Note: No virus culture or isolation or initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens can be performed in any UofSC laboratory. These experiments can only be conducted in a Biosafety Level 3 (BSL-3) laboratory using BSL-3 practices.

OVERVIEW & SCOPE

This document provides biosafety guidance for research laboratories that will be handling samples from COVID-19 suspected or positive patients. The guidance outlined below serves to assist labs in implementing proper biosafety procedures to handle and transport COVID-19 samples. All COVID-19 research projects using biohazardous materials must be approved by the Institutional Biosafety Committee (IBC) prior to performing any experiments. Please notify the Biosafety Office (Sherika Smith or Mark Robbins) if you plan to conduct any COVID-19 research using biological materials.

RISK ASSESSMENT

The CDC has provided laboratory biosafety and COVID-19 guidance that encourages labs to take precautions in handling specimens that are suspected or confirmed for SARS-CoV-2 until more information becomes available. According to this CDC guidance, “All laboratories should perform a site-specific risk assessment to identify and mitigate risks and determine if enhanced biosafety precautions are warranted based on situational needs...Risk assessments and mitigation measures are dependent on the procedures performed, identification of the hazards involved in the process and/or procedures, the competency level of the personnel who perform the procedures, the laboratory equipment and facility, and the resources available.” The CDC also indicates the risk assessment should identify activities that could produce a negative outcome, and prioritize those negative outcomes or risks based on their likelihood and the consequences of each identified risk. Control measures should be effective and based on this risk assessment. These issues should be carefully evaluated for COVID-19 research projects.

Questions to ask when conducting a lab-specific risk assessment include:

- What are the types of specimens that will be handled (blood, respiratory secretions, fixed or unfixed tissues, etc.)?
- What lab procedures will be used when handling specimens that could increase risk of exposure (centrifugation, sharps usage, procedures outside a BSC, etc.)?
- What is the relevant training and experience for lab personnel performing COVID-19 related experiments?
- What potential situations are there in which exposure or release could occur?
- What is the likelihood of an exposure/release occurring?
  - Unlikely: not very possible to occur in near future
  - Possible: feasible to occur in the near future
  - Likely: very possible to occur in the near future
- What is the severity of the consequences of an exposure/release (negligible, moderate, severe)?

IBC PROTOCOLS
The following biosafety containment considerations should be addressed (if applicable) for experiments involving COVID-19 patient specimens in the Human-Derived Materials Summary of your IBC protocol:

- The PI will control access to the laboratory.
- All lab personnel will wash hands after working with potentially infectious samples and before leaving the lab.
- The use of sharps will be eliminated whenever possible. If sharps are used, describe type of contaminated sharps that will be used and the precautions to prevent exposure. If no sharps will be used, then indicate that no sharps will be used for any experiments involving potentially infectious samples.
- All procedures will be performed to minimize the potential for generating splashes or aerosols.
- Work surfaces will be decontaminated after completion of work and after any spill or splash of potentially infectious material using EPA List N: Disinfectants for Use Against SARS-CoV-2.
- All potentially infectious materials will be decontaminated before disposal. If materials will be decontaminated outside the lab, they will be transported in a durable, leak-proof container.
- If potentially infectious samples are centrifuged in the open lab, a centrifuge with sealed rotor heads or centrifuge safety cups will be used.
- The PI will ensure lab personnel receive appropriate training and will be provided information regarding immune competence and conditions that may predispose them to infection. Individuals with health conditions or concerns will be encouraged to contact UofSC Student Health Services for counseling and guidance.
- The PI will ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with samples used in this project.
- Lab equipment will be routinely decontaminated. Spills involving infectious materials will be contained, decontaminated and cleaned up according to the BSL-2 spill procedures.
- Incidents that may result in exposure to infectious materials will be immediately reported using the Laboratory Incident Report Form, evaluated and treated. Lab personnel will follow the university’s procedures for incidents involving a biological hazard.
- All procedures involving the manipulation of potentially infectious materials that may generate an aerosol will be conducted in a biosafety cabinet.
- Eye and face protection will be used any time potentially infectious samples will be handed outside the biosafety cabinet or containment device.
- Gloves will be changed when contaminated or the integrity has been compromised.
- Protective clothing will be removed before leaving for non-lab areas.

