**Institutional Biosafety Committee Guidance for Work with Potential SARS-CoV-2 Samples**

**Scope:**

This document is intended to serve as a starting point for researchers that propose to work with potential SARS-CoV-2 samples. It outlines the process for obtaining approval to work with SARS-CoV-2 materials, the types of experiments that can be considered in at Augusta University, exposure reporting requirements and the minimum laboratory features and safety precautions that are required for different types of manipulation. This document will be updated as new information is made available regarding the safe handling of SARS-CoV-2 for research.

**Obtaining approval before work with potential SARS-CoV-2 samples:**

* Any research involving potential SARS-CoV-2 samples must be reviewed and approved by the Institutional Biosafety Committee (IBC) prior to collection/receipt of specimens or initiation of experiments. Principal Investigators (PIs) must submit a biosafety protocol application/amendment that outlines the specific experiments that will be conducted and that includes a completed **Standard Operating Procedures for SARS-CoV-2/CoVID19 Research** document for those experiments. The IBC may require additional safety measures depending on the nature of the experiments that will be conducted.
* Please note that different containment is required for different types of samples and for different sample manipulation. Therefore, approvals will be granted for specific experiments only. Any additional experiments that are planned will require a biosafety protocol amendment and additional IBC review and approval before they can begin.
* The Biological Safety Office will conduct an inspection of the proposed research space to ensure that the appropriate safety measures are in place and that staff have been adequately trained.

**Occupational health requirements:**

All research personnel must be cleared by Employee Health for work with human materials (hepatitis B titer/vaccination/waiver process) and fit-tested for an N95 respirator (respirator physical and fit testing must be done annually).

**Training requirements:**

* All research personnel must be added to the appropriate biosafety protocol (BSP) and must complete ***Initial Biosafety and Bloodborne Pathogen Training***, available for self-assignment through Workforce Learn Online; refresher training must be completed annually.
* Anyone participating in the shipping process (preparing specimens for shipment, packing and sealing shipping containers, preparing shipment paperwork) must complete ***2022-2024 Shipping Biological Substances and Support Materials Training***,available for self-assignment through Workforce Learn Online.
* Anyone collecting or processing specimens from actively infected or convalescent CoVID19 subjects must be able to demonstrate their ability to comply with the general laboratory safety and SARS-CoV-2 SOPs in place for their research team. This will be assessed by the Biological Safety Office during inspection of the proposed research spaces.
* The PI is responsible for ensuring that the above training modules have been completed and for conducting the following lab-specific training for all research personnel:
  + 1. General laboratory safety SOPs
    2. SARS-CoV-2 SOPs
    3. Competency verification for each procedure performed
    4. Demonstrated competency on working in a BSC

PIs should maintain a signature log for all training, as documentation of lab-specific training will be reviewed at the time of the laboratory inspection.

**Laboratory attire and personal protective equipment (PPE) requirements:**

* Disposable surgical masks (not reusable cloth masks) should be worn when working in the laboratory with potentially infectious materials, including specimens from COVID-19 patients.
* Long pants or ankle length skirts (no shorts or short skirts) and shoes that cover the entire foot (no sandals or flip flops, no ballet flats) are required for entry into laboratory areas.
* PPE required for work with SARS-CoV-2 materials varies based on the nature of the experiments and is outlined in the following sections.

**Laboratory space requirements:**

In selecting a suitable space for SARS-CoV-2 experiments, please select a laboratory with limited traffic (ideally a designated lab), a biosafety cabinet, a sink and eyewash, and inward flow of air (negative pressure) without recirculation to spaces outside of the laboratory.

**Mandatory reporting of illness or biological spills/accidents/possible exposures:**

* All spills, injuries or exposures involving SARS-CoV-2 samples must be reported to the Principal Investigator and the Biological Safety Office
* Possible exposure events must also be reported to Employee/Student Health.
* Researchers must self-monitor for signs and symptoms of COVID-19; any illness must be reported to the PI. Signs and symptoms of COVID-19 include
  + Fever or chills
  + Cough
  + Shortness of breath or difficulty breathing
  + Fatigue
  + Muscle or body aches
  + Headache
  + New loss of taste or smell
  + Sore throat
  + Congestion or runny nose
  + Nausea or vomiting
  + Diarrhea

**EXPERIMENTS THAT REQUIRE BSL2 CONTAINMENT**

The following types of experiments require BSL2 containment and may be considered at Augusta University:

* Analysis of stool, whole blood, serum and urine
* Use of automated instruments and analyzers that have an aerosol containment features
* Staining and microscopic analysis of fixed smears
* Examination of bacterial cultures
* Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues (inactivation methods must be validated)
* Molecular analysis of extracted nucleic acid preparations (NO nucleic acid extraction/isolation)
* Final packaging of specimens for transport to diagnostic laboratories for additional testing (specimens should already be in a sealed, decontaminated primary container)
* Electron microscopy with glutaraldehyde-fixed grids
* FACS analysis of fixed samples

**BSL2 safety precautions:**

* PPE: surgical mask, gloves, lab coat, eye protection
* Good Standard Microbiological Practices are followed (these should be outlined in the general lab safety SOPs)
* Access to the laboratory is restricted when work is being conducted
* All procedures in which infectious aerosols or splashes may be created are conducted in a biosafety cabinet (BSC)
* Centrifuge safety caps should be used to avoid exposure to aerosols
* Surface decontamination at every step using EPA List N disinfectants and contact times
* All contaminated items should be treated as biomedical waste.

**EXPERIMENTS THAT REQUIRE BSL2+ CONTAINMENT**

The following types of experiments require BSL2+ (also known as BSL2 enhanced, or BSL2 with BLS3 precautions) containment and may be considered at Augusta University:

* Aliquoting or diluting specimens
* Inoculating bacterial or mycological culture media
* Performing diagnostic lab tests that do not involve propagation of viral agents *in vitro* or *in vivo*
* Nucleic acid extraction procedures
* Preparation and chemical- or heat-fixing of smear for microscopic analysis
* Procedures with respiratory samples and secretions
* FACS analysis of non-fixed samples
* Inactivated virus lysate

**BSL2+ safety precautions:**

* PPE: surgical mask or N-95 respirator (for respiratory secretions), double gloves, disposable impervious gown, goggles/safety glasses with side shields/face shield.
* Good Standard Microbiological Practices are followed (these should be outlined in the general lab safety SOPs)
* All samples opened inside BSC in case of spills/leakage
* Surface decontamination at every step using EPA List N disinfectants and contact times
* Scheduled time for handling SARS-CoV-2 samples
* Two person method to minimize withdrawing hands from BSC
* Centrifugation of specimens in safety cups or sealed rotor, loaded and unloaded in BSC
* All contaminated items should be disinfected before being removed from BSC and placed in biomedical waste container for disposal

**EXPERIMENTS THAT REQUIRE BSL3 CONTAINMENT**

The following types of experiments require BSL3 containment and cannot be conducted at Augusta University at this time:

* Virus culture or isolation
* Initial characterization of viral agents recovered in culture
* *In vitro* or *in vivo* models of infection involving wild type virus
* High speed cell sorting
* Inactivation of viral cultures for transfer out of containment