



# ESTABLISHMENT OF A NETWORK OF BIOREPOSITORIES IN INDIA

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DEPARTMENT OF HEALTH RESEARCH  
MINISTRY OF HEALTH AND FAMILY WELFARE,  
GOVERNMENT OF INDIA

## Background

In the backdrop of the COVID-19 pandemic, while it is of paramount importance to provide early diagnosis and treatment to all infected individuals, it is also critical to promote research and development for larger public health benefit. For development and validation of new diagnostics, therapeutics or vaccines, access to different kinds of clinical samples from infected patients is an essential requirement. Niti Aayog has recently issued guidelines for sharing of biospecimens and data for research related to COVID19. This document in tandem lays down the brief processes and operational mechanisms for establishing COVID19 biorepositories in the country.

## Rationale

Currently, there is no structured mechanism for collecting and storing these valuable clinical samples. In view of this, it is important to create designated biorepositories for collecting, storing and maintaining clinical samples (oropharyngeal / nasopharyngeal swabs, bronchoalveolar lavage, sputum, blood, urine and stool) of COVID19 patients. Such samples will be used to develop validated diagnostics, therapeutics, vaccines etc. Additionally, the samples will be a valuable resource for research & development related activities to understand the early predictors of disease severity, immunopathogenesis of the disease etc.

## Objectives

- To establish organized and dedicated bio-repositories of well characterized clinical samples of COVID-19 patients.
- To judiciously use these samples to promote research and development towards indigenous diagnostics, therapeutics and vaccines in line with the “make in India” initiative.
- To promote Indian academia, industry and commercial entities for developing novel solutions for COVID19 prevention, control and treatment.
- To conduct research to better understand the COVID19 disease in the Indian scenario.

## Methods

- A total of 16 National COVID19 bio-repositories identified by ICMR and other Science Ministries [Department of Biotechnology (DBT) and Council of Scientific & Industrial Research (CSIR)] will be established (Annexure 1).
- The designated bio-repositories will be responsible for earmarking/arranging dedicated space, storage facilities, staff etc. for establishing and maintaining the facility.
- The designated biorepositories will need to establish strong links with the identified COVID hospitals in their catchment area and ensure systematic influx of clinical samples.
- A detailed clinical proforma (Annexure 2) needs to be filled up for each patient.
- All samples will be collected after obtaining informed consent / assent of the patient / family member (Annexure 3).

- The clinical samples once received will need to be aliquoted in small batches and systematically stored under recommended conditions.
- The designated facilities will need to develop uniform Standard Operating Procedures (SoPs) for sample collection, transportation, aliquoting, storage, and sharing.
- The purpose of sharing clinical specimens by each biorepository and their intended use will be examined by the National Oversight Committee.

### **Types of samples to be collected**

- i. Oropharyngeal swab / throat swab
- ii. Nasopharyngeal swab / nasal swab
- iii. Bronchoalveolar lavage
- iv. Sputum
- v. Blood
- vi. Urine
- vii. Stool

*Limited number of samples from COVID19 negative patients may also be collected and stored for comparative analysis.*

*\*Biorepositories notified with BSL-3 facility with all requisite biosafety approvals in place as per the existing National and International laws and treaties, can handle, culture and/or store live SARS-CoV-2 virus.*

### **Approvals**

- All Institutions will be required to obtain approvals from the respective Expert Groups / Task Force of their respective Institution to operationalize funding mechanisms and undertake projects in the designated Institutions with biorepositories.
- All Investigators of institutions with designated biorepositories will go through their institutional review mechanisms and seek independent approvals from their own institutions for undertaking any project of their priority / interest.
- Approval of Health Ministry Screening Committee (HMSC) may be taken for all Indo-foreign collaborations in order to avoid overlap in activities of various Investigators and ensure judicious use of samples.
- Each repository will need to set up an “Access Control Committee” at Institutional / Departmental level. This Committee will review the proposals for sharing clinical material and provide fast – track decisions on the same.
- A National Oversight Committee (Annexure 4) has been set to take periodic reviews of the activities undertaken by the biorepositories.
- Each Institute will need to obtain Institutional Ethical Committee Clearance for establishing, maintaining and using clinical specimens of COVID19 patients for various purposes as indicated above.
- Requisite approvals of state govt./ municipal commissioners/ hospital authorities for uninterrupted flow of samples will also be required.

**Funding mechanisms:**

Each Institutional biorepository will be supported by the respective department / Ministries.

**Ownership**

The Director / Head of the respective Institution will be responsible for all the issues pertaining to the biorepository.

