

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

Research Activity	Biosafety Level	Regulatory Requirements
<ul style="list-style-type: none"> ➤ Cultures of or using live SARS-CoV-2 virus, including isolation, characterization, expansion, and in assays, including virus capture/binding, therapeutic MIC, and live cell sorting <ul style="list-style-type: none"> • Cultures/isolates must be transported as Category A, UN2814 ➤ Any other work with or storage of cultures, seed stocks, or specimens of the virus with the intent to grow live virus at the University of Miami 	BL3	There are currently no BL3 facilities at the University of Miami, therefore this research is not authorized at the University
<ul style="list-style-type: none"> ➤ Use of live SARS-CoV-2 virus in animals 	BL3-N	There are currently no BL3-N facilities at the University of Miami, therefore this research is not authorized at the University
<ul style="list-style-type: none"> ➤ Processing, aliquoting or preparing specimens for research use and storage ➤ Preparing samples to be fixed or otherwise inactivated for lab assessment or microscopic analysis ➤ Preparing samples for nucleic acid extraction of specimens for culture or molecular analysis 	BL2 with enhancements	<ul style="list-style-type: none"> ❖ Biosafety Officer (BSO) ❖ Institutional Review Board (IRB) ❖ Institutional Biosafety Committee (IBC)
<ul style="list-style-type: none"> ➤ Work with attenuated strains or otherwise non-viable virus* 	BL2-N / BL3-N	<ul style="list-style-type: none"> ❖ Biosafety Officer (BSO) ❖ Institutional Animal Care and Use Committee (IACUC) ❖ Institutional Biosafety Committee (IBC)
<ul style="list-style-type: none"> ➤ Performing diagnostic tests (e.g. serology) that do not involve activities with the potential to propagate virus <ul style="list-style-type: none"> • Final packaging of specimens already in a sealed, decontaminated primary container for transport to collaborating laboratories for additional analyses • Specimens from suspected or confirmed cases must be transported as Category B, UN3373 	BL2	<ul style="list-style-type: none"> ❖ Biosafety Officer (BSO) ❖ Institutional Review Board (IRB) ❖ Institutional Biosafety Committee (IBC)
<ul style="list-style-type: none"> ➤ Work/analysis of already fixed or inactivated samples, including: <ul style="list-style-type: none"> • Molecular analysis of already extracted nucleic acid preparations • Pathologic/microscopic examinations • Routine staining of fixed smears 	BL1	<ul style="list-style-type: none"> ❖ Institutional Review Board (IRB) ❖ Biosafety Officer (BSO)
<ul style="list-style-type: none"> ➤ Assays/testing that is performed on COVID-19 patients and concluded/discarded in patient room 	Clinic Patient Room	<ul style="list-style-type: none"> ❖ Institutional Review Board (IRB) ❖ Biosafety Officer (BSO)
<ul style="list-style-type: none"> ➤ Collecting samples from individuals recovered from COVID-19, or otherwise healthy individuals with no signs suspected of COVID-19 	BL2	<ul style="list-style-type: none"> ❖ Biosafety Officer (BSO) ❖ Institutional Review Board (IRB)

❖ **Contacts:**

- Biosafety Office (BSO) – contact Shane Gillooly at sxg1519@med.miami.edu
- Institutional Biosafety Committee (IBC) – contact Lizzeth Meza at lmeza@med.miami.edu
- Institutional Animal Care and Use Committee (IACUC) – contact Ellen Kapsalis at ekapsali@med.miami.edu
- Institutional Review Board (IRB) – contact Cindy Gates at cmg345@med.miami.edu

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

❖ **Required Enhancements to standard BL2:**

- 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.
- Centrifugation of specimens must be performed using sealed centrifuge rotors or sample cups.
- The use of sharps should be eliminated wherever possible.

***Will need to be assessed on a case by case basis by the IBC**