being treated in hospitals or intensive care units and those who are in convalescent stage (beyond 10 days and 6 weeks of origin of symptoms) or followed up for a further period post-convalescence. Sera/Plasma/NP/OP panels, standards and calibrators designed and developed at the biorepository will be archived and shared.

4.1.2. **Complex derivative:** Biological samples derived as primary isolates i.e. pure microbial or viral sample that has been obtained from an infected individual, nucleic acids, proteins, antibodies accessed from institutions, sorted cells, cultured cells, immortalized cells.

4.2. **Data:** Data covers anonymized raw data, processed data on individuals or aggregated, summarized data in the form of reports and information sheets shared on mails along with the COVID-19 bioresources.

4.3. **Sample / Data Sharing:** This encompasses samples/data release and transfer to institutional or external applicants.

4.4. **Access Control Committee:** A designated Access Control Committee will evaluate the application for request of the samples/data on the basis of its scientific merit, feasibility and usefulness in terms of public health importance.

4.5. **Institutional Biosafety Committee:** This Committee shall be constituted by all institutions handling hazardous samples and/or GE organisms.

4.6. **Institutional Ethics Committee** shall mean the Ethics Committee of the hospitals from where the biospecimen are being collected from enrolled consented participants and that of institutes where the biorepository is hosted.

4.7. **ISBER:** ISBER is a global biobanking organization.

5. Abbreviations

5.1. **ACC:** Access Control Committee

5.2. **COVID-19:** Corona Virus Disease- 2019

5.3. **IBSC:** Institutional Biosafety Committee

5.4. **IEC:** Institutional Ethics Committee

5.5. **IP:** Intellectual Property

5.6. **ISBER:** International Society for Biological and Environmental Repositories

5.7. **Jr. Res. Scientist:** Junior Research Scientist

5.8. **MTA:** Material Transfer Agreement

5.9. **PI:** Principal Investigator

5.10. **PS:** Post Script

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5.11. **RCGM**: Review Committee on Genetic Manipulation

5.12. **Sr. P. Associate:** Senior Project associate

6. Responsibility

At the biorepository the process of receiving and processing applications, working with researchers to develop/ refine the study protocols (if required), preparing and submitting the proposals to the ACC for peer review, identifying and matching samples, consolidating reports and transferring data, and responding to subsequent requests for clarification of data involves a broad range of functions.

S. No.	Personnel	Roles and responsibilities assigned
6.1.	Funding Body	Commits to skilled human resource generation and availability of infrastructure at the research facility to support studies on COVID-19 Bioresource.
6.2.	Executive Director	6.2.1. Executes to oversee the functioning of the facility through the biorepository team. 6.2.2. Ensures management and sustainability planning, access and governance of biorepository.

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S. No.	Personnel	Roles and responsibilities assigned
6.3.	Program coordinator of the Study	6.3.1. Responsible for inputs in the final study objectives and protocols for the collection of COVID-19 bioresource. 6.3.2. Responsible for decisions on the proposals submitted for sample and data access to the ACC.
6.4.	Biorepository faculty In-charge	6.4.1. Ensures management of biospecimen collection, processing, storage, archival, retrieval and transport. 6.4.2. Biospecimen/data sharing, governance and SOPs of the biorepository. 6.4.3. Coordinates the ACC review process. 6.4.4. Responsible for management, troubleshooting and smooth running of the biorepository processes.
6.5.	Biorepository Scientist	6.5.1. Is the lead contact for biorepository access requests and shipping.

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S. No.	Personnel	Roles and responsibilities assigned
		6.5.2. Facilitates the Biorepository Faculty In-charge in discussions with PIs requesting samples prior to sample/ data access and the ACC review process. 6.5.3. Assists in recording the minutes of the ACC and circulation. 6.5.4. Contributes to cost-recovery of individual projects (As and when required) 6.5.5. Contributes to keeping website content up-to-date
6.6.	Senior Project Associate	6.6.1. Receives requests and compiles availability of data/ samples on the requested proposal in coordination with the data management team and the Biorepository Scientist. 6.6.2. Assists the Biorepository Scientist in consolidating the minutes of the ACC. 6.6.3. Facilitates the submission of ethics/notifications application to the Institutional IEC. 6.6.4. Assists in consolidating amendments, annual reports and end-of-study reports.