**Annexures**

- Annexure 1 – List of designated biorepositories
- Annexure 2 – Clinical proforma
- Annexure 3 – Consent form
- Annexure 4 – Composition of the National oversight Committee and Terms of Reference.

**Annexure 1:****Designated Biorepositories for COVID19**

SNo	Name of the Institute	Name of contact
	ICMR Institutes	
1	ICMR-NIV, Pune	Dr Priya Abraham, Director Indian Council of Medical Research National Institute of Virology (ICMR-NIV) 20-A, Dr Ambedkar Road, Pune 411001 Telephone: 020-26006201 Email: director.niv@icmr.gov.in
2	ICMR-NIV Field Unit, Bangalore	Dr Ashok M Scientist B & Director-in-Charge Field Unit, NIV Bangalore ICMR-National Institute of Virology (NIV), Bangalore Unit, 1st main, Someswarnagar (RGICD Premises) Dharmaram College (Post), Bengaluru-560029 Telephone: 080-26654084/26654074 Email: ashokmphdns@gmail.com
3	ICMR-NIV Field Unit, Allapuzha, Kerala	Dr. A.P. Sugunan Director In Charge Field Unit Kerala, Vandanam Hospital campus, NIV Allapuzha, Kerala -688005 Telephone: 0477-2970004 Email: apsugunan@gmail.com
4	ICMR-NICED, Kolkata	Dr. Shanta Dutta, Director, National Institute of Cholera and Enteric Diseases (NICED), P-33, CIT Rd, Subhas Sarobar Park, Phool Bagan, Beliaghata, Kolkata, West Bengal 700010 Telephone: 033-2363-3373 Email: drshantadutta@gmail.com
5	ICMR NIOH, Ahmedabad	Dr. Kamalesh Sarkar, Director, National Institute of Occupational Health (NIOH) Near Raksha Shakti University, Meghaninagar, Ahmedabad, Gujarat 380016 Telephone: 079-22686110 Email: kamalesh.sarkar@gmail.com
6	ICMR- NIIRNCD, Jodhpur	Dr. G S Toteja, Director,

		National Institute for Implementation Research on Non-Communicable Diseases (NIIRNCD) New Pali Rd, Air Force Area, Jodhpur, Rajasthan 342005 Telephone: 0291-2720618 Email: gstoteja@gmail.com
7	ICMR-NIMR, Delhi	Dr. Amit P Sharma, Director, National Institute of Malaria Research (NIMR) Sector 8 Dwarka, Dwarka, New Delhi, Delhi 110077 Telephone: 011-25307103 Email: directornimr@gmail.com
8	ICMR-NIE, Chennai	Dr. Manoj Murhekar, Director, National Institute of Epidemiology (NIE) R 127, 3rd Avenue, 2nd Main Rd, near Ambattur, Ayapakkam, Chennai, Tamil Nadu 600077 Telephone: 044-26136201 Email: mmurhekar@nieicmr.org.in
9	ICMR-NIRRH, Mumbai	Dr. Smita D Mahale, Director, National Institute for Research in Reproductive Health (NIRRH), J Merwanji St, Parel East, Parel, Mumbai, Maharashtra 400012 Telephone: 022-24192000 Email: <a href="mailto:smitamahale@hotmail.com">smitamahale@hotmail.com</a>
	<b>DBT Institutes</b>	
10	DBT-NCR Biotech Cluster (a) Clinical Sample – THSTI  (b) Viral Sample – RCB	Dr. Gagandeep Kang, Executive Director Translational Health Science and Technology Institute, NCR Biotech Science Cluster, 3rd Milestone, Faridabad-Gurgaon Expressway PO Box#4, Faridabad, Haryana-120001 Phone <a href="tel:+911292876400">+91 129 2876400</a> Email: <a href="mailto:gkang@thsti.res.in">gkang@thsti.res.in</a>  Prof. Sudhanshu Vrat, Executive Director Regional Centre for Biotechnology NCR Biotech Science Cluster, 3rd Milestone, Faridabad-Gurgaon Expressway Faridabad-121001 Phone: <a href="tel:01292848801">0129-2848801</a>

