Requirements for SARS-CoV-2 samples

Scope/Summary: This policy outlines the requirements for the use of samples known to contain or suspected to contain SARS-CoV-2, the virus that causes COVID-19, at MIT.

Background: The CAB/ESCRO is responsible for establishing policies that promote the safe and responsible conduct of biological research at MIT. The CAB/ESCRO reviews all procedures using biological materials to ensure safe practices and procedures, use of an appropriate laboratory space, and that the risks inherent in the proposed laboratory projects do not exceed the research experience and expertise of the participants.

SARS-CoV-2 is currently classified as a Risk Group 3 by NIH, and most research work involving the live virus requires BL3 containment. SARS-CoV-2 has clear pandemic potential and is known to mutate frequently, making it a pathogen of concern despite the availability of vaccines. The virus is currently considered endemic to the United States, according to the CDC[1].

This policy aims to clarify the appropriate containment level for various experiments that either use SARS-CoV-2, use samples to are known to contain the virus, or use samples that potentially contain the virus. Like all other biological research at MIT, approval from the CAB/ESCRO is required prior to initiating any work with SARS-CoV-2 or samples from COVID-19 patients. Contact your Biosafety Officer to discuss the details of your proposed experiment for it to be considered by the Committee.

I. Work with live cultures of SARS-CoV-2

- SARS-CoV-2 is classified as a Risk Group 3 by NIH, and research involving live cultures or the virus or its use in animal models requires BL3 containment. Currently this work is not allowed at MIT because there are no BL3 laboratories.

II. Work with samples from COVID-19 patients

a. High risk samples:

Research samples that are very likely to contain infectious SARS-CoV-2 need to be handled under BL3 containment. Examples include respiratory or saliva samples from acutely sick COVID-19 patients or from individuals who tested positive for the virus. Such samples can be considered for work in BL2 containment if inactivated using a validated method at the discretion of the CAB/ESCRO.

b. Low risk samples:

Samples from COVID-19 patient which are unlikely to contain infectious virus can be handled under BL2+ containment and must fulfill all BL2+ policy requirements. Examples include blood or urine samples.

c. Risk of propagating SARS-CoV-2:

No culturing is allowed in samples where propagation might lead to the production of infectious SARS-CoV-2. An example is culturing respiratory samples from a COVID-19 patient in a way that supports propagation of either the human cells or any virus that may be in the sample.

III. General human-derived samples

- Human-derived samples such as saliva or blood always have the potential for containment infectious agents and should always be handled using universal precautions. These samples, in the absence of specific concerns related to the presence of SARS-CoV-2 (for examples based on negative test results, or absence of symptoms) can be used under BL2 containment. Some samples fall under the OSHA Bloodborne Pathogen standard[2] and have additional training requirements. At MIT[3], work with any human derived material must be registered on the Biological Research Registration, and personnel handling such material must take Bloodborne Pathogens for Researchers training.

IV. Inactivated SARS-CoV-2 samples

- Samples that have been inactivated by a validated procedure (e.g. chemical fixation or heat inactivation) can be approved for use in BL2 containment.
- SARS-CoV-2 has a single-stranded positive sense RNA genome and introduction of the full RNA genome in a permissive cell could lead to the production of infectious virus, therefore introducing the full genome of SARS-CoV-2 into cells is not allowed outside BL3 containment.
- Inactivation of SARS-CoV-2 cultures from high containment laboratories need to also be done using validated procedures before being allowed into lower containment laboratories. For more information, refer to Policy# 04: High Consequence Pathogens: Attenuated Strain and Inactivation Verification.

V. Work with segments from the SARS-CoV-2 genome

- Work using parts of the SARS-CoV-2 genome need to be registered on the Biological Research Registration.
- Work with and amplification of elements used in clinical diagnostic for COVID-19 (such as the N2 amplicon) could lead to false positive tests if not contained. Talk to your Biosafety Officer for more details.

References:

[1] CDC Yellow Book 2024

[2] Occupational Safety and Health Administration (OSHA) Occupational Exposure to Bloodborne Pathogens standard, 29 CFR § 1910.1030

[3] MIT Biosafety Manual

Revision History:

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