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S. No.	Personnel	Roles and responsibilities assigned
6.7.	Data Management team	6.7.1. Extraction and documentation of clinical and all meta data and responsible for secure transfer of data, as required. 6.7.2. Responsible for the website management.
6.8.	Technical Officer/ Technical Assistant/Technicians	6.8.1. Collection, processing, storage and retrieval of biospecimens collected from study participants, as per the study SOPs. 6.8.2. Day to day management and inventory of maintenance activities at the biorepository.

7. Safety

All documents (forms, MTAs, approvals, minutes etc.) to be filed, scanned and uploaded on hard drive/ institutional server.

8. Material and equipment

All hard copies of forms and formats are properly placed in closed cabinets with limited access to authorized biorepository personnel only.

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9. Procedure

9.1. Accessibility

The true impact of a repository is measured in terms of how many samples have been disbursed. To increase accessibility, the data on available COVID-19 bioresources shall be posted on the biorepository website and revised on regular intervals. Organizational membership of global bio banking organizations will help to gain national and international visibility (e.g. ISBER).

9.2. Governance of sharing

9.2.1. Custodianship of the samples and associated data

Custodianship of the samples and associated data should be with the designated authorized biorepository personnel. Investigators/organizations/companies requesting access to the samples will follow instructions for access and sharing approved for each designated biorepository as mentioned in the COVID-19 Biorepository (as provided in this document) guidelines and the guidelines published by the NITI Aayog (https://niti.gov.in/sites/default/files/2020-04/Guidelines-forsharing-of-Biospecimen-and-data-for-research-related-toCOVID-19..pdf).

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The basic principles for access are:

9.2.1.1. The clinical data, sample management and quality control data should be managed by standard operating protocols to include the metadata in machine-readable formats. This is to ensure rapid retrieval and sharing.

9.2.1.2. The data and samples should be made available to all bonafide researchers'/product developers for research and development that is in the public interest. All applicants will be subject to the same application process and approval criteria.

9.2.1.3. Access procedures, ethics and governance framework should be made available in the public domain.

9.2.1.4. Access to the biological samples that are limited should be coordinated; judged on potential benefits, with advice from appropriate experts as required.

9.2.1.5. Anonymity and confidentiality of participants' data should be maintained.

9.2.1.6. The clinical data and biospecimens should be prioritized for developing solutions which have the highest public health implications.

9.2.1.7. Those provided access to data and samples should provide proof of optimal utilization of samples through demonstration of public health interventions, or

products, scientific discovery and/or publication of results based on data or samples obtained through this mechanism.

9.3. **Access Control Committee (ACC)**

9.3.1. An empowered Access Control Committee (ACC) has been established to facilitate the access to the biospecimen and data of the COVID-19 bioresource. ACC comprises of members from varied disciplines e.g. clinicians, geneticists, lawyers, basic scientists, sociologists, epidemiologists, statisticians and ethicists (as per ICMR Guidelines, 2017). It includes at least four members. It will have one member from the host institute where the Biorepository is hosted. ACC could seek advice from domain experts as and when required depending on the nature of the research proposals and requests for the scientific merit of the proposal. The decisions of the ACC stand complete only if at least three members are present at the review meeting.

9.3.2. The ACC shall meet on a regular basis to review biospecimen/data access request proposals and monitor the progress reports from already approved proposal/s either in person or through mail correspondence, depending on the availability of the members.

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9.3.3. This committee will oversee and approve of all data and biospecimen-access after prioritizing based on **sample availability, scientific merit, usefulness in terms of public health importance, feasibility, appropriate use, ethical appropriateness and novelty of the proposal**. Given the national crisis situation, priority will have to be given for public health interventions or development and validation of products for COVID-19.

9.3.4. **PS. In case of research during humanitarian emergencies and disasters proposals should be reviewed through an expedited process.**

9.3.5. Overall timeline for providing biospecimen/ live culture/culture isolate/data from the time of submission of application by the investigator will be 5 working days (https://niti.gov.in/sites/default/files/2020-04/Guidelines-for-sharing-of-Biospecimenand-data-for-research-related-toCOVID-19.pdf) subject to availability of the specimen (type and amount) requested.

