



सत्यमेव जयते

भारत सरकार के प्रमुख वैज्ञानिक सलाहकार का कार्यालय
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F.No.Prn.SA/COVID-19/2020
Dated: 22nd April, 2020

Office Memorandum

A Task Force for focused Research on Corona Vaccines, and other S&T issues (referred to as the Vaccine Task Force, VTF) Co-Chaired by Dr Vinod Paul, Member, NITI Aayog and Prof K VijayRaghavan, Principal Scientific Adviser to the Government of India has been constituted by the PMO.

The Empowered Technology Group (ETG) has been approved by the Cabinet and is Chaired by Prof K VijayRaghavan, Principal Scientific Adviser to the Government of India.

The Joint Committee of the Empowered Technology Group and PMO constituted Task Force for Focused Research on Corona Vaccine and other S&T, met on April 16 and April 20, 2020. The ETG and VTF have approved, inter alia, the following:

1. The Joint ETG and VTF approves, and allows, research institutions and laboratories to use patient sample for R&D purposes, subject to their following due process and consent, as normally required in using such material for research.
2. The 'Guidelines for sharing of biospecimen and data for research related to COVID-19.' framed by the 'Empowered Group 1' chaired by Dr. Vinod Paul should be followed and the stipulated timelines for sharing/providing biospecimens should be adhered to. The Guidelines document is attached herewith for convenience. This will allow those who host specimen/samples to speedily and correctly share biospecimen for research collaboration.
3. Further, research institutions which have received clearances from ICMR as COVID-19 testing-sites and wish to use samples for R&D, should inform the ETG and VTF after the above steps have been taken, delineating the specific research intended to be undertaken. The joint Committee will examine each request where the R&D objectives and protocols are clearly presented and defined.
4. Field applications and deployment of the R&D results will need necessary subsequent approvals following due process.

This issues with the approval of the Co-Chairs of the Committee.

(Shailja Vaidya Gupta)
Senior Adviser/Sc H,

Office of Principal Scientific adviser to Govt. of India
Email: shailja.psa@gov.in

To:

All concerned Research Institutes (respective Secretaries may inform)

Copy to:

- | | |
|---|----------|
| 1. Dr Vinod Paul, Member Health, NITI Aayog, | Co Chair |
| 2. Prof K. VijayRaghavan, PSA to Gol, | Co Chair |
| 3. Secretary, Health Research, DG ICMR | Member |
| 4. Secretary, Ministry of Health &family Welfare | Member |
| 5. Secretary, Department of Science and Technology | Member |
| 6. Secretary, Department of Biotechnology | Member |
| 7. Secretary, DSIR, DG CSIR | Member |
| 8. Secretary, MeITY | Member |
| 9. Secretary, Department of Telecommunications | Member |
| 10. Secretary, DRDO | Member |
| 11. Secretary, AYUSH | Member |
| 12. Secretary, Science and Engineering Research Board | Member |
| 13. Chairman, DAE | Member |
| 14. Director General Health Services, MoHFW | Member |
| 15. Drug Controller General of India | Member |
| 16. Secretary, MHRD | Member |

No. 15(8)/2020-H&FW
NITI Aayog
H&FW Division

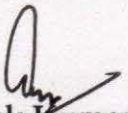
New Delhi-110001
21st April, 2020

OFFICE MEMORANDUM

Subject: Guidelines for sharing of Biospecimen and data for research related to COVID-19.

The Empowered Group 1 "Medical Emergency Management Plan" headed by Dr. V.K Paul, Member (H), constituted vide MHA Order No. 40-3/2020-DM-I(A) dt. 29.03.2020, has deliberated and finalized the guidelines for sharing of Biospecimen and data for research related to COVID-19.

I am directed to enclose a copy of the guidelines for compliance and necessary action.


(Alok Kumar)
Adviser (Health)

To

1. Secretary, H&FW, Ministry of Health & Family Welfare, Nirman Bhawan, New Delhi.
2. Secretary & DG, ICMR, Department of Health Research 2nd Floor, IRCS Building, 1, Red Cross Road, New Delhi, 110001.
3. Secretary, Department of Biotechnology, New Delhi.
4. Secretary, Department of Science and Technology, New Delhi.
5. Secretary, Department of Scientific and Industrial Research, New Delhi

Copy to:

1. Members of the Empowered Group "Medical Emergency Management Plan".
2. Dr. Amandeep Garg, Joint Secretary, Cabinet Sectt., New Delhi.
3. Sh. Rajendra Kumar, Director, PMO, South Block, New Delhi

Copy for information to:

1. O/o Home Secretary, Ministry of Home Affairs, North Block, New Delhi.
2. O/o Principal Scientific Adviser, Vigyan Bhavan Annexe, Maulana Azad Road, New Delhi - 110011.



(Alok Kumar)
Adviser (Health)

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Government of India

April, 2020

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GUIDELINES FOR SHARING OF BIOSPECIMEN AND DATA FOR RESEARCH RELATED TO COVID-19

I. BACKGROUND

The world is witnessing the pandemic of severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), causing coronavirus infectious disease 2019, commonly known as COVID-19. COVID-19 has been declared as pandemic by the World Health Organization. The scientists and researchers across the globe are working towards the development of rapid diagnostic methods, prophylactics, therapeutics and for detection, prevention, treatment and management of COVID-19 infections.

