**PI Name:**

**Safety Protocol for COVID-19 patient (insert sample type)**

**1. Hazard Communication Statement**

COVID-19 is the infectious disease caused by the most recently discovered coronavirus SARS-CoV-2. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.

SARS-CoV-2 can be transmitted from person to person through small droplets from the nose or mouth that are spread when a person infected with SARS-CoV-2 talks, exhales, or coughs. It is also possible that very small droplets remain suspended in the air for a long time enabling aerosol transmission. Droplets also land on objects and surfaces and are transmitted when individuals touch these objects or surfaces, then touch their eyes, nose or mouth.

People may be sick with the virus for 1 to 14 days before developing symptoms or remain asymptomatic. The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Most people (about 80%) recover from the disease without needing special treatment. More rarely, the disease can be serious and even fatal. Older people, and people with other medical conditions (such as asthma, diabetes, or heart disease), may be more vulnerable to becoming severely ill.

In SARS-CoV-2 infected individuals infectious particles are present in mucous secretions (from respiratory system) but have also been detected in feces ([*https://wwwnc.cdc.gov/eid/article/26/8/20-0681\_article*](https://wwwnc.cdc.gov/eid/article/26/8/20-0681_article)*)* and blood *(*[*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7135848/*](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7135848/)*).* Viral RNA is detected in about 1% of blood samples but it has not been established whether these constitute infectious particles ([*https://doi.org/10.1038/s41586-020-2196-x*](https://doi.org/10.1038/s41586-020-2196-x)*).*

The Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19) are continually being updated as new information becomes available. Please refer to: [*https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html*](https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html) and[*https://absa.org/covid19toolbox/*](https://absa.org/covid19toolbox/)

Personnel will follow these guidelines when selecting PPE appropriate for proposed procedures. In addition the MUSC guidance document should be consulted to determine which level of biosafety containment is required for the procedure. MUSC cannot accommodate any work that requires BSL3/ABSL-3. (add link to guidance document)

**2. Standard Biological Safety Practices**

The following precautions are adapted from the NIH and CDC publication, [Biosafety in Microbiological and Biomedical Laboratories, 5th ed.,](https://www.cdc.gov/biosafety/publications/bmbl5/bmbl5_sect_iv.pdf%23x2013%3B%20Laboratory%20Biosafety%20Level%20CriteriaSection%20IV%E2%80%94Laboratory%20Biosafety%20Level%20Criteria%20%5BPDF%20-%20354%20KB%5D%3C/a%3E) which should be followed by study personnel when handling the patient samples, which is potentially infectious in nature

**2a. Basic Safety Practices**

1. Access to areas containing the investigational product is limited or restricted by the Principal Investigator.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the room where they are utilized.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in areas containing the investigational product. Food must be stored outside of these areas in cabinets or refrigerators designated and used for that purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
* Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
* Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
* Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.
1. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. It must be collected in an approved contained for disposal. Plastic ware should be substituted for glassware whenever possible.
2. Perform all procedures to minimize the creation of splashes and/or aerosols.
3. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
4. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:
* Materials to be decontaminated outside of the immediate work area must be placed in a durable, leak proof container and secured for transport.
* Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
1. A sign incorporating the universal biohazard symbol must be posted at the entrance to the work area when infectious agents are present. Posted information must include: the biosafety level, supervisor’s name (or other responsible personnel), telephone number, agent information should be posted in accordance with the institutional policy.
2. An effective integrated pest management program is required.
3. The supervisor must ensure that study personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Study personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual’s susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all study personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution’s healthcare provider for appropriate counseling and guidance.