9.3.6. The comments of the ACC members will be documented as the minutes of meeting. All minutes of the meeting are signed by members present in the meeting and placed in file for future reference. All recommendations of the committee are communicated to the requesters and subsequently implemented. Reasons for any

decisions will be provided, as a summary, to the applicants by the Biorepository team through e-mails.

9.4. Procedure of biospecimen/ data sharing

9.4.1. Application process

Detailed description of processes to access biospecimens and bioresources available at the biorepository shall be available on the website https://thsti.res.in/biorepository.php

The investigators should follow the below mentioned steps to access the biospecimens stored at the biorepository.

9.4.1.1. Submission of the fully filled form along with supporting documents to the Faculty-in-charge Biorepository at (biorepository@thsti.res.in).

9.4.1.1.1. COVID-19 Bioresource Access Request forms

9.4.1.1.2. Letter of Intent (Two Pages)

9.4.1.2. The biorepository will assign a unique number to the application for future reference and forward the application/s to ACC with a complete report on the availability of the requested samples and associated data (that will be maintained in the biorepository database with help from the data management).

9.4.1.3. ACC will review the proposal and invite domain experts wherever required.

9.4.1.4. Institutional Bio-Safety Committee (IBSC) approvals should be obtained from the respective institutes where the research will be conducted and submitted with the COVID-19 Bioresource Access Request forms.

9.4.1.5. Review Committee on Genetic Manipulation (RCGM): Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens http://dbtindia.gov.in/sites/default/files/Interim_Guidance_Document_COVID%2019.pdf. The guideline includes a whole range of basic minimal procedures to be followed, risk management and mitigation measures, routine laboratory procedures, specimen and nucleic acid storage, viral isolation, disinfectants and lab waste management, specimen packaging and shipment procedures etc. Institutes / organizations requesting viruses will have to take the registration certificate from RCGM for the operational BSL3 facility in use.

9.4.1.6. For samples leaving the institutional biorepository, additional project information and MTA will be required (as detailed in section 9.5). The Material Transfer agreement will be shared with the requester to complete the same, sign and stamp. The scanned copies of completely filled, signed and stamped MTA forms will be signed by the authorized signatory of the institute.

Once the MTA is signed by both the parties, biorepository would share the scanned copy of the same with the requester. Once the ACC approvals are obtained, scanned copies of all the supporting documents need to be submitted by the requesting investigators to Faculty-in-charge Biorepository (biorepository@thsti.res.in). The biospecimens will be released from the biorepository subject to all the above-mentioned approvals.

9.4.1.7. The transport/ shipping of the COVID-19 patient specimens (Blood, Serum, Plasma, NP/OP swabs)) from suspected or confirmed cases of COVID19 should be transported as UN3373, "Biological Substance Category B"; Viral cultures or isolates should be transported as Category A, UN2814, "infectious substance, affecting humans" respectively as per the WHO's Guidance on regulations for the transport of infectious substances 2019- 2020.

9.4.1.8. Requesting institutes will have to make their own arrangements for the shipment of COVID-19 bioresources as per IATA guidelines. (https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-pi650.pdf) and (https://ehs.uccs.edu/sites/g/files/kjihxj1296/files/inline-files/IATA_pack_instr_620.pdf)

9.5. **Material Transfer Agreement (MTA)**

The requesting institute/organization should be notified at the appropriate stage of the review process by the biorepository team so that suitable agreements can be prepared immediately after a successful review. Agreements will be prepared between institutions/organizations (institution where the biorepository is held and the institution/organization hosting the investigators requesting for the biospecimens and data) and not at an individual level for samples/data shared and leaving the institute.

The Agreements/ MTA should specify the following:

9.5.1. Manner in which the data will be used; the data can only be used for the purposes for which it has been released.

9.5.2. Procedures on how anonymity and confidentiality of the patients will be maintained at all times (no data will be used to identify individual patients).

9.5.3. Details on how Intellectual Property Rights will be protected and will be made available to the public forum as publications, presentations and products.