TRANSPORT OF PATIENT SPECIMENS

Patient specimens transported by personal or university vehicle are considered materials of trade according to the Hazardous Materials Regulations (HMR). Materials of Trade are hazardous materials other than a hazardous waste, that are carried on a motor vehicle for purposes that include being carried by a private motor carrier to directly support a principal business that is not transportation. (e.g. academic and laboratory research, pest control, plumbing, painting) (49 CFR 171.1). Because patient specimens are being transporting for research purposes, transport directly from hospitals or clinics to university laboratories is a function not subject to the requirements of the HMR. Specimens from patients positive for or suspected of COVID-19 are considered a Category B infectious substance according to the Hazardous Materials Regulations.
**Infectious substance Material of Trade definition** (49 CFR 173.6): Division 6.2 material, other than a Category A infectious substance, contained in human or animal samples (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or is a biological product or regulated medical waste.

When transported by motor vehicle in conformance with section 173.6 (Materials of Trade Exceptions), a material of trade is only subject to the requirements referenced in the following section:

- The material must be contained in a combination packaging. For liquids, the inner packaging must be leakproof, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. For sharps, the inner packaging (sharps container) must be constructed of a rigid material resistant to punctures and securely closed to prevent leaks or punctures, and the outer packaging must be securely closed to prevent leaks or punctures. For solids, liquids, and sharps, the outer packaging must be a strong, tight packaging securely closed and secured against shifting, including relative motion between packages, within the vehicle in which it is being transported.

- Other than a regulated medical waste, the amount of Division 6.2 material in a combination packaging must conform to the following limitations: (A) One or more inner packagings, each of which may not contain more than 0.5 kg (1.1 lbs) or 0.5 L (17 ounces), and an outer packaging containing not more than 4 kg (8.8 lbs) or 4 L (1 gallon); or (B) A single inner packaging containing not more than 16 kg (35.2 lbs) or 16 L (4.2 gallons) in a single outer packaging.

- The operator of a motor vehicle that contains a material of trade must be informed of the presence of the hazardous material (including whether the package contains a reportable quantity) and must be informed of the requirements of this section.

Patient specimens must be transported in such a way as to minimize exposure to infectious agents (packages must always remain upright and secured in the vehicle). The inner or outer container must be labeled with the contents and contact information for the lab. The secondary container is required by the Bloodborne Pathogens Standard to be labeled with the biohazard symbol. All outer labeling must be included on the package per DOT/IATA requirements for “Biological Substance, Category B”. Biohazardous materials must never be left unattended during transport and must always be under the supervision of lab personnel trained in proper spill and emergency procedures.

If dry ice will be used, the packaging must be constructed in a way to allow for the release of carbon dioxide gas and the outside must be labeled “Dry ice”. The package should be located as far away from the passengers as possible and windows must be opened to allow for adequate ventilation of the cabin.

It is strongly recommended that only university vehicles be used in the transport of patient specimens. Consult with your Department Chair for guidance on the availability of a university vehicle and request approval from your Chair before using a personal vehicle for transporting specimens. If a personal vehicle will be used, it must be exclusively used to transport patient specimens during the transport operation (no stops in between). If an employee is approved by their Chair or supervisor to use their own vehicle, they are encouraged to speak with their auto insurance carrier for liability and coverage questions.

All spills or exposures during transport must be reported immediately to the supervisor and EH&S using the Laboratory Incident Report Form. A spill kit must be present in the vehicle. The person transporting patient specimens must have knowledge of the emergency procedures in case of an accident or spill.
DISINFECTION/INACTIVATION

Work surfaces and equipment should be routinely decontaminated. Appropriate disinfectants with proven activity against enveloped viruses should be used for disinfection. These include sodium hypochlorite, alcohol, hydrogen peroxide, quaternary ammonium compounds, and phenolic compounds. Refer to the EPA’s List N for registered disinfectants for use against SARS-CoV-2.

