VA NORTHEAST OHIO HEALTHCARE SYSTEM
Louis Stokes Cleveland DVAMC
Medical Research Service
Subcommittee on Research Safety Policy

Effective Date: FEBRUARY 14, 2023

Policy Title: INFECTION CONTROL PROCEDURES FOR WORK INVOLVING SARS-CoV-2

Policy Number: SRS--027

Policy Version: .06

Author:

Name: John M. Schaffer, B.A.
Title: Research Safety Coordinator
Department: Medical Research Service

JOHN M SCHAFFER 417267 Digitally signed by JOHN M SCHAFFER 417267 Date: 2023.02.23 13:28:46 -05'00'

John M. Schaffer, B.A.

Reviewed By:

Chair, Subcommittee on Research Safety

Curtis J Donskey 402815 Digitally signed by Curtis J Donskey 402815 Date: 2023.02.27 12:37:19 -05'00'

Curtis J. Donskey, M.D.

Approved By:

Associate Chief of Staff/Research

Neal Peachey 411157 Digitally signed by Neal Peachey 411157 Date: 2023.02.27 15:01:16 -05'00'

Neal S. Peachey, Ph.D.

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1. **PURPOSE:**

This policy promotes the prevention of exposure to SARS-CoV-2.

a. By defining permitted work with SARS-CoV-2 in research.

b. By mandating actions that protect personnel/eliminate exposure to SARS-CoV-2.

c. By developing a safe environment in which to conduct research involving the use of SARS-CoV-2.

2. **DEFINITIONS:**

a. SARS-CoV-2; the coronavirus that causes Coronavirus disease 2019 (COVID-19).

b. Research Protocol Safety Survey (RPSS) – A detailed survey of all hazards associated with a Principal Investigator's research plan.

c. In Appendix B-III-D of the NIH Guidelines (April 2019), coronaviruses other than SARS-associated coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV) are classified as Risk Group 3 (RG3) agents. This classification reflected the state of knowledge prior to the emergence of the novel coronavirus SARS-CoV-2. RG3 agents are those that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. At the present time, SARS-CoV-2 best meets the definition of a RG3 agent and Institutional Biosafety Committees (IBCs) should consider the agent to be RG3 as a starting point in their risk assessments when reviewing research subject to the NIH Guidelines. The RG classification may change over time as additional information about the virus, such as potential treatments or the development of an effective vaccine, becomes available.

3. **RESPONSIBILITY:**

a. Research personnel working with SARS-CoV-2 are required to be familiar with and comply with this policy and all policies set-forth by the Microbiology Lab, Pathology and Laboratory Medicine Service (PALMS), and all Medical Center Infection Control Policies, including:
   - Isolation and Infection Control Precautions, MCP 011-056
   - Bloodborne Pathogen Exposure Control Plan, MCP 011-039
   - Personnel Health Infection Control Policy

- Pathology and Laboratory Medicine Service Infection Control Policy No. 113-2

b. The Principal Investigator is responsible for ensuring that their lab has safety protocols (RPSS) in place and approved and that their laboratory personnel and trainees are fully credentialed and trained prior to starting work. The PI is ultimately responsible for the safety and oversight of work with SARS-CoV-2 virus. The PI must provide the SRS a detailed step-by-step protocol for procedures for work with SARS-CoV-2 up to and including the steps in which the sample is inactivated of live virus; please see Appendix D for an example. In cases where inactivation is not possible as it alters downstream experimentation, please see Section 5k. Furthermore, the procedure for inactivation of the virus, must be verified, please see Appendix D for an example. Verification that the virus has been inactivated may be performed via PCR or Plaque Assay, which measure viral infectivity and multiplication in cultured cells. This verification must be performed with the start of each new protocol, and if a new piece of equipment, kit, etc. is introduced, this verification process ***must*** be repeated. In cases where verification is not possible, please see Section 5k.

   The PI must also provide experimental evidence to the SRS that their inactivation and verification protocols are effective on either SARS-CoV-1, SARS-CoV-2, or MERS-CoV; a peer-reviewed publication, recommendation from Centers for Disease Control (CDC), Association on Biosafety and Biosecurity (ABSA) International or similar may be acceptable, pending SRS approval. If a surrogate is used to verify the inactivation procedures, primary literature or experimental evidence must also be provided for the chosen surrogate. All submitted materials will be scrutinized by the SRS and may be rejected if contradictory experimental evidence is found.