It is imperative to ensure that biological samples and data are appropriately managed. The Government of India is committed to providing an enabling research ecosystem in the country to develop tests, diagnostics, drugs, therapeutics and vaccines for COVID 19. To address this, there is an urgent need for having a sharing mechanism for Biospecimen and Data between researchers and different institutions during an unprecedented public health emergency of COVID-19.

II. SCOPE

The present Guideline provides a basic framework for sharing of Biospecimens and Data amongst all national and public research Institutions, healthcare facilities and those private entities who are working in collaboration with the Government Departments and are undertaking research activities related to COVID-19. These guidelines have been aligned with the existing International framework of Biological Weapons Convention to which India is a signatory. The present Guidelines are consistent to the National Guidelines/ Policies and regulatory frameworks related to conduct of scientific research, clinical trials, medical practice and data privacy.¹

The present Guidelines follow Article X, Section (1) of the Biological Weapons Convention that provides, "The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes".

It will be obligatory upon every Custodian of Biospecimens (the Biorepositories and Hospital) to share the Biospecimen as per the procedure and timeline prescribed in these guidelines. Delays if any will be liable for appropriate action and necessary accountability will have to be fixed for the same. Any delay will be communicated to the Grievance email grievance.covidsample@nic.in

¹Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017 can be accessed at https://ibkp.dbtindia.gov.in/DBT_Content_Test/CMS/Guidelines/20181115134719867_Regulations-Guidelines-for-Reocminant-DNA-Research-and-Biocontainment-2017.pdf

III. DEFINITIONS

(i) Biospecimen will include

a. Biological Sample – Shall mean Primary isolate consisting of a pure microbial or viral sample that has been obtained from an infected individual, secondary isolate grown in a laboratory or Repository, isolate including DNA, RNA and antibodies accessed from institutions.

b. Clinical Sample – Shall mean blood, plasma, urine, tissue, cells, cell cultures, naso-oro-pharyngeal swabs or saliva collected from persons presenting to screening centres 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)

(ii) Research- "Research" shall mean research, development and innovation activities carried out at academia, labs, healthcare facilities, incubators, industry and other places having research capability by academic entities, national and public laboratories, institutes, healthcare providers or private entities in compliance with the relevant approval mechanism. Recipient define indenting organisation, donor organisation, custodian organisation.

(iii) Organization may include:

a. Recipient/ Indenting Organization-Any entity(institution, hospital, laboratory etc.)requesting for access to biospecimens and/or data is the Recipient/ Indenting Organization.

b. Donor Organization- Any entity (institution, hospital, laboratory etc.) providing access tobiospecimens and/or data is the Donor organization.

c. Custodian Organization- Any entity (institution, hospital, laboratory etc.) collecting biospecimens and /or storing data will be the custodian for that specific specimen and data sets.

(iv) IBSC- Institutional Biosafety Committee (IBSC) shall mean the Committee as defined under the "Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989" notified by the Ministry of Environment Forests and Climate Change (MoEF&CC), Government of India under the Environment (Protection) Act (1986).

(v) RCGM- Review Committee on Genetic Manipulation (RCGM) shall mean the Committee defined under the "Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989" and functions in the Department of Biotechnology to monitor the safety related aspects in respect of on-going research projects and activities involving genetically engineered organisms/hazardous microorganisms.

(vi) CDSCO- The Central Drugs Standard Control Organisation (CDSCO shall mean the Regulatory Authority under Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India.

(vii) IATA- shall mean the International Air Transport Association (IATA) that has developed policies for international air transport to be carried out with global standards of airline safety, security and efficiency.

(viii) IEC: Institutional Ethics Committee shall mean the Ethics Committee of the institution

(ix) ISBER: International Society for biological and environmental repositories. a global biobanking organization.²

IV. SAMPLE COLLECTION, STORAGE AND SHARING

Sharing of collected biospecimens and associated data can be vital for addressing the pandemic of COVID-19, as progress in science & technology and subsequent medical research for development of products is driven by such biological samples. Therefore, rapid and timely dissemination of biospecimens and sharing of associated data must be simple and transparent, without compromising the research interests of the sample providers and confidentiality of the study participants.

1.0 Sample Collection

(i) All biospecimens for conducting research & product development on COVID-19 shall be collected and handled in accordance with the Guidelines for Clinical Samples issued by ICMR under the 'Strategy of COVID 19 testing in India' (Updated as on Date) and Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens as issued by Department of Biotechnology, Ministry of Science & Technology(ref-BT/BS/17/635/2015 dated 08.04.2020) (**Annexure- A**)

(ii) Sample collection from consenting participants shall include the scope of storing for future research purposes, including publication of results. This shall be included in the informed consent forms (consent by self or legally accepted Representative; relative) by the facilities, institutions and other entities. The specific Annexure that provides for Guidelines related to Sample Collection should be referred for the detailed considerations in this regard. (**Annexure – B**)

(iii) All facilities, institutions and other entities should collect biospecimens for research and product development purposes as approved by institutional or national authorities, as appropriate. The approvals granted shall be under the frameworks governing research and clinical trials from respective Institutional Ethics Committees, IBSC, RCGM or CDSCO as applicable, before initiating sample and/or data collection.

