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

• Storage and laboratory work with seed stocks, working stocks or specimens[1] with the intent to grow or use live virus at Duke.
  • 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:
  • 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/ABSL3[3]	**Scott Alderman, MS, CBSP**
		Director of Facilities and Safety, DHVI
		Interim Director, Regional Biocontainment Laboratory
		
		Duke Human Vaccine Institute
		Phone: 919-668-6593
		scott.alderman@duke.edu
		https://shared-resources.dhvi.duke.edu/rbl

• Processing, aliquoting or preparing specimens[1] for research use and storage • Preparation of chemical- or heat-fixed specimens[1] for microscopic analysis • Nucleic acid extraction of specimens[1] for molecular analysis • Preparation of inactivated specimens for other laboratory assessments • Performing diagnostic tests (e.g. serology) that do not involve activities with the potential to propagate virus • Inoculating bacterial or mycological culture media	**BSL-2 *with* enhancements[4]**	**Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA)** Director, Biological Safety / BSO / RO **Occupational and Environmental Safety Office** Phone: 919-684-8822 antony.schwartz@duke.edu https://www.safety.duke.edu/biological-safety
• Molecular analysis of already extracted nucleic acid preparations • Analysis of specimens[1] that have been inactivated by a method approved by Duke Biological Safety. • Final packaging of specimens[1] already in a sealed, decontaminated primary container for transport to collaborating laboratories for additional analyses • Specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance, Category B • Pathologic/microscopic examination of fixed specimens[1] (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**	**Antony Schwartz, Ph.D., SM(NRCM), CBSP(ABSA)** Director, Biological Safety / BSO / RO **Occupational and Environmental Safety Office** Phone: 919-684-8822 antony.schwartz@duke.edu https://www.safety.duke.edu/biological-safety

***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 OESO-Biological Safety Division. For details, email biosafety@duke.edu.**

[1] Specimens are defined as, but not limited to, blood, serum, plasma, tissues, feces, urine, sputum, mucosal swabs or washes/secretions collected from any species.
[2] For assistance with *required* import permits and export licenses contact **Duke Office of Export Controls** (export@duke.edu; 919-613-6800).
[3] Animal Biosafety Level-3 (ABSL-3)
[4] **Required enhancements to standard BSL2**:

- Any procedure with the potential to generate aerosols or droplets (e.g., flipping open snap-cap tubes, pipetting, vortexing, cell sorting, ELISA plate washing) should be performed in a certified Class II Biological Safety Cabinet (BSC). BSC must be decontaminated with an EPA approved disinfectant for coronavirus.
- If a BSC is unavailable for aerosol or droplet generating procedures, a combination of PPE (lab coat, gloves, and mucous membrane and respiratory protection such as a N95 respirator with a faceshield, safety glasses, or goggles) along with equipment (e.g. splash guards, sealed centrifuge rotors, and/or gasketed centrifuge caps) must be implemented. N95 users must be adhere to the Respiratory Protection Policy.
- The use of sharps should be eliminated wherever possible. When the use of sharps is unavoidable, strict sharps safety measures must be followed.