

Guidelines on the Use of SARS-CoV-2 in Research at USA

The emergence of SARS-CoV-2 and the evolving COVID-19 pandemic has resulted in widespread interest for researchers to acquire and work with clinical specimens from presumptive or confirmed COVID positive patients. This policy establishes current biosafety research guidelines for conducting SARS-CoV-2 research at the University of South Alabama. Due to the evolving nature of our knowledge about SARS-CoV-2, University policy will be updated as NIH and CDC guidelines are updated.

Currently, all University research involving SARS-CoV-2 must be reviewed and approved by the Institutional Biosafety Committee (IBC) before initiation of the work. **NIH has designated SARS-CoV-2 as Risk Group 3.** Accordingly, IBC is asking that all work involving COVID-19 specimens, SARS-CoV-2 viral RNA, lysates, sequences (including synthetic sequences), or the expression of viral proteins be submitted as **new protocols**. Risk assessments by the Principal Investigator and the IBC will be conducted using the *CDC Interim Biosafety Guidelines for Handling and Processing Specimens Associated Coronavirus Disease 2019 (COVID-19)*. Protocols will be approved with containment conditions and special precautions specific to the proposed COVID-19 or SARS-CoV-2 research activities.

Guidelines for work at the University, consistent with CDC recommendations, are provided in the matrix below.

Research Activities	Biosafety Level
<ul style="list-style-type: none"> - Viral isolation, characterization, or cultivation - Storage of seed stocks, working stocks, or infected specimens¹ - Recovery of viral agents - Live virus functional assays including plaque assays, infected cell culture, capture or binding assays, and cell sorting - Genetic manipulation of the virus - Working with a live virus in animals 	BSL3/ABSL3
<ul style="list-style-type: none"> - Procedures likely to generate aerosols - Processing or preparing specimens¹ for research or storage - Chemical or heat fixation² of specimens¹ for microscopic analysis - Nucleic acid extraction - Preparation of inactivated² specimens¹ 	<p style="text-align: center;">BSL2 with special precautions</p> <ul style="list-style-type: none"> - Class II Biological Safety Cabinet - EPA approved decontamination procedure³ - Face shield and double gloves - Sealed centrifugation rotors and samples cups - Avoid the use of sharps
<ul style="list-style-type: none"> - Molecular analysis of extracted nucleic acids - Analysis of inactivated specimens¹ - Microscopy analysis including staining of fixed specimens 	BSL2

¹Specimen is defined as blood, serum, plasma, tissues, feces, urine, sputum, mucosal swabs, or washes and secretions from any species

²See recommended procedures for viral inactivation

³EPA decontamination procedures

In addition to research use at the University, shipping or transport of COVID-19 specimens, SARS-CoV-2 viral RNA, lysates, sequences (including synthetic sequences), or purified viral proteins needs to comply with CDC and DOT guidelines. Live viral samples are considered Category A, UN2814. Sealed and decontaminated specimens are considered Category B, UN3373.

These guidelines apply to all research, sponsored and unsponsored, conducted under the auspices of the University. This policy applies to all University locations.

References

1. List N: Products with Emerging Viral Pathogens AND Human Coronavirus claims for use against SARS-CoV-2.
https://www.epa.gov/sites/production/files/2020-06/documents/sars-cov2_listn_06122020.pdf