9.5.4. Statement on how credit will be given to the data contributors (institutions and their investigators who have contributed to collection and processing of biospecimens and the meta data) while reporting, presenting or publishing the results of the research/ project in any manner and if results in a successful commercial product

must state in their product information sheet that "We acknowledge the significant contribution of NCR Biotech Science Cluster biorepository, DBT India Consortium in development/validation/testing of our product". The requesting institute/organization must agree to list all the members/ collaborating hospitals of the DBT India Consortium, as annexure documents of the product information sheet/website.

9.5.5. Details on the process of arbitration (if required)

9.5.6. Format of documents that will have to be submitted to the biorepository team and ACC at regular intervals as report on progress (see section 9.6).

9.5.7. **The MTA should clearly specify that it is mandatory that applicants should publish reports/ data and return the generated data to facilitate an "open research" platform.**

9.6. **Biospecimen/ data receipt and progress reporting**

9.6.1. Applicants should acknowledge receipt of biospecimen/data and report immediately if there are any problems with the data/ biospecimens (appropriate forms will be provided for feedback).

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9.6.2. Onward sharing of data/ residual samples is not permitted, interested investigators will have to submit fresh applications to the biorepository.

9.6.3. The following documents should be submitted to the biorepository team and ACC at regular intervals:

9.6.3.1. Progress updates to be obtained from the requesters as per the designated progress reporting format.

9.6.3.2. Results of the research study in the form of presentation/s (poster/talks) at conferences, published abstracts, publications as per the terms and conditions agreed upon in the Material Transfer Agreement.

9.6.4. Overall accountability of reporting to funding bodies for research projects should be the responsibility of requesting PI.

9.7. **Publications and return of all generated data to allow 'open research'**

9.7.1. All generated data on the biospecimen/metadata should be published in peer reviewed journals, unless it is waived by the ACC for specific reasons (i.e. patent filing).

9.7.2. Applicants should take fresh approvals for any secondary/other analyses that they wish to publish other than what they had obtained initial permissions from the ACC.

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9.7.3. Authorship on manuscripts should reflect contribution. All contributors (institutions and their investigators who have contributed to collection and processing of biospecimens and the metadata) and funders should be given appropriate credit by researchers (details in the MTA and the access forms).

9.7.4. A copy of the final manuscript accepted for publication should be sent to the biorepository for records.

9.8. **Intellectual property**

Sharing of data and biological samples needs to be performed in a way that protects intellectual property rights of the parties involved. It also needs to address the requirements of institutions and third-party funders.

9.8.1. IP will be transferred for commercialization on a royalty-free and nonexclusive basis (in case discovery of new and better methods of diagnosis).

9.8.2. Organizations involved in the process of clinical site research, sample collection, product innovation and evaluation will voluntarily forfeit monetary benefit as royalty from the product; however, these organizations must be given credit as co-developers in the final commercialized product by the manufacturer (in collaborative studies)

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10. Validity Statement

10.1. This document is valid for two years from the effective date.

11. References

These guidelines are based on existing good practices from global organizations (References attached). This document provides the usage of valuable biospecimens collected under COVID-19 studies that can be accessed using the "rules of access".

Guidance and guidelines from relevant bodies is as below:

11.1. National Data Sharing and Accessibility Policy 2012

11.2. ICMR Guidelines 2017

11.3. ISBER Best Practices

11.4. Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens http://dbtindia.gov.in/sites/default/files/Interim_Guidance_Document_COVID%2019.pdf

11.5. https://www.cuimc.columbia.edu/news/new-covid-19-biobank-columbiaopens-researchers,https://www.ps.columbia.edu/research/core-and-sharedfacilities/core-facilities-category/columbia-university-biobank

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11.6. https://medschool.ucsd.edu/research/actri/Laboratory/Pages/UCSD-COVID-19-Research-Biobank-Sample-Request.aspx.

12. Appendices

12.1. Form 1: COVID-19 Biological Sample Access Request Form.

12.2. Form 2: COVID-19 Clinical Sample Access Request Form.

12.3. Form 3: Material Transfer Agreement (MTA).

12.4. Form 4: Feedback Form.

12.5. Form 5: Progress Report.

12.6. Guidelines for sharing of Biospecimen and data for research related to COVID-19 (Office Memorandum- NITI Ayog, H&FW Division, NO. 15(8)/2020-H&FW, dated: 21st Apr 2020).

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