SARS-CoV-2 is suspected of being inactivated by heat (70°C for 5 min or 60°C for 30 min) and UV radiation (30 min)

Commonly used disinfectants in laboratories that can be used against SARS-CoV-2:
- 10% bleach, 20% bleach (0.5% and 1% sodium hypochlorite, respectively; contact times vary with concentration and organic matter present)
- 70% ethanol (10 min contact time)
- Cavicide, Caviwipes, Caviwipes Bleach, Cavicide Bleach (3 min contact time)
- Lysol® Disinfecting Wipes, Lysol® Disinfectant Spray (10 min contact time)
- Lysol® Brand All Purpose Cleaner (2 min contact time)
- HaloSpray (10 min contact time)

TRAINING

Laboratory personnel that will be conducting COVID-19 research using patient specimens or other biohazardous materials must be up to date on BSL-2 and Bloodborne Pathogen training. Due to the University closure and suspension of face to face meetings, training will be delivered online.

BSL-2 Training for Labs: Training will be conducted through Microsoft Teams. Personnel should still register by sending an email to smiths69@mailbox.sc.edu. Future dates will be added to the training schedule on the Training webpage. Those who register for the training and attend the virtual meeting will receive a certificate by email.

Bloodborne Pathogens Training for Labs: A training PowerPoint will be posted on the Biosafety Training webpage. Lab personnel should review the slides and complete a quiz with a score of 80% or higher to receive a certificate. Certificates will be emailed to you upon successful completion of the quiz.

SARS-CoV-2 AGENT SAFETY INFORMATION

CHARACTERISTICS
SARS-CoV-2 is a novel coronavirus that is responsible for the COVID-19 pandemic. It is a positive sense single stranded RNA β Coronavirus that is genetically similar to SARS-CoV.

HOST RANGE
Reservoir likely bats. There may be an intermediate animal host that is currently unknown.

TRANSMISSION
Human to human; animal (unknown species) to human

INCUBATION PERIOD
SYMPTOMS OF EXPOSURE
Symptoms range from mild symptoms (cough, fatigue, fever) to severe disease (difficulty breathing, persistent pain or pressure in the chest, and confusion or inability to arouse). The main symptoms are fever, cough, and shortness of breath. Symptoms usually appear 2-14 days after exposure.

LAB-ACQUIRED INFECTIONS (LAI's)
None currently but there have been 4 reported LAIs for SARS-CoV. Since this is a novel virus, laboratory work involving SARS-CoV-2 started relatively recently and data on reported LAIs is limited.

PRIMARY HAZARDS
Respiratory transmission (inhalation): droplets (primarily) and aerosols
Fomite transmission: contaminated surfaces and inanimate objects

SURVIVAL OUTSIDE HOST
Detectable in aerosols for 3hrs, on copper for 4hrs, cardboard for 24hrs, and 2-3 days on plastic and stainless steel

INFECTIOUS DOSE
Unknown

PERSONAL PROTECTIVE EQUIPMENT
Lab coats, gloves, face/eye protection (when risk of splashes, sprays, droplets), surgical mask (blood) or N-95 (respiratory secretions; requires enrollment in Respiratory Protection Program)

LAB CONTAINMENT
BL5-2 containment to be used for:
Molecular analysis of already extracted nucleic acid preparations, pathologic examination and processing of formalin-fixed or otherwise inactivated tissues, analysis of inactivated specimens such as specimens in nucleic acid extraction buffer, certain patient specimens (stool, whole blood, serum, and urine), and flow cytometry for fixed samples