(iv) The samples collected for research activity will not interfere with the standard Guidelines on Clinical Management of COVID – 19 issued by the Ministry of Health and Family welfare.

(<https://www.mohfw.gov.in/pdf/GuidelinesonClinicalManagementofCOVID1912020.pdf>)

²ISBER Best Practices for Repositories Fourth Edition can be accessed at <https://www.isber.org/page/BPR>

2.0 Storage of Samples

The collecting entity can store samples at authorized biorepositories/research laboratories, in compliance with relevant biosafety and biosecurity guidelines stated herein as Annexure B and as per best practices of ISBER.

3.0 Data Acquisition and Storage

- (i) The facilities, institutions and other entities that collect Data distinctly or along with biospecimens should initiate the collection after the grant of due approval for the research or study protocol and shall adhere to the principles of a proper informed consent from the participating human subjects.
- (ii) All collected Data should be catalogued and shall be managed to ensure findability, accessibility, interoperability and reusability. For sharing of biospecimens, de-identification methods should be used as appropriate.
- (iii) Misuse or unauthorized access to the Data should be prevented by suitable protection measures.

4.0. Biospecimen Sharing

- (i) The sharing of the biospecimen collected at/by the National and public research Institutions, healthcare facilities and those private entities which are working in collaboration with the Government Departments shall be undertaken at the level of the respective Custodian (the designated/ authorized: biorepository/laboratory).
- (ii) The request for Biological samples shall be as per the process defined in **Annexure - C**. The request for clinical samples can be submitted in the form appended hereto as **Annexure- D**.
- (iii) Provision of further access to the Clinical Samples among the stakeholders and their sharing for undertaking pertinent activities shall be based on the approved protocol or research scope for which permission has been granted by the designated/ authorized: biorepository/laboratory through a properly developed material transfer agent.
- (iv) Transit of Biospecimen samples including labelling, packaging, shipment or transport shall be as prescribed by ICMR, DBT (Regulations & Guidelines for Recombinant DNA Research and Biocontainment, 2017 and Interim Guidelines on laboratory biosafety to handle COVID 19 specimen for R & D purpose 2020) and IATA Dangerous Goods Regulations, as applicable.
- (v) The comprehensive overview of the mechanism for biospecimen sharing is provided at **Annexure - E**.

5.0. Data Sharing

The sharing of Data among the collaborators and the participating entities can be undertaken by the respective Custodian (the designated/ authorised: biorepository/laboratory) in strict adherence to the corresponding statutory

requirements related to personal and sensitive data: where such data has been collected, disclosed, shared or otherwise processed within the territory of India.

6.0 Internal Governance Mechanism

(i). The request for access to the Data and/or the biospecimen will be considered by the Internal Governance Mechanism of the provider entities such as the designated/ authorised: biorepository/laboratory/Institution, Such consideration shall be in line with the proposed study or research protocol, sensitivity of the Data, specific legal and Commercial requirements that have approved by relevant authority and evinced through the documents submitted by the requesting entity(ies).

(ii) If the sharing of the biospecimen/ Data was proposed at a stage later than protocol submission, then the entities and organizations participating in research information exchange initiatives can also execute agreements such as data sharing agreements, Data Use Agreements (DUA), Collaborative Research Agreements (CoRA), and Participation Agreements (PA): collectively known as Data Sharing Agreements (DSAs) for further sharing of Data and/or Samples. The DSA can be considered by the Internal Governance Mechanism to determine Data/ Biospecimen sharing and intimated to Donor Organization.

(iii). **The timeline for giving approval should not be more than 5 working days after receipt of application.**

V. CONFIDENTIALITY OF DATA AND/OR BIOSPECIMEN AND DUE CREDIT

(i) Any of the entities accessing the Data and/or the Biospecimen shall abide by the norms of de-identifying them while reporting or publishing the results of their respective research/study/trial/registry.

(ii) However, all reports and presentations at research platforms should describe how to access underlying Data/ biospecimen through due acknowledgement to the concerned source and by citing express credit to all concerned for the contribution.

VI. GOVERNANCE OF RESULTS

a. Intellectual Property: The sharing of the interests in the resultant Intellectual Property shall be based on the organizational policy or the mutually agreed upon clauses among the contributors provided; they shall adhere to the prompt public access requirements in national interest.

b. Publications: The Institutions, facilities and the entities who access and share the Biospecimens and/or Data under this Guideline shall strive to publish the results in a prompt and ethical manner while the authorship can be determined based on the mutually agreed upon Clauses between the providers and users of the biospecimens and data.

VII. ANNEXURES

(i) ANNEXURE-A

Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens as issued by DBT (ref-BT/BS/17/635/2015 dated 08.04.2020) (http://dbtindia.gov.in/sites/default/files/OM_Interim_Guidance_COVID.pdf)

(ii) ANNEXURE- B

Guidelines for Sample Collection

(iii) ANNEXURE-C

Request form for access of Biological samples

(iv) ANNEXURE- D

Request form for access of Clinical samples

(v) ANNEXURE-E

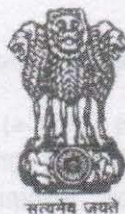
Process flow for access to COVID-19 Resources

NOTE:

1. Apart from the above guidelines pertaining to sharing of Data and Samples related to COVID-19, specific activities undertaken by participating entities shall also comply with appropriate frameworks issued by concerned authorities as on date.

