IBC Policy for working with SARS-CoV-2

Adopted 6/17/2025

In December 2024 The CDC (Centers for Disease Control and Prevention) updated its biosafety guidance for work with SARS-CoV-2. The CDC now recommends that work with SARS-CoV-2 be conducted at a **minimum** of biosafety level 2 (BSL-2). The National Institutes of Health (NIH) is aligning by rescinding the interim risk group classification of Risk Group 3 for SARS-CoV-2. The NIH Guidelines now classify SARS-CoV-2, and most other human coronaviruses, as Risk Group 2. (SARS-CoV and Middle East Respiratory Syndrome (MERS-CoV) remain classified as RG3 agents and require a minimum of BSL-3 for work.)

This revised guidance is specific to SARS-CoV-2 and should not be extrapolated to other members of the Coronaviridae family or to other members of the species Betacoronavirus pandemicum (such as severe acute respiratory syndrome coronavirus).

The University of Missouri (MU) Institutional Biosafety Committee (IBC) has final determination on the biosafety level based on a risk assessment of the proposed work with SARS-CoV-2 and COVID-19 materials. The MU IBC will decide on the appropriate biosafety level based on a comprehensive risk analysis of the proposed experiments/personnel and location.

Certain experiments, such as those involving **genetic modifications or other specific manipulations**, may require BSL-3 containment. Additionally, any deliberately manipulated SARS-CoV/SARS-CoV-2 chimeras with nucleic acids coding for SARS-CoV virulence factors are Select Agents and must comply with applicable Select Agent regulations and requires BSL-3 containment.

About SARS-CoV-2

SARS-CoV-2 is a human beta coronavirus and the causative agent of the respiratory disease COVID-19. It is a positive-sense single-stranded RNA virus (+ssRNA) with a lipid envelope, a nucleocapsid that covers the RNA, and a “halo” of spike proteins, which assist with cellular entry and give viruses in this family the characteristic crown-like shape.

IBC Protocol Submissions

IBC review and approval are required **prior** to receipt and initiation of any work with materials containing SARS-CoV-2 virus or derived from COVID-19 patients. This includes previously approved protocols at higher containment levels (BSL-3/ABSL-3). The IBC will require a re-write of existing approved IBC protocols to include new risk assessments and scope of work for any protocols for which work with SARS-CoV-2 at a lower containment level (BSL-2 or BSL-2 enhanced) is desired.

Biosafety Level Determination

Biosafety Levels set the standard for the appropriate facility, engineering controls, administrative controls, work practices, and personal protective equipment to manage the hazards and risks inherent in life science research. The following Biosafety Levels, materials, or procedures serve as a

framework to aid researchers in performing a risk assessment to determine the acceptable biosafety level for SARS-CoV-2 virus and COVID-19 patient samples.

BSL-1

The following activities are suitable for BSL-1:

- Fixed specimens or samples
- Inactivated samples including inactivated virus lysate
- Staining and microscopic analysis of fixed smears
- Molecular analysis of extracted nucleic acid preparations rendered non-viable
- Using automated instruments and analyzers (if aerosol containment is a feature) FACS – fixed samples
- Performing electron microscopic studies with glutaraldehyde-fixed grids
- Work with synthetically generated SARS-CoV-2 nucleic acids which lack a means of cellular entry.

BSL-2

The following activities are suitable for BSL-2 (BSL-2 facilities with BSL-2 work practices):

- Aliquoting and/or diluting patient or environmental specimens
- Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
- Nucleic acid extraction procedures involving potentially infected specimens (human or animal).
- Precipitation or membrane filtration
- Preparation and chemical- or heat-fixing of smears for microscopic analysis
- Work with SARS-CoV-2 recombinant nucleic acids in host-vector systems (e.g. in viral vectors or prokaryotic models).
- Work with samples that generate aerosols must be handled within the biosafety cabinet.
- Handling of animal models within a biosafety cabinet (ABSL-2)
- Housing post infection (ABSL-2).

BSL-2 (Enhanced) BSL-2 facility and BSL-3 Work Practices

Work which may require BSL-2 facilities with BSL-3 work practices includes, but is not limited to, processing of certain clinical samples from COVID-19 patients and work with the virus.

