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Research Involving SARS-CoV-2

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Background

The following update was released on December 20, 2024. As stated by the National Institutes of Health (NIH) Office of Science Policy:

“In May 2020, the CDC issued Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 indicating that they should be handled in Biosafety Level 3 (BL) facilities, given the COVID-19 outbreak at the time, the unknown properties of SARS-CoV-2, and the data available at that time. Following CDC’s issuance of its Interim Guidelines, the NIH Office of Science Policy (OSP) issued companion guidance to align with CDC’s assessment. The NIH Interim Guidance stated that ‘SARS-CoV-2 best meets the definition of a RG3 agent and Institutional Biosafety Committees (IBCs) should consider the agent to be RG3 as a starting point in their risk assessments when reviewing research subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*.’

Over the course of the last several years, researchers, biosafety professionals, and biosecurity experts have continued to monitor the scientific landscape as it has evolved. An interagency working group reviewed updated information about the virus, population immunity and the availability of medical countermeasures to culminate in a scientifically rigorous and extensive re-evaluation to determine if the elevated handling criteria should remain in place. Informed by the assessment of that group, CDC has rescinded their interim elevated BL3 guidance, and to align NIH has rescinded the interim RG classification. As such, IBCs should consider the agent to be RG2 as a starting point in their risk assessments when reviewing research subject to the *NIH Guidelines*.”

Risk Group (RG) Classification for SARS-CoV-2 in the *NIH Guidelines*

As of December 20, 2024, after reviewing the current pathogen characteristics and population impact the NIH downgraded SARS-CoV-2 to RG2 and the Centers for Disease Control (CDC) recommend work conducted at BSL2 at a minimum.

SARS-CoV and Middle East Respiratory Syndrome (MERS-CoV), are specifically listed as RG3 agents in Appendix B-III-D, all other coronaviruses, including SARS-CoV-2, are classified under the existing RG2 category for Coronaviruses in Appendix B-II-D.

University of Michigan (U-M) Requirements for Performing SARS-CoV-2 Research

As determined by a facility specific risk assessment using RG2 as a starting point, and in consultation with the Institutional Biosafety Committee (IBC) and Principal Investigator subject matter experts, U-M



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will consider SARS-CoV-2 as RG2 and BSL2/ABSL2 with enhancements. Research will be conducted in the dedicated SARS-CoV-2 research space, now classified as enhanced BSL2/ABSL2.

Principal Investigators currently approved to work with SARS-CoV-2 at BSL3/ABSL3 must amend the IBC Protocol and Animal Use Protocol (if applicable) to change this work to BSL2/ABSL2. This amendment will be reviewed and a comprehensive risk assessment of the work performed. Based on the risk assessment of a specific research protocol, the IBC may require further enhancements or a higher level of containment.

SARS-CoV-2 Enhanced Facility

The dedicated SARS-CoV-2 Facilities are defined as enhanced BSL2 or enhanced ABSL2 laboratories. All standard U-M BSL2 practices and policies will apply. The enhanced BSL2/ABSL2 builds upon BSL2 practices and procedures with the addition of practices and modified PPE requirements that are often used in higher containment level laboratories.

Facility Work practices

- Conduct aerosol generating procedures in a BSC or other containment device
- Minimize the use of sharps
- Validation/verification of inactivation and EHS approval prior to removal of samples is no longer needed
- Inactivation of samples is still recommended for removal and further work outside of the dedicated facility
- Users approved by and granted access by Facility Director(s)
- Facility/experimental supplies and PPE will be the responsibility of each user
- It is recommended that biological waste be autoclaved and monthly BI testing continue since there are dedicated autoclaves for the facilities. This will help to keep the autoclaves operational and maintained.
 - If not able to autoclave, biological waste can be disposed of following normal BSL2/ABSL2 guidelines such as taken to designated vendor pickup bins or carcasses disposed of within the carcass cooler following standard practices.
- Incidents/near miss reported through the MISP

Facility PPE Requirements

- Respiratory protection is required
 - Users may choose to use the PAPR or N95
 - PAPR hoods
 - replaced routinely or whenever contaminated
 - N95 masks are one time use
- Street clothes (in accordance with U-M proper lab attire policy)
- Reusable gown
 - Gowns should be replaced routinely or when contaminated



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- Double gloves
- Eye protection (if wearing N95)
- Shoe covers (enhanced ABSL2)

EHS Biosafety Requirements

- Respiratory protection is required, users will still need to be enrolled in the Medical Surveillance Program and Respiratory Protection Program
- BSL2/ABSL2 training requirements will apply and include lab specific training for work with SARS-Cov-2
 - The PI, lab manager, or designee are responsible for ensuring staff are trained
 - Training records for all users must be maintained within the facility or with the respective Facility Director or Facility Manager to be accessible during annual inspection
- SARS-Cov-2 vaccine is recommended
- Annual facility shutdown and testing
- Annual Biosafety inspection
- Use of EPA registered disinfectants effective against SARS-CoV-2
- Facility specific SOP(s) to ensure consistency among users
 - Facility specific procedures
 - Incident and near miss reporting
 - How waste will be handled (preference is to use facility autoclave)
 - Monthly BI testing
 - PPE, use care & maintenance
 - Housekeeping, tracking and ordering of supplies
 - Facility communication (e.g., new user Slack channel)
 - Disinfectant used and spill clean up