Followed by Annexures

**Regulations & Guidelines for Recombinant DNA Research &
Biocontainment- Interim Guidance Document on Laboratory Biosafety
to Handle COVID-19 Specimens for R&D purpose**



**Department of Biotechnology
Ministry of Science & Technology
Government of India**

8th April, 2020

For compliance by all IBSCs and host institutions involved in research, development and handling COVID-19 specimens. Non-compliance shall attract the provisions of Section 15, 16 and 17 of Environment Protection Act (EPA), 1986.
The guidelines are notified at www.dbtindia.nic.in

Department of Biotechnology
Ministry of Science and Technology
Government of India

Interim Guidance Document on Laboratory Biosafety to Handle COVID-19 Specimens

Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2), commonly known as 2019 novel coronavirus (COVID-19) has been declared as pandemic by the World Health Organization. With little scientifically validated information on this novel virus as well as the absence of vaccine and medications to treat or limit the spread, the laboratories planning for R & D work on suspected/confirmed positive COVID-19 samples should follow the precautions as enlisted for the Risk Group 3/4 organisms in the "*Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017*".

The purpose of this document is to provide an interim guideline on laboratory biosafety (in tune with the international norms) to be followed in handling and processing clinical samples/infectious virus for diagnostic testing and R&D work to develop new diagnostics / therapeutics for COVID-19. All virus-related manipulations should be performed in a BSL2/3 laboratory depending on the nature of the work and only by laboratory staff trained in the relevant technical and safety procedures with strict adherence to sample inventory, Personal Protective Equipments and Waste Management SoPs.

The basic minimal procedures to be followed are:

All Institutional Biosafety Committee's (IBSCs) must assess the available facilities, trained manpower in handling high risk group (RG3 and above) hazardous microorganisms, personal protection equipment (PPE) and waste disposal mechanism to meet all the requirements prior to initiation of work involving COVID-19. Prior to the initiation of R&D work involving COVID-19, proposals should be submitted online at IBKP portal along with IBSC recommendation for the approval by the Review Committee on Genetic Manipulation (RCGM). All applications for the development of vaccines, diagnostics, prophylactics and therapeutics will be considered under Rapid Response Regulatory Framework for COVID-19 by RCGM and CDSCO as per DBT OM No. BT/03/27/2020-PID, dated 20.03.2020.

- i. Appropriate personal protective equipment (PPE) as determined by a detailed risk assessment, should be worn by all laboratory personnel handling these specimens.
- ii. All procedures must be performed based on risk assessment and only by personnel with demonstrated capability in strict observance to any relevant protocols at all times.
- iii. Where the work involves the use of only the viral components and not the live SARS-CoV-2 virus, patient specimens collected in the COVID treatment ward

in collection tubes, sealed properly and containing virus inactivation reagents that denature the viral envelope, and inactivate the virus may be transported from the hospital wards to respective Laboratories, similar to transportation of biomedical samples from the hospital wards to laboratory.

- iv. Patient specimens from suspected or confirmed cases 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 and transported as per the WHO **"Guidance on regulations for the transport of infectious substances 2017–2018"**. As a first step, it is imperative that periodical recording of inventory of sample collection, storage, authorization of use, transfer and disposal of all materials are adhered to.
- v. Initial processing (before inactivation) of all suspected specimens should take place in a validated biological safety cabinet (BSC) or primary containment device.
- vi. Non-propagative diagnostic laboratory work (e.g. nucleic acids, sequencing, NAAT, PCR, isolation of antibodies, serum proteins) should be conducted in laboratories with facilities and procedures equivalent to BSL-2. Further, infective agent should be inactivated in BSL-2 cabinet under suitable PPE before any laboratory procedure. Based on the biological material required, if sample collected in inactivation medium, such procedure could be adopted.
- vii. All propagative work (e.g. virus culture, isolation or neutralization assays) should be performed only by properly trained and competent personnel in laboratories capable of meeting additional essential containment requirements and practices (BSL-3).
- viii. Appropriate disinfectants with proven activity against enveloped viruses should be used (e.g. hypochlorite (bleach), alcohol, hydrogen peroxide, quaternary ammonium compounds and phenolic compounds).
- ix. All technical procedures should be performed with standard operating protocols that minimize the generation of aerosols and droplets.
- x. IBSC should quarterly update status of such work in the organization along with details of inventory and biosecurity information.
- xi. Periodic reports of the staff handling the work and their medical surveillance reports duly certified by a medical doctor should be complied with.
- xii. For work related to COVID-19, RCGM may constitute an empowered Committee, if necessary to visit the laboratory to ensure due diligence to protocols and other requirements
- xiii. To prevent spread of disease in animals, if any, tested animals should be properly isolated and taken care.

Risk assessment and mitigation measures

Risk assessment and mitigation measures are dependent on the procedures performed and the competency level of the personnel performing the procedures in

addition to identification of the hazards involved in the process and/or procedures, the laboratory equipment and facility, and the resources available. It is highly recommended to start by performing a local risk assessment for each of the process step, i.e. starting from sample collection, to the different processes that are planned in the laboratory) and for each of the process step the potential hazards (e.g., aerosol exposure, potential spillage etc.,) have to be considered and assessed with a grade of risk. Appropriate risk control measures are to be identified and implemented to mitigate the risk identified to an acceptable level.

