COVID-19 BIORESOURCE ACCESS REQUEST

COVID-19 Biological Sample Access Request Form

SARS CoV2

Handling and culturing of virus requires certified & validated BSL-3 laboratory since, it belongs to risk group III category.

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/docs/default-source/coronaviruse/laboratory-biosafety-novel-coronavirus-version-1-1.pdf

Other interim guidelines are also available:
https://www.cdc.gov/sars/guidance/f-lab/app5.html
https://www.who.int/csr/disease/coronavirus_infections/Biosafety_InterimRecommendations_Novel Coronavirus_19Feb13.pdf?ua=1

ln 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 pandemic, 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.

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Instructions:

Please read the instructions carefully before filling the COVID-19 Biological 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 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, especially in case of virus requests.

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 from the regulatory bodies 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.

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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.	**PRINCIPAL INVESTIGATOR/S**	
	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.	**AREA OF RESEARCH**	

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6.	**TITLE OF THE RESEARCH PROJECT**	
7.	**A. 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:**	
8.	**MULTI-CENTRIC STUDY**	**Yes** ☐ **No** ☐
9.	**VIRUS REQUIREMENT**	
	SARS-CoV-2 Live virus strain ☐ **SARS-CoV-2 Heat inactivated** ☐ **SARS-CoV-2 Synthetic molecular standard (genomic RNA)** ☐	
10.	**FUNDING** (*If you are applying for a grant please provide details about the funding application)*	**Applied** ☐ **Approved** ☐ **Yet to be applied** ☐
11.	**FUNDING AGENCY**	
12.	**ETHICAL APPROVAL** (If approved attach copy of the approval letters from the respective IRBs)	**Approved** ☐ **Applied for** ☐ **Not applied** ☐ **Not applicable** ☐
13.	**Institutional Biosafety Committee (IBSC)** (If approved attach copy of the approval letters from the respective IBSCs)	**Approved** ☐ **Applied for** ☐ **Not applied** ☐ **Not applicable** ☐

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14.	**Review Committee on Genetic Manipulation (RCGM) approvals** (If approved attach copy of RCGM approval)	**Approved** ☐ **Applied for** ☐ **Not applied** ☐ **Not applicable** ☐
15.	**Undertaking for proper use of live virus and for giving due credit in publications and resultant products (Please sign to confirm all the below mentioned undertakings)** I/we undertake that: a. Viral samples/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** (only for samples that have been collected under this consortia study), 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.*	

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- *"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 & Signature of Principal Investigator**

Date: **Name & Signature of the Head of the Organization with Seal**

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, Biosafety Approvals and RCGM Approvals (as per requirement/s mentioned).

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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 live virus/ inactivated virus/ genomic RNA

B. Volume of sample remaining if project approved

C. Any Other comments:

(Authorized signatory)