**2b. Safety Equipment (Primary Barriers and Personal Protective Equipment)**

1. Properly maintained Biosafety Containers (BSC), appropriate personal protective equipment (PPE), or other physical containment devices must be used whenever:
* Procedures with a potential for creating infectious aerosols or splashes may be conducted. This may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
* High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
1. Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Protective clothing must be removed before leaving the work area. Protective clothing is disposed of appropriately, or deposited for laundering by the institution. Laboratory clothing should not be taken home.
2. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated waste or decontaminated before reuse. Persons who wear contact lenses must also wear eye protection.
3. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the work area designated for infectious agents. In addition, BSL-2 workers should:
4. Change gloves when they become contaminated, when glove integrity is compromised, or when otherwise necessary.
5. Once gloves are removed, employees must also wash their hands when their work with hazardous materials has been completed and before leaving the work area. Disposable gloves cannot be washed or reused. Used gloves must be disposed of with other contaminated waste. Hand washing protocols must be rigorously followed.
6. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

**2c. Facilities (Secondary Barriers) Intended for Use with Infectious Agents**

1. Doors should be self-closing and have locks in accordance with the institutional policies.
2. Work areas involving the investigational product must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.
3. The work area should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted in areas utilized in conjunction with infectious agents.
4. Furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
5. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
6. Chairs, in conjunction with infectious agents, must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
7. Windows that open to the exterior are not recommended. However, if windows exist that open to the exterior, they must be fitted with screens.
8. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled areas, and other possible airflow disruptions.
9. Vacuum lines should be protected with liquid disinfectant traps.
10. An eyewash station should be readily available. If an eye wash is not available, compensate with use of eye protection such as safety glasses or goggles when utilizing infectious agents.
11. There are no specific requirements for ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the facility.
12. HEPA filtered exhaust air from a Class II BSC can be safely recirculation back into the facility if the cabinet is tested and certified at least annually and operated according to manufacturer’s recommendations. BSCs can also be connected to the facility exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.
13. A method for decontaminating all wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

**3A. Receiving and storage**

1. Fill in information how the sample is transported to storage area. From where, what container?
2. Fill in information about the storage location (key card secured?, locked freezer, who has the key and how is it secured)
3. Fill in storage condition (freezer, fridge, liquid N2, BSL-2 placard affixed)
4. Fill in PPE worn when handling the sample

**3B. Procedures used to sample extraction and analysis**

1. Fill in information how the sample will be handled until inactivated
2. Add PPE required
3. Add other safety equipment used
4. Any other relevant information

**3C. Procedures for inactivation and waste disposal**

1. Fill in agent used for disinfection
2. Add contact time
3. List disposal of solid and any liquid waste

***4. Emergency procedures***

4A. Spills of the agent:

1. Notify workers in the area.
2. Leave the area for 15 minutes to allow aerosols to settle. Replace contaminated PPE.
3. Upon return, mix spill with a clinical grade disinfectant and allow the appropriate contact time.
4. Absorb spill with paper towels and dispose them into biohazard bags.
5. Use dustpan and broom to sweep up debris. Broken glass must be deposited into broken glass or sharps box.
6. Wipe the spill area with clinical grade disinfectant
7. Dispose of contaminated PPE in autoclavable biohazard bags.

4B. In the event of injury or exposure

1. **CLEANSE WOUND:** Wash all wounds immediately with antiseptic soap and a high volume of water for up to 15 minutes.
2. **CONTROL BLEEDING**
3. **ACCIDENTAL INGESTION:** Rinse mouth with water but do not swallow.
4. **SEEK IMMEDIATE MEDICAL FOLLOW-UP** (*do not wait 24 hrs)*

Employees *and* students go to:

* **Employee Health Services** (during business hours: Monday-Friday, 7:30 am -4 pm). Address/Location: 57 Bee Street, Charleston SC 29425; Phone: (843) 792-2991
* **MUSC Emergency Room** (after business hours)

Address/Location: 96 Jonathan Lucas Street, Charleston SC 29425

1. **REPORT EXPOSURE IMMEDIATELY** to the Principal Investigator and notify Biosafety Officer (843-792-3604).
2. **NOTIFY** Employee Health Services within 24 hours by filing an ACORD First Report of Injury form at <https://isserve.musc.edu/acord/>

By signing below I attest that I have read and understood these safety instructions and agree to adhere to these rules at all times. Furthermore, I feel I have been properly notified and trained of the hazards in this laboratory.

Name (print) Signature

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