The following activities are suitable for BSL-2 with enhancements (BSL-2 facilities with BSL-3 work practices):

- Work with respiratory samples and secretions
- Work with virus including virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens
- High Speed Cell Sorting or FACS with viable virus (inside BSC or with aerosol evacuation system).
- Inoculation of animal models using live virus

In addition to BSL-2 practices and containment, when working with SARS-CoV-2 virus the following BSL-3 practices are required:

1. All work must be performed in a **biosafety cabinet** and all items are disinfected prior to removal from the biosafety cabinet.
    - No work on the open bench or in open bay laboratories. Any work on the open bench or in open bays requires detailed procedural description, aerosol mitigation measures, and IBC review and approval.
    - Sealed samples must be wiped with disinfectant upon removing them from the biosafety cabinet for transfer.
    - Waste is managed within a Biosafety cabinet. Disinfect tips with a 0.5% sodium hypochlorite bleach solution prior to disposal as biohazard waste. Disinfect the exterior of the biohazard waste bag prior to removal from BSC.
    - Exterior gloves are decontaminated and changed after working in the biosafety cabinet. All researchers must wash their hands with soap and water immediately after removing gloves.
2. Respiratory protection: Fit-tested N95 mask or other approved respirator.
3. Negative airflow for the laboratory from clean to potentially contaminated areas.
4. Restriction of the lab space to personnel actively involved in the work while it is in progress.
5. **Sealed safety cups or sealed rotors** must be used when centrifuging outside of the biosafety cabinet. Cups and rotors must be opened within a biosafety cabinet.
6. All sharps must have **engineered protection devices**.
    - Provide a written response as to why this cannot be accomplished in the IBC protocol application for IBC to review and approve. The IBC will review exceptions on a case by case basis.
7. **No glass** is to be used.
    - Provide a written response as to why this cannot be accomplished in the IBC application for IBC to review and approve. The IBC will review exceptions on a case-by-case basis.
8. Dedicated rear-closing gown/lab coat must be worn.
9. **Double gloves** must be worn;
    - In cases where double gloving limits dexterity, then a single layer of nitrile gloves can be used. This exception must be approved by the IBC.
    - When using double gloves, the interior glove must cover the cuff of the rear closing laboratory coat/gown. Can use lab tape, masking tape, painters' tape with gloves and cuff to prevent bare skin exposure.
10. Regular and thorough surface disinfection is required with an EPA registered disinfectant effective against SARS-CoV-2.
11. Vaccination against SARS-CoV-2 is highly recommended. All those handling SARS-CoV-2 virus must follow the MU IBC Vaccination Policy found on the Division of Research's IBC website: https://ars.research.missouri.edu/files/policies/vaccination_policy_and_guidelines.pdf and

are required to update their Occupational Health and Safety Program (OHSP) Risk Assessment and Hazard Evaluation Form (HEF) to include work with SARS-CoV-2.

12. SARS-CoV-2 is a regulated agent under the United States Government (USG) policy for **Dual Use Research of Concern and Pathogens of Enhanced Pandemic Potential (DURC-PEPP)** as Category 2. Work with this agent may require review by the MU Institutional Review Entity (IRE). For questions or assistance about DURC-PEPP materials and requirements, please visit the IBC website at https://research.missouri.edu/institutional-biosafety-committee/institutional-biosafety-committee

BSL-3

Experiments and agents are assigned Biosafety Level 3 if considered high risk for the individual, community, or environment. Researchers can request re-evaluation of the Biosafety Level as additional information is known. The IBC will evaluate these requests on a case-by-case basis.

Note that any agents worked with in a BSL-3 laboratory will not be allowed to be removed from containment unless it has been inactivated using an approved inactivation protocol (no live agents).

All BSL-3/ABSL-3 work must be conducted at LIDR (Laboratory for Infectious Disease Research).

The following is required to be performed at BSL-3:

- Emerging variants of SARS-CoV-2 virus not yet characterized that will be cultured or grown out. Patient samples should continue to be handled at BSL-2 unless determined by the IBC to require BSL-3.
- Strains that are no longer circulating (for which a current vaccine wouldn't provide good coverage).
- Work with no caging or open caging stays at ABSL3.
- Chimeric viruses
- Experiments or agents determined by the IBC on a case-by-case basis

Incident Reporting and Emergency Procedures

All incidents involving potential exposure to SARS-CoV-2 must be reported immediately to the MU Biosafety Office. Researchers should follow established protocols for post-exposure evaluation and response.