		Email: <a href="mailto:vrati@rcb.res.in">vrati@rcb.res.in</a>
11	DBT-ILS, Bhubaneswar	Dr. Ajay Parida, Director Institute of Life Sciences (Dept. of Biotechnology, Govt. of India) NALCO Square, Chandrasekarpur Bhubaneswar - 751023, India Ph: +91-674-2301900; Fax: +91-674-2300728 e-mail: <a href="mailto:director@ils.res.in">director@ils.res.in</a>
12	DBT – InSTEM – Bangalore	Dr. Apurva Sarin, Director Institute for Stem Cell Science and Regenerative Medicine, GKVK - Post Bellary Road, Bangalore 560065 Phone: 91 80 23666001 Email: <a href="mailto:sarina@instem.res.in">sarina@instem.res.in</a>
13	DBT funded Biorepository – ILBS, New Delhi	Dr. Shiv Kumar Sarin, Director Institute of Liver and Biliary Sciences D-1, Vasant Kunj, New Delhi Email: <a href="mailto:sksarin@ilbs.in">sksarin@ilbs.in</a>
	<b>CSIR Institutes</b>	
14	CSIR – IGIB	Dr. Anurag Agrawal, Director, CSIR Institute of Genomics and Integrative Biology, Bus Depot, South Campus, Mathura Road, Opp:, Sukhdev Vihar, New Delhi 110025 Phone no: +91-11-2766 6156/7 Extn: 171 e-mail: <a href="mailto:a.agrawal@igib.in">a.agrawal@igib.in</a>
15	CSIR – CCMB	Dr. Rakesh K Mishra, Director Centre for Cellular & Molecular Biology Habsiguda, Uppal Road Hyderabad - 500 007 Telangana, India Telephone: +91 40 27160222-31, Email: <a href="mailto:director@ccmb.res.in">director@ccmb.res.in</a>
16	CSIR - IMTECH	Dr. Sanjeev Khosla, Director CSIR - Institute of Microbial Technology 39A, Sector 39A, Chandigarh, 160036 Email: <a href="mailto:director@imtech.res.in">director@imtech.res.in</a>

**Annexure 2:****Case Record Form**

<b>DATE</b>	DD:MM:YYYY
<b>SERUM ID</b>	HHHNNNNN

<b>1. TREATMENT SITE</b>		
1.1	Name of the Hospital	
1.2	Contact number of the hospital (Medical Superintendent)	Mob: Landline: Fax: Email Id:
1.3	City	
1.4	District	
1.5	State	

<b>2. PATIENT IDENTIFIER</b>		
2.1	Name of the Patient	
2.2	Name of Father/Mother/Spouse	
2.3	Hospital Registration No.	
2.4	Date of Admission	[ ][ ]/[ ][ ]/[ ][ ][ ][ ] D D M M Y Y Y Y
2.5	Contact Number of the Patient	[ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ] ]
2.6	Address	House No/Name:  Street:  Area:  Village/City:  Taluk/Tahsil:  District:  State:



		PIN CODE:
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### 3. PATIENT DEMOGRAPHICS

3.1	Age	[ ] [ ] Years
3.2	Gender	[ ] Male [ ] Female [ ] Other
3.3	Occupation	
3.4	Pregnant?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> N/A If Yes, gestational age [ ] [ ] weeks

### 4. COVID19 Diagnosis Details

	Type of sample	Collected [Yes/No]	Date of collection	Date of result	Result [Positive/Negative]
4.1	Oro-pharyngeal swab				
4.2	Nasopharyngeal swab				
4.3	Broncho-alveolar lavage (BAL)				
4.4	Tracheal aspirate				
4.5	Nasopharyngeal aspirate				
4.6	Nasal wash				
4.7	Sputum				
4.8	Serum				
4.9	Whole blood				

### 5. EXPOSURE HISTORY

5.1	Travel in the 14 days prior to onset of symptoms	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
5.1.1	If Yes to Q. 9.1, list all the places travelled during 14 days prior to onset of symptoms	
	Country	City Visit date Return date
5.2	Contact with known COVID case in the 14 days prior to onset of symptoms	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

### 6. ADMISSION SIGNS AND SYMPTOMS

(observed/reported at admission and associated with this episode of acute illness)

6.1	Fever	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.2	Cough	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
	With sputum production	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

	Bloody/haemoptysis	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.3	Sore throat	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.4	Runny nose	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.5	Ear pain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.6	Chest pain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.7	Wheezing	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.8	Lower chest wall indrawing	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.9	Shortness of breath	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.10	Muscle aches	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.11	Joint pain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.12	Fatigue/Malaise	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.13	Headache	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.14	Altered consciousness/confusion	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.15	Seizures	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.16	Abdominal pain	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.17	Vomiting/Nausea	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.18	Diarrhoea	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.19	New loss of taste	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
6.20	New loss of smell	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown

<b>7. CO-MORBIDITIES</b>		<b>Status</b>
7.1	Chronic cardiac disease, including Congenital heart disease ( <i>not hypertension</i> )	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.2	Chronic pulmonary disease ( <i>not asthma</i> )	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.3	Asthma ( <i>physician diagnosed</i> )	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.4	Chronic kidney disease	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.5	Moderate or severe liver disease	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.6	Chronic neurological disorder	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.7	Malignant neoplasm	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.8	Chronic hematologic disease	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.9	AIDS / HIV	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.10	Diabetes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.11	Hypertension	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown
7.12	Others	[ _____ ]

<b>8. INTENSIVE CARE OR HIGH DEPENDENCY CARE UNIT ADMISSION</b>		
8.1	ICU admission (or high dependency unit)?	<input type="checkbox"/> Yes( <i>complete the rest of this section</i> ) <input type="checkbox"/> No( <i>skip this section</i> )
8.2	ICU admission date	[ ____ ]/[ ____ ]/[ ____ ] D D    M M    Y Y Y Y

<b>9. CLINICAL PARAMETERS</b>		
9.1	Respiratory Rate	/min
9.2	Temperature	Degree C

9.3	Blood Pressure (SBP/DBP)		SBP -                   mm of Hg DBP -                   mm of Hg	
9.4	Pulse rate		/min	
9.5	Altered Mental status		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
9.6	Mechanical ventilation Required		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<b>Parameter</b>	<b>Done</b>	<b>Value</b>	<b>Unit</b>
9.7	FiO2 (0.21-1.0)	<input type="checkbox"/> Yes <input type="checkbox"/> No	[__].[__][__]	%
9.8	SaO2 at time of FiO2	<input type="checkbox"/> Yes <input type="checkbox"/> No	[__][__][__]	
9.9	PaO2 at time of FiO2	<input type="checkbox"/> Yes <input type="checkbox"/> No	[__][__][__]	<input type="checkbox"/> kPaor <input type="checkbox"/> mmHg
9.10	Platelet Count	<input type="checkbox"/> Yes <input type="checkbox"/> No	[__][__][__][__]	x10^9/L
9.11	Mean arterial pressure	<input type="checkbox"/> Yes <input type="checkbox"/> No	[__][__][__]	Mm of Hg
9.12	Glasgow Coma Score	<input type="checkbox"/> Yes <input type="checkbox"/> No	[__][__]	(GCS / 15)

#### 10. LABORATORY PARAMETERS

	<b>Parameter</b>	<b>Done</b>	<b>Value</b>	<b>Unit</b>
10.1	Haemoglobin	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ][ ][ ]	<input type="checkbox"/> g/L or <input type="checkbox"/> g/dL
10.2	WBC count	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ][ ]	<input type="checkbox"/> x10 <sup>9</sup> /L or <input type="checkbox"/> x10 <sup>3</sup> /μL
10.3	Platelet Count	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ]	<input type="checkbox"/> x10 <sup>9</sup> /L or <input type="checkbox"/> x10 <sup>3</sup> /μL
10.4	APTT/ PTT	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ]	seconds
10.5	Prothrombin Time (PT)	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ]	seconds
10.6	INR	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ].[ ]	seconds
10.7	Total Bilirubin	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ][ ]	μmol/L
10.8	ALT	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ][ ]	U/L
10.9	AST	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ][ ]	U/L
10.10	Serum Amylase	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ][ ]	U/L
10.11	Glucose	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ][ ][ ]	<input type="checkbox"/> mmol/L or <input type="checkbox"/> mg/dL
10.12	Blood Urea	<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> mmol/L or <input type="checkbox"/> mg/dL
10.13	Lactate	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ][ ][ ]	<input type="checkbox"/> mmol/L or <input type="checkbox"/> mg/dL
10.14	Creatinine	<input type="checkbox"/> Yes <input type="checkbox"/> No	[ ][ ][ ][ ]	<input type="checkbox"/> mmol/L or <input type="checkbox"/> mg/dL

## **Annexure 3:**

### **Patient Information Sheet & Consent Form:**

#### **Information Sheet**

The novel coronavirus 2019 SARS CoV2 and COVID-19 disease is an emerging infectious disease due to a novel coronavirus. In order to develop diagnostic assays as well as to evaluate therapeutics against this virus, it is important to have well characterised samples from individuals who have had COVID-19 disease and have been infected by the SARS CoV2 virus.