Routine laboratory procedures

Clinical samples being processed for non-culture-based laboratory diagnostic procedures and PCR analysis from patients suspected or confirmed to be infected with the novel coronavirus should adopt procedures and practices routine to a clinical and microbiology laboratory. A validated biosafety cabinet (BSC) to be strictly used for all manipulations that might potentially result in droplets or aerosol (e.g. loading and unloading of sealed centrifuge cups, grinding, blending, vigorous shaking or mixing, sonic disruption, opening of containers of infectious materials whose internal pressure may be different from the ambient pressure), from infectious COVID-19 samples.

Specimen and nucleic acid storage

Suspected or confirmed COVID-19 specimens, with appropriate identification labeling, should be stored at a designated place with controlled access to authorized personnel only at 2-8 °C or at -70°C depending on the nature of the experiment(s). Extracted nucleic acid samples should be stored at -70 °C or lower. All diagnostic laboratories should strictly follow the retention period as per standard guidelines for the samples submitted to them for testing.

Viral isolation

Viral isolation from clinical specimens suspected or confirmed to be infected with the novel coronavirus (COVID-19) should be performed only in Biosafety level 3 (BSL3) and above facilities.

Disinfectants and Laboratory waste management

For the selection of appropriate decontamination and disinfection strategies for biomedical waste treatment and disposal should be in accordance to those mentioned in the **"Revised Guidelines for Common Bio-medical Waste Treatment and Disposal Facilities" (2016)** developed by Central Pollution Control Board (CPCB). In the light of the comparable genetic characteristics with SARS-CoV

and COVID-19, COVID-19 is likely to be susceptible to disinfectants with proven activity against enveloped viruses, including sodium hypochlorite (bleach) (e.g. 1,000 ppm (0.1%) for general surface disinfection and 10,000 ppm (1%) for disinfection of blood spills), 62-71% ethanol, 0.5% hydrogen peroxide, quaternary ammonium compounds and phenolic compounds and used as per manufacturer's recommendations. The contact time for disinfection, dilution/concentration of the active ingredient and its shelf life should also be considered. The waste generated in the laboratory handling live virus be incinerated. The laboratory waste should be handled like other biohazardous waste as per the DBT notified **"Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment, 2017"**.

Specimen packaging and shipment

All specimens being transported should have appropriate packaging, labeling and documentation. For details, follow WHO's **"Guidance on regulations for the transport of infectious substances 2017–2018"**. This document provides practical guidance to facilitate compliance with applicable international regulations for the transport of infectious substances by all modes of transport, both nationally and internationally, and include the changes that apply from 01 January 2017.

- i. All materials to be transported should be placed in a leak proof unbreakable primary container followed by a leak proof, watertight secondary packaging with absorbent material and a rigid outer packaging to minimize the potential for breakage or spillage.
- ii. Patient specimens from suspected or confirmed cases to be transported for diagnostic or investigational purposes - as UN3373, "Biological Substance, Category B"
- iii. Transporting viral cultures or isolates - as Category A, UN2814, "infectious substance, affecting humans".
- iv. Transport of specimens within national borders should comply national regulations.
- v. For cross boundary transport of novel coronavirus specimens should follow the UN Model Regulations, Technical Instructions by the International Civil Aviation Organization and other applicable regulations depending on the mode of transport being used.

Note: For further information, the IBSCs are advised to refer to the following two Interim Laboratory Biosafety Guidelines.

1. WHO interim guidelines: Laboratory biosafety guidance related to the novel coronavirus (COVID-19) (as on 19 March 2020)
2. CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19) (as on March 31, 2020).

ANNEXURE - B

Collection of data and Biospecimens for COVID-19 research purposes

While diagnosis and management of the disease is paramount in a pandemic, it is also essential to empower the healthcare system with the ability to develop novel diagnostic, preventive and therapeutic tools at an expedited pace to manage the pandemic effectively. Data and samples collected from patients can be used for measuring and monitoring disease and to develop and test diagnostics and vaccines.

The following guidelines should be adopted for sample collection, transport and storage. Institutional ethics approval should be obtained on expedited basis from Institutional Ethics Committees/Institutional Review Boards on expedited basis for any collection involving samples that are minimal risk (e.g. blood, naso-/oropharyngeal swabs, urine, saliva). Additional clinical research involving other specimen types may require a convened meeting, which, if required, should be held rapidly.

Categories of patients from whom samples should be collected:

1. Patients presenting to screening centres with suspected COVID-19 infection
2. Diagnosed cases of COVID-19 infection being kept under home quarantine or hospital isolation
3. Patients with moderate and severe COVID-19 being treated in high dependency units or intensive care units
4. Convalescent blood sample beyond 3-4 weeks from diagnosis for authorised biorepository/research laboratory

Guidelines for data and sample collection of patients presenting to screening centres with suspected COVID-19 infection:

1. Obtain informed consent before specimen collection, informing patients that if they test positive they will be asked to provide samples and data during and after their illness.
2. In addition to the respiratory (nasopharyngeal, nasal and oropharyngeal) samples collected by the hospital for diagnostic purposes, an additional set of nasopharyngeal, nasal and/or oropharyngeal samples should be collected for sending to authorised biorepository/research laboratory.
3. The process of collecting the biospecimens should follow the steps detailed in the Guidance on specimen collection, processing, transportation, including related biosafety procedures, that is available on <https://mohfw.gov.in/media/disease-alerts>

4. In addition to the respiratory samples, blood and/or other biological specimens should be collected from the patients (following approval from institutional ethics committee of the screening centre if attached to a hospital or of the government institution linked to the laboratory/centre).
5. Relevant clinical data should be collected from the patients.

