

SARS-CoV-2 (COVID-19) Research Laboratory Biosafety Guidelines

Research Activities with Known or Likely Infected Specimens from Humans or Animal Models	Assigned Biosafety Level	Contact for Help, Approvals & Access to Appropriate Laboratory Facilities
<ul style="list-style-type: none"> • Storage and laboratory work with seed stocks, working stocks or specimens¹ with the intent to grow or use live virus at Duke. <ul style="list-style-type: none"> • Virus isolation, characterization and/or expansion • Viral cultures or isolates should be transported as Category A, UN2814, “infectious substance, affecting humans”² • Use of live SARS-CoV-2 virus in functional assays: <ul style="list-style-type: none"> • Plaque/Focus Forming Unit assays • Serologic virus capture/binding assays • Therapeutic MIC assays • Live cell sorting with intact virus • Use of live SARS-CoV-2 virus in animal 	BSL-3/ABSL3³	<p>Gregory D. Sempowski, Ph.D., Director, Duke Regional Biocontainment Laboratory</p> <p>Duke Human Vaccine Institute Phone: 919-684-4386 greg.sempowski@duke.edu https://shared-resources.dhvi.duke.edu/rbl</p>
<ul style="list-style-type: none"> • Processing, aliquoting or preparing specimens¹ for research use and storage • Preparation of chemical- or heat-fixed specimens¹ for microscopic analysis • Nucleic acid extraction of specimens¹ for molecular analysis • Preparation of inactivated specimens for other laboratory assessments • Performing diagnostic tests (e.g. serology) that <u>do not</u> involve activities with the potential to propagate virus • Inoculating bacterial or mycological culture media 	BSL-2 with enhancements⁴	<p>Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA) Director, Biological Safety / BSO / RO</p> <p>Occupational and Environmental Safety Office Phone: 919-684-8822 antony.schwartz@duke.edu https://www.safety.duke.edu/biological-safety</p>
<ul style="list-style-type: none"> • Molecular analysis of already extracted nucleic acid preparations • Analysis of specimens¹ that have been inactivated by a method approved by Duke Biological Safety. • Final packaging of specimens¹ already in a sealed, decontaminated primary container for transport to collaborating laboratories for additional analyses <ul style="list-style-type: none"> • Specimens from suspected or confirmed cases should be transported as UN3373, “Biological Substance, Category B • Pathologic/microscopic examination of fixed specimens¹ (e.g. formalin-fixed tissues or glutaraldehyde-fixed grids). • Routine staining and microscopic analysis of fixed smears • Routine examination of bacterial and mycotic cultures 	BSL-2	<p>Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA) Director, Biological Safety / BSO / RO</p> <p>Occupational and Environmental Safety Office Phone: 919-684-8822 antony.schwartz@duke.edu https://www.safety.duke.edu/biological-safety</p>

***Please note that all proposed research with SARS-CoV-2 (COVID-19) requires review by the Biological Safety Division of OESO and will require approval of a Standard Operating Procedure (SOP) for the research. In addition, some research will also require approval by the Institutional Biosafety Review Committee (IBRC) and/or the Institutional Biosafety Committee (IBC), which will be coordinated by Biological Safety Division, biosafety@dm.duke.edu.**

¹Specimens are defined as, but not limited to, blood, serum, plasma, tissues, feces, urine, sputum, mucosal swabs or washes/secretions collected from any species.

²For assistance with *required* import permits and export licenses contact **Duke Office of Export Controls** (export@duke.edu; 919-613-6800).

³Animal Biosafety Level-3 (ABSL-3)

⁴Required Enhancements to standard BSL2:

- Any procedure with the potential to generate aerosols or droplets (e.g. vortexing, cell sorting, ELISA plate washing) will be performed in a certified Class II Biological Safety Cabinet (BSC). BSC must be decontaminated with an EPA approved disinfectant for coronavirus.
- Personnel will wear a closed front gown, face shield and double pair of gloves.
- Centrifugation of specimens must be performed using sealed centrifuge rotors or sample cups.
- The use of sharps should be eliminated wherever possible.