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OFFICE MEMORANDUM

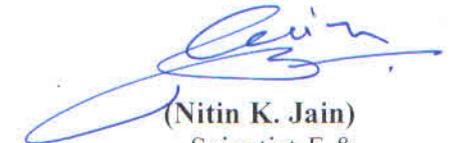
**Subject: Regulations & Guidelines for Recombinant DNA Research & Biocontainment-
Interim Guidelines on laboratory biosafety to handle COVID-19 specimen for
R&D purpose**

In continuation of this Department Office Memorandum of even No. dated 1.4.2018 and the powers conferred through the Sections 6, 8 and 25 of Environment Protection Act (EPA), 1986 and based on the recommendations of Review Committee on Genetic Manipulation (RCGM) in its meeting held on 7.4.2020, Department of Biotechnology hereby notify attached interim guidelines to handle COVID-19 specimens for R&D purpose. The guidelines include a whole range of basic minimal procedure to be followed, risk assessment & mitigation measures, routine laboratory procedure, specimen & nucleic acid storage, viral isolation, disinfectants & lab waste management, specimen packaging and shipment procedure etc.

2. As per the provisions of Rule 1989, all IBSCs and host institutions involved in research, development and handling of COVID-19 specimens are required to comply with these interim guidelines with immediate effect. Non-compliance shall attract the provisions of Section 15, 16 and 17 of Environment Protection Act (EPA), 1986.

3. For further information, IBSCs may also refer to interim guidelines issued by WHO and CDC on handling of COVID-19 specimens.

4. The interim guidelines on laboratory biosafety to handle COVID-19 specimens are notified at www.dbtindia.nic.in.


(Nitin K. Jain)
Scientist-F &
Member Secretary- RCGM

To:

- I. All Ministries and Departments of Govt. of India
- II. All IBSCs
- III. Communication Cell, DBT

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

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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

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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

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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).**