Guidelines for data and sample collection of diagnosed cases of COVID-19 infection being kept under home quarantine or hospital isolation:

1. These are patients admitted to designated COVID-19 hospitals or advised home quarantine following their diagnosis and clinical assessment.
2. If they are at the hospital, the sample collection process should follow the same protocol as described above. In addition to the respiratory samples, blood and/or other biological specimens should be collected from the patients (following approval from institutional ethics committee of the screening centre if attached to a hospital or of the government institution linked to the laboratory/centre).
3. If they are not at a hospital, blood should be collected either at home or at a designated place where the sample collection guidelines of ICMR can be followed. All measures should be taken to ensure that the participant can be brought to this place conveniently.
4. Relevant clinical data should be collected from the patients.

Guidelines for data and sample collection of patients with moderate and severe COVID-19 being treated in high dependency units or intensive care units:

1. These are patients admitted to High Dependency Units or Intensive Care Units with moderate or severe disease with/ without complications.
2. The medical personnel in the ICUs should administer the consent to the patient or their attendant if the patient is unable to participate in the consenting process, reconsenting should be done when the participant regains his ability to participate.
3. Biological specimens should be collected following the above described collection process in coordination with the attending clinicians.
4. Lower respiratory tract samples may also be collected when these are readily available (for example, in mechanically ventilated patients).
5. Relevant clinical data should be collected from the patients/ clinician/ patient's attendant.

Guidelines for data and sample collection of patients who are beyond 3-4 weeks of confirmed COVID-19 for authorized biorepository/research laboratory:

1. With informed consent (taken at the time of acute sample, and with institutional review board approval of authorised biorepository/research

group), additional samples will be collected from cases subsequently testing positive for SARS-CoV2 by the authorised biorepository/research laboratory, based on test results provided by the testing laboratory.

2. Similar procedures should be followed for obtaining patients' blood samples at 6 and 12 months wherever required.
3. Biospecimens can be collected either at home or at a designated place where the sample collection guidelines of ICMR can be followed. All measures should be taken to ensure that the participant can be brought to this place conveniently.

Any additional samples as approved in the protocol, may include urine, stool, saliva etc

Principles of Access to the samples and associated data

The basic principles for access are:

- The clinical data and the 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.
- Data and samples should be made available to all bona fide 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.
- Access procedures, ethics and governance framework should be made available in the public domain.
- Access to the biological samples that are limited and depletable should be coordinated; judged against potential benefits, with advice from appropriate experts as required.
- Anonymity and confidentiality of participants' data and samples should be maintained.
- The clinical data and biospecimens should be used for developing solutions which have the highest public health implications.
- Those provided access to data and samples should provide proof of optimal utilisation of samples through demonstration of product and/or publication of results based on data or samples obtained through this mechanism.

COVID-19 Biological Sample Access Request Form

SARS CoV2

Handling and culturing of this virus requires certified & validated BSL-3 laboratory since, it belongs to risk group III category. However, if inactive/killed virus is to be used it can be handled in BSL-2 laboratory.

The SARS CoV2 is a coronavirus that is the etiologic agent for human respiratory illness and interim biosafety guidelines for handling and processing of the specimens and laboratory work associated with the virus has been laid down WHO https://www.who.int/csr/sars/biosafetv2003_04_25/en/.

Other interim guidelines are also available:

<https://www.cdc.gov/sars/suidance/f-lab/app5.html>

https://www.who.int/docs/default-source/coronaviruse/laboratory-biosafetv-novel-coronavirus-version-1-1.pdf?sfvrsn=912a9847_2

In the view of the need to rapidly support collateral multi-sectoral research & development activities to further strengthen India's capacity in dealing with the COVID-19 situation, the following SARS-CoV 2 research material: can be shared with the authorized laboratories.

1. SARS-CoV-2 Live virus strain
2. SARS-CoV-2 Heat inactivated
3. SARS-CoV-2 Synthetic molecular standard (genomic RNA)

Obligations of the recipient:

The recipient of the virus and parent organization will have to give an undertaking on compliance issues mentioned at the end of the form. Please note that this is mandatory. All users will be ultimately assigned unique IDs for assuring best services from the repository.

Instructions:

Please read the instructions carefully before filling the virus indent request form. Complete information sought under the following fields is mandatory. Please note that requests with incomplete information will be rejected. It is also mandatory to complete the declaration on responsibility/liability clauses with authorization from office of appropriate authority of the indenting organization.

The information requested needs to be filled, duly signed on each page by the indenter and forwarded through the appropriate authority with a covering letter to the Director of the Donor institute, signed and sealed on official stationery.

The indenter is requested to make sure that all information provided is factual and auditable/verifiable under National and International regulatory/ Biosecurity laws and any other guidelines of Govt. of India as amended from time to time. Please note that provision of the information does not make it mandatory for the institute to provide the requested sample. This will be done subject to all necessary approvals.