#### **Purpose of Study**

This is a research study and the **purpose** is to create a well characterised collection/biorepository of blood samples from individuals who have tested positive for SARS CoV2 by a laboratory test. These samples will be collected from such individuals at different time points as per the clinical requirement and for follow-up. These samples will be used to develop and validate diagnostic assays and facilitate effective tests for antibodies as well as other immune markers of COVID-19 disease.

Please read all of the information or listen to the person explaining it to you carefully. Ask to have explained to you, any words, terms or sections which are unclear to you. Your participation in this study is entirely voluntary. You will be asked to sign this agreement/consent form, which states that the study has been explained, that your questions have been answered and that you agree to participate.

#### **Procedure to be followed**

If you agree to participate in this study, 5-10 ml blood samples will be collected from you at the health care facility where you

You will also be asked to answer a few questions related to your current illness, exposure history and travel history relevant to your current disease.

#### **Benefits**

You may not directly benefit from this study.

But the inclusion of blood samples contributed by you will be valuable in developing and validating diagnostic tests and therapeutics for COVID-19 disease.

#### **Confidentiality**

Data obtained from you and related to the blood samples you provide will be recorded using a unique study identification number. Any publication arising from this study will maintain your anonymity by excluding all information that could potentially identify you.

#### **Storage and use of blood samples**

The blood samples collected from you will be stored at a designated biorepository centre [Include Name of Biorepository Centre here].

These blood samples may be used to assess the performance of antibody tests as well as immune markers of disease and disease severity for COVID-19

#### **Investigators' phone numbers**

If you have questions about this study at any time, please call:

[NAME OF THE PI from the Biorepository Centre]  
[Contact Details.]

### **PARTICIPANT'S CONSENT**

I have read this consent form and have discussed with Dr. \_\_\_\_\_ or his/her representative the procedures described above. I have been given the opportunity to ask questions, which have been answered to my satisfaction. I understand that any questions that I might have will be answered verbally or, if I prefer, with a written statement.

The study procedures have been explained and I agree to comply with the instructions of the research team.

### **STRIKE OUT INAPPLICABLE STATEMENT**

-I give consent for the long-term storage of the sample (blood sample) collected in the study and its use for tests to understand the immune markers for COVID-19 disease

-I give consent for the utilisation of the sample for evaluating tests for detecting antibodies as well as other immune markers of COVID-19 testing.

-I understand that I will be informed of any new findings developed during the course of this research study if I chose to follow up

- I understand that my participation in this study is completely voluntary.

If I have any questions concerning my rights as a research participant in this study, I may contact the [Name of the Biorepository Institute] Institutional Ethics Committee at [Give phone number].

I have been fully informed of the above-described study with its risks and benefits to me, and I hereby consent to the procedures set forth above. I have received a signed copy of this consent form.

I understand that as a participant in this study my identity, and data relating to this research study will be kept confidential, except as required by law.

Signature / Thumb impression

Name

Date

Signature of witness

Name

Date

I have fully explained to \_\_\_\_\_ the nature and purpose of the above-described study and the risks that are involved in its performance. I have answered all questions to the best of my ability.

-----  
Date

\_\_\_\_\_  
Principal Investigator or Representative's Signature

## **Annexure 4:**

<b>National Oversight Committee</b>
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### **A. The National Advisory Group is as follows:**

1. Dr. V. M. Katoch, NASI ICMR Chair on Public Health Research & RUHS, Jaipur, Chairperson
2. Dr. D. A. Gadkari, Former Director, NIV Pune, Member, co-Chair
3. Dr. Madhuri Thakar, Scientist F, NARI, Pune Member
4. Prof. Udaykumar Ranga, JNCASR, Bangalore, Member
5. Dr. Nikhil Tandon, AIIMS, New Delhi, Member
6. Dr. Lalit Dar, Professor, Virology, AIIMS, New Delhi
7. ICMR Nominee - Dr. Nivedita Gupta, Scientist F, ICMR Delhi, Member & Convenor
8. CSIR Nominee – Dr. Vibha Malhotra Sahni, Scientist – ‘H’, Member & Convenor
9. DBT Nominee - Dr. Sundeep Sarin, Adviser/Scientist – ‘G’, DBT, Member & Convener

### **B. Terms of Reference:**

- To conduct periodic review of the activities undertaken by the National biorepositories for COVID19 and their compliance to the defined governance framework/ approved guidelines.
- To review and approve all the SoPs for sample sharing.
- To review and approve the proposals for sharing such samples outside the host Institution keeping in mind the primary benefit of such sharing to the people of India.
- To ensure desirable use of this resource for making diagnostics, therapeutics, vaccines etc. first to the people of India before making them available to others.



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