COVID-19 BIORESOURCE ACCESS REQUEST

COVID-19 Clinical Sample Access Request Form

Clinical Sample- Shall mean blood, plasma, urine, tissue, cells, cell cultures, naso-oro-pharyngeal swabs or saliva collected from persons 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)

COVID-19 Resources* ready to use:

Development / Evaluation sera panel (details on website)

- RBD IgG ELISA data available for all the sera panel samples

Instructions:
Please read the instructions carefully before filling the COVID-19 Clinical Sample Access Request Form. 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 the office of appropriate authority of the requesting organization.
The information requested needs to be filled, duly signed by the requester and forwarded through the director/ competent authority of the requesting institute.
Please 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 following the access policy guidelines.

Note: **The Access Control Committee (ACC) will oversee and approve of all data and biospecimen-access that will be prioritized based on sample availability, scientific merit, usefulness in terms of public health importance, translational component, feasibility, appropriate use, ethical appropriateness and novelty of the proposal.** Given the national crisis situation, priority will be given to product development for Covid-19. Material Transfer Agreement (MTA) will be executed for all samples leaving the institute.

***Will be updated as and when new resources are developed.**

COVID-19 BIORESOURCE ACCESS REQUEST

Covid-19 Clinical Sample Access Request Form

1.	**ORGANIZATION** **(Name and address)**	_____ _____ _____
2.	**CATEGORY OF ORGANIZATION**	**Please (✓)** **a) Academia** ☐ **b) Industry** ☐ **c) THSTI Labs** ☐ • For research purpose ☐ • For providing service to others ☐
3.	**TITLE OF THE RESEARCH PROJECT:**	
4.	**AREA OF RESEARCH**	
5.	**PRINCIPAL INVESTIGATOR/S**	
	Name	
	Organization	
	Address	
	Telephone	
	Email	

COVID-19 BIORESOURCE ACCESS REQUEST

6.	**RESEARCH TEAM /CO-INVESTIGATORS (NAME AND ORGANIZATION)** Please add more co-investigators if required	
	Co-investigator (1)	
	Co-investigator (2)	
	Co-investigator (3)	
7.	**PROJECT SUMMARY:** **Brief description of the proposal highlighting its strategic importance along with potential outcomes should be provided as a letter of intent (max 500 word count):** **Title** **Rationale/Background:** **Primary Objectives:** **Methodology:** **Outcome:** For development of sero-diagnostic kits: Information on the nature and the source of the capture antigens to be provided.	
8.	**MULTI-CENTRE STUDY**	**Yes** ☐ **No** ☐
9.	**SAMPLES AND META DATA REQUIREMENTS:**	
	(i) **Sample size** A. Cases: No of Participants: No of Samples: B. Control: No of Participants: No of Samples:	

COVID-19 BIORESOURCE ACCESS REQUEST

	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 (µl/ml/Cell count)	
	Clinical data/Metadata required (Please describe data particulars that will be required) *Blank case recording forms of the study will be shared upon request*	Yes ☐ No ☐
10.	**STUDY PERIOD**	
	Estimated Start Date	Estimated End Date
11.	**FUNDING** (*If you are applying for a grant please provide details about the funding application.*	**Applied** ☐ **Approved** ☐ **Yet to be applied** ☐
12.	**FUNDING AGENCY**	
13.	**ETHICAL APPROVAL** (If approved attach copy of the approval letters from the respective IRBs)	**Approved** ☐ **Applied for** ☐ **Not applied** ☐ **Not applicable** ☐
14.	**Institutional Biosafety Committee (IBSC)** (If approved attach copy of the approval letters from the respective IBSCs)	**Approved** ☐ **Applied for** ☐ **Not applied** ☐ **Not applicable** ☐

COVID-19 BIORESOURCE ACCESS REQUEST

15.	**Undertaking for proper use of biospecimen/data and for giving due credit in publications and resultant products** (Please sign to confirm all the below mentioned undertakings) I/we undertake that: a. Biospecimen/data requested will be used exclusively for purposes of the approved project detailed in the application submitted to the COVID-19 Biorepository. b. Due credit/ acknowledgement shall be given to the data contributors (institutions and their investigators who have contributed to collection, processing of biospecimens and the generation of meta data) while reporting, presenting or publishing the results of the research/ project in any manner. Funders should be given appropriate credits. c. For all the sample/data access requests coming to biorepository either for development/ testing/ validation due credit/ acknowledgement shall be given as stated below: *"The RECIPIENT who receives MATERIAL/ MODIFICATIONS from the BIOREPOSITORY, if results in a successful commercial product must state in their product information sheet that* "We acknowledge the significant contribution and expertise of THSTI, NCR Biotech Science Cluster BIOREPOSITORY, DBT India Consortium in development/testing/validation of our product". The RECIPIENT must agree to list all the members/ collaborating hospitals of the DBT India Consortium**, as annexure documents of the product information sheet/website. ***** Name of all the collaborating Institutes/ Hospitals: Translational Health Science Technology Institute,*** *Clinical partners: Maulana Azad Medical College, Lok Nayak Jai Prakash Hospital, and Lady Hardinge Medical College in Delhi, ESI Medical College Hospital, Faridabad, Civil Hospital, Gurugram, Haryana; Civil Hospital, Palwal, Haryana; Al-Falah School of Medical Science & Research Centre and Hospital, Dhauj, Haryana; Medanta Hospital, Gurugram; Shaheed Hasan Khan Mewati Government Medical College, Nalhar, Haryana.* • *"The RECIPIENT agrees to acknowledge the source of the MATERIAL/ MODIFICATIONS in any publication reporting on its use. The acknowledgement note should read as "This research has been conducted with the significant contribution*

	and expertise of THSTI, NCR Biotech Science Cluster BIOREPOSITORY and DBT India Consortium". d. The bioresource shared are for national use only. e. All data generated from this project will be returned as part of the "open research" platform sharing. I/we approve THSTI to list us in their database/presentation/reports/website as one of the organizations who had access to the COVID-19 Bioresources. **Place:** **Name of Principal Investigator** **Date:** **Sign and stamp of the Principal Investigator**

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 Agreements, Ethics and Biosafety Approval

COVID-19 BIORESOURCE ACCESS REQUEST

For use of the Biorepository 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)