1.	CATEGORY OF ORGANIZATION	
2.	PRINCIPAL INVESTIGATOR	
	Name:	
	Organization	
	Address	
	Telephone	
	Email	
3.	RESEARCH TEAM /CO-INVESTIGATORS (NAME AND ORGANIZATION)	
	Please add more co-investigators if required	
	Co-investigator (1)	
	Co-investigator (2)	
	Co-investigator (3)	
4.	AREA OF RESEARCH	
5.	TITLE OF THE RESEARCH PROJECT	
6.	A. PROJECT SUMMARY: Brief description of the proposal highlighting its strategic importance along with its potential outcomes. (max 500 word count). <div style="margin-left: 40px;"> a. Title b. Scientific Hypothesis c. Key/Research questions (100 words): d. Rationale: e. Primary Objectives: f. Methodology: </div>	

7.	MULTI-CENTRIC STUDY	Yes <input type="checkbox"/> No <input type="checkbox"/>
8.	VIRUS REQUIREMENT	
	SARS-CoV-2 Live virus strain	<input type="checkbox"/>
	SARS-CoV-2 Heat inactivated	<input type="checkbox"/>
	SARS-CoV-2 Synthetic molecular standard(genomic RNA)	<input type="checkbox"/>
10.	FUNDING (If you are applying for a grant please provide details about the funding application. The preference would be for Biorepository to be a named partner organization and study team members to be a collaborator/co- investigator as appropriate on the grant).	Applied <input type="checkbox"/> Approved <input type="checkbox"/> Yet to be applied <input type="checkbox"/>
11.	FUNDING AGENCY	
12.	ETHICAL APPROVAL (If approved attach copy of the approval letters from the respective IRBs)	Approved <input type="checkbox"/> Applied for <input type="checkbox"/> Not applied <input type="checkbox"/>
13.	Institutional Biosafety Committee (IBSC) (If approved attach copy of the approval letters from the respective IBSCs) Review Committee on Genetic Manipulation (RCGM) (If approved attach copy of RCGM approval letters)	Approved <input type="checkbox"/> Applied for <input type="checkbox"/> Not applied <input type="checkbox"/> Approved <input type="checkbox"/> Applied for <input type="checkbox"/> Not applied <input type="checkbox"/>
14.	Particulars of other Agreements on Material Transfer or Data Sharing	

15.	Intellectual Property Status: A. Describe the different types of intellectual property anticipated from the current proposal. B. Details on any relevant patent information or background IP issues	
16.	UNDERTAKING FOR PROPER USE AND FOR GIVING DUE CREDIT IN PUBLICATIONS AND WHILE REPORTING THE RESELUTS OF THE RESEARCH: <i>I/we undertake that:</i> <ol style="list-style-type: none"> <i>the live virus/ inactivated virus/ genomic RNA requested will be used exclusively for the purposes of the ethically approved project detailed in this proposal; and</i> <i>The research will be conducted in compliance with all relevant, policies, Rules/Act Governing this biological samples - Any violation, misuse and willful mala-fide intention/violation of the same will be fully prosecutable under the relevant acts/laws of Government of India as applicable.</i> <i>due credit shall be given to the provider(s) while reporting, presenting or publishing the results of the research/ project in any manner (please sign below to confirm)</i> <div style="display: flex; justify-content: space-between;"> <div style="width: 20%;">Place:</div> <div style="width: 80%;">Name & Signature of Principal Investigator</div> </div> <div style="display: flex; justify-content: space-between;"> <div style="width: 20%;">Date:</div> <div style="width: 80%;">Name & Signature of the Head of the Organization with Seal</div> </div>	

List of attachments to be submitted along with the Form:

1. Proposal submitted to the funding body that has been approved/pending approval
2. CV of the investigators/ Co-Investigators.
3. Scanned copies of the Material Transfer or Data sharing Agreements, Ethics and Biosafety Approvals and RCGM Approvals.

For use of the Virus Provider only:

REQUEST FORM ID:

Additional information to be completed before consideration by the Internal Governance Mechanism

A. Availability of requested live virus/ inactivated virus/ genomic RNA

B. Volume of sample remaining if project approved

C. Any Other comments:

(Authorized signatory)

Covid-19 Clinical Sample Access Request Form

1.	TITLE OF THE RESEARCH PROJECT	
2.	AREA OF RESEARCH	
3.	PRINCIPAL INVESTIGATOR	
	Name:	
	Organization	
	Address	
	Telephone	
	Email	
4.	RESEARCH TEAM /CO-INVESTIGATORS (NAME AND ORGANIZATION)	
	Please add more co-investigators if required	
	Co-investigator (1)	
	Co-investigator (2)	
	Co-investigator (3)	
5.	A. PROJECT SUMMARY: Brief description of the proposal highlighting its strategic importance along with its potential outcomes. (max 500 word count) g. Title h. Scientific Hypothesis i. Key/Research questions (100 words): j. Rationale: k. Primary Objectives: l. Methodology:	
6.	MULTI-CENTRIC STUDY	Yes <input type="checkbox"/> No <input type="checkbox"/>