BL5-2+ (BL5-2 containment with BL5-3 practices) to be used for:
Analysis of respiratory samples and secretions from COVID-19 positive or suspected patients, work with any COVID-19 samples or patient specimens performed outside a biosafety cabinet that may produce an aerosol, and flow cytometry for non-fixed samples

- BSL-3 practices include: all procedures with potential to generate aerosols or droplets done in BSC, enhanced PPE (disposable lab coats, double gloves, face shield, respiratory protection- determined by risk assessment), use of sealed centrifuge rotors or sample cups when centrifuging specimens

Biosafety Cabinet (BSC): any procedure that has the potential to generate droplets or aerosols (e.g. centrifuging, vortexing, opening containers, pipetting) must be performed in a certified Class II BSC. Centrifuging of specimens should be in safety cups or sealed rotors that are loaded and unloaded in a BSC.
MEDICAL PRECAUTIONS/TREATMENT
Prophylaxis: None currently available
Vaccines: None currently available
Diagnosis: Real-Time RT-PCR for upper and lower respiratory specimens, serology (antibody) test
Treatment: None currently available; supportive care for hospitalized COVID-19 patients

SPILL PROCEDURES
Follow UofSC’s Spill Clean-up Procedures

OCCUPATIONAL HEALTH
Lab personnel health status may impact an individual’s susceptibility to infection, ability to receive immunizations or prophylactic interventions as they may become available. Therefore, lab personnel are encouraged to consult with UofSC’s Student Health Services for information regarding immune competence and conditions that may predispose them to infection, or for counseling and guidance. Lab personnel can also contact UofSC’s Workers’ Compensation for guidance on the management of work-related accidents or exposures and for guidance on how to properly seek prompt treatment for incidents.

EXPOSURE PROCEDURES
An exposure incident means a specific eye, mouth, other mucous membrane, non-intact skin, parenteral contact (e.g. needle stick) or inhalation of aerosols involving a potentially infectious material that results from the performance of an employee's duties. A potentially infectious material or biological hazard may include an incident involving a microorganism (e.g. bacterial agent, viral agent, fungal agent), human-derived material, biological toxin, or an incident involving recombinant DNA research.

Procedures for exposures to a potentially infectious material:
1. Stop work and immediately wash or flush the exposed area with soap and water for 10 minutes. If exposure is to the eyes, flush eyes (holding open) using the eyewash station for 10 minutes.
2. Follow steps outlined in the USC Workers’ Compensation Guidance for Work Related Accidents or Injuries.
3. Complete and submit the USC Laboratory Incident Report Form [docx] to the Biological Safety Officer (BSO) at smiths69@mailbox.sc.edu and the Institutional Biosafety Committee (IBC) at ibc@mailbox.sc.edu (within 3 days of the incident).

Note: The exposed employee and/or their supervisor should provide the healthcare professional evaluating the exposure incident with a description of the job duties relevant to the exposure incident, route(s) of exposure, circumstances of exposure, biological agent or hazard involved in the incident (e.g. HIV+ blood, Vibrio parahaemolyticus, lentiviral vector), and relevant medical records.

WASTE MANAGEMENT
Currently, there is no evidence to suggest that COVID-19 laboratory waste needs any additional packaging or disinfection procedures. Biohazardous waste collected as normal for BSL-2 laboratories.

SPECIAL CONSIDERATIONS
Lab personnel who need to take extra precautions should consult with UofSC Student Health Services:
- Older adults (65 years and older)
People of any age with underlying health conditions (e.g. asthma, chronic lung disease, serious heart conditions, immunocompromised, diabetes, obesity, liver disease, chronic kidney disease)

RESOURCES

- Labconco Biosafety Recommendations for SARS-CoV-2 and COVID-19 [https://www.labconco.com/articles/laboratory-biosafety-recommendations-for-sars-co]
- CDC Information for Laboratories [https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html]

Packaging and Transport Information

- Labels for UN3373
  - Dry ice [https://www.cdc.gov/coronavirus/mers/downloads/lab/UN3373-label-dry-ice.pdf]