7.	SAMPLES AND META DATA REQUIREMENTS	
	<p>(i) Sample size</p> <p>A. Cases:</p> <p>No of Participants:</p> <p>No of Samples (please describe if serial longitudinally collected samples are being requested):</p> <p>B. Control:</p> <p>Matching Criteria:</p> <p>No of Participants:</p> <p>No of Samples:</p>	
	Please give the justification for the use of volume and number of biospecimen to ensure proper utilization and minimal wastage of sample:	
	Biospecimen type	
	Biospecimen volume (μ l/ml)	
	<p>Clinical data/Metadata required</p> <p>(Please describe data particulars that will be required) <i>Blank case recording forms of the study will be shared upon request</i></p>	<p>Yes <input type="checkbox"/> No <input type="checkbox"/></p>
	Selection Criteria	<p>Inclusion Criteria</p> <p>Exclusion Criteria</p>
8.	STUDY PERIOD	
	<p>Estimated Start Date</p> <p>_____</p>	<p>Estimated End Date</p> <p>_____</p>
9.	<p>FUNDING (If you are applying for a grant please provide details about the funding application. The preference would be for Biorepository to be a named partner organization and study team members to be a collaborator/co- investigator as appropriate on the grant).</p>	<p>Applied <input type="checkbox"/> Approved <input type="checkbox"/></p> <p>Yet to be applied <input type="checkbox"/></p>
10.	FUNDING AGENCY	

11.	ETHICAL APPROVAL (If approved attach copy of the approval letters from the respective IRBs)	Approved <input type="checkbox"/> Applied for <input type="checkbox"/> Not applied <input type="checkbox"/>
12.	Institutional Biosafety Committee (IBSC) (If approved attach copy of the approval letters from the respective IBSCs)	Approved <input type="checkbox"/> Applied for <input type="checkbox"/> Not applied <input type="checkbox"/>
13.	Particulars of other Agreements on Material Transfer or Data Sharing	
14.	Intellectual Property Status: A. Describe the different types of intellectual property anticipated from the current proposal. B. Details on any relevant patent information or background IP issues	
15.	UNDERTAKING FOR PROPER USE AND FOR GIVING DUE CREDIT IN PUBLICATIONS AND WHILE REPORTING THE RESELUTS OF THE RESEARCH: <i>I/we undertake that:</i> <ol style="list-style-type: none"> <i>the biospecimen/data/ requested will be used exclusively for the purposes of the ethically approved project detailed in this proposal; and</i> <i>due credit shall be given to the sample/data provider(s) while reporting, presenting or publishing the results of the research/ project in any manner (please sign below to confirm)</i> <div style="display: flex; justify-content: space-between;"> <div> Place: Date: Investigator </div> <div> Name of Principal Investigator Signature of the Principal </div> </div>	

List of attachments to be submitted along with the Form:

1. Proposal submitted to the funding body that has been approved/pending approval
2. CV of the investigators/ Co-Investigators.
3. Scanned copies of the Material Transfer or Data sharing Agreements, Ethics and Biosafety Approvals.

For use of the Sample/Data Provider only:

REQUEST FORM ID:

Additional information to be completed before consideration by the Internal Governance Mechanism

A. Availability of requested biospecimen and its associated data

B. Volume of sample remaining if project approved

C. Any Other comments:

(Authorized signatory)

ANNEXURE E

Process Flow for Access to COVID-19 Biospecimen

I. Access to COVID-19 Biological Sample

1	Biospecimen/data stored in the biorepository should have all regulatory approvals. Request for all viral isolates/cultures should be in compliance with the guidelines of handling the same them in a BSL 3 facility
2	Request for access to viral isolate/ culture should be made by the Principal investigator using the COVID-19 Biological sample Access Request (enclosed as ANNEXURE C).
3	This form should be forwarded by the Head of the Organization with Letter of Intent (technical proposal) and accompanied by necessary approvals (IEC, IBSC, RGCM for working with Live virus) to the Institutional Biorepository.
4	In case the Ethics of the institute is not available then IEC of the institute where the bio repository is held hosted should facilitate an expedited review to obtain relevant approvals within 48 hours
5	Each biorepository should have an Access Control Committee (ACC), established by their respective biorepository. ACC should facilitate an expedited technical review of the proposal and will be expected to give their decision in 48 hours
6	Scanned copies of the relevant approval letters should be submitted to Institutional Biorepository prior to Live Virus/culture being released
7	For Live Virus/culture leaving the institutional biorepository, MTA will be required and IATA regulations will be followed for shipping.

II. ACCESS TO COVID 19 Clinical Sample

1	Request for access to Biospecimen should be made by the Principal investigator using the COVID-19 Clinical Sample Access Request form (enclosed as ANNEXURE D)
2	This form should be forwarded by the Head of the Organization with Letter of Intent (technical proposal) and accompanied by IEC and IBSC approvals to the Donor Institution
3	In case the Ethics of the institute is not available then IEC of the institute which is to give the sample should conduct an expedited review to obtain relevant approvals within 48 hours
4	Each Donor organisation should have an Access Control Committee (ACC), established as per defined in Internal Governance mechanism. ACC should facilitate an expedited peer review of the proposal and will be expected to give their decision in 48 hours
5	Scanned copies of the relevant approval letters should be submitted to Donor Institution prior to samples being released.
6	For samples leaving the institutional biorepository, MTA will be required and IATA regulations will be followed for shipping.

Overall timeline for providing Biospecimen / live virus /culture isolate from the time of submission of application by the investigator is 5 working days.