   Note: At this time, it cannot be confirmed that inactivation procedures for SARS-CoV-2 are 100% effective at VANEOHS, as these experiments must be conducted under BSL-3.

   Post-inactivation: Research personnel are recommended to use an abundance of caution when working with inactivated samples. It is recommended that a PAPR is worn when working with inactivated samples due to the limitation listed above and that a Biological Safety Cabinet is used when feasible.

c. Subcommittee on Research Safety (SRS) is responsible for updating this policy as needed by reviewing guidelines from the CDC and ABSA International, as they are released. Based on these guidelines, the SRS is responsible for assessing the risks associated with research on SARS-CoV-2 and determining the procedures (Section 5) to be used by VA research personnel within the VA Northeast Ohio Healthcare System. Risk assessments were made based on the following criteria: the procedures being performed and associated hazards, competency level of personnel, laboratory facility, and available resources. The SRS will also investigate and approve, if deemed acceptable, any virus inactivation protocols provided by PIs.

4. **POLICY:**

To ensure compliance as described in Section 5, PROCEDURES, below. Please note, this policy is a living document and will be updated as new data and recommendations come forth. SARS-CoV-2 is an incompletely characterized virus and as such this document aims to provide risk management guidelines that extend beyond current recommendations of the CDC based on knowledge that has been made available over this short period of time. The guidelines, here in, are in-line with the CDC's Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with

Coronavirus Disease 2019 (SARS-COV-2) available at https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html and the recommendations ABSA available at https://absa.org/wp-content/uploads/2020/03/ABSA2020_SARS-CoV-2-dr3.pdf

5. **PROCEDURES:**

a. Approved research personnel: To limit the potential for exposure and be able to track any accidental exposures to SARS-CoV-2, a limited number of research personnel at the VA NORTHEAST OHIO HEALTHCARE SYSTEM Louis Stokes Cleveland DVAMC will be permitted to work with specimens that are suspected or confirmed for SARS-CoV-2. The Research Safety Coordinator, Administrative Officer for Research, Associate Chief of Staff for Research, and Chairperson of the Subcommittee on Research Safety will coordinate with all Principal Investigators (with an approved Research Protocol Safety Survey) to conduct research on SARS-CoV-2 with approved personnel only.

NOTE: Only three trained individuals* (at one time, one person per research team) will be permitted to work with specimens with suspected or confirmed for SARS-CoV-2 and/or inactivated samples in the enhanced BSL-2+ laboratory space (B-D360) in Medical Research. Only two trained individuals* (at one time) will be permitted to work with specimens with suspected or confirmed for SARS-CoV-2 and/or inactivated samples at Case Western Reserve University (CWRU); see Appendix A for guidance.

*By limiting the number of study staff working in one given area, this will reduce the risk of exposure to personnel that need not be present.

Training in enhanced BSL-2+ procedures must be conducted prior to initiation of work in the enhanced BSL-2+ Lab, which is conducted by an SRS-approved VA employee who is knowledgeable about handling/working with infectious agents (including SARS-CoV-2) and the Research Safety Coordinator. Training must be documented and repeated annually.

This stipulation is based on preliminary data found in the Rapid Expert Consultation Update on SARS-CoV-2 Surface Stability and Incubation for the SARS-COV-2 Pandemic (March 27, 2020) report from the National Academy of Sciences, Engineering and Medicine, available at http:// http://nap.edu/25763, "Aerosol and surface distribution of severe acute respiratory syndrome coronavirus 2 in hospital wards, Wuhan, China, 2020." Emerg Infect Dis. 2020 Jul. https://doi.org/10.3201/eid2607.200885, "Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1." N Engl J Med. 2020 Apr 16;382(16):1564-1567. doi: 10.1056/NEJMc2004973, "Stability and Viability of SARS-CoV-2", NEJM, April 13, 2020 Correspondence https://www.nejm.org/doi/full/10.1056/NEJMc2007942?query=recirc_curatedRelated_article, "Stability of SARS-CoV-2 in different environmental conditions." The Lancet Microbe. 2020 Apr https://doi.org/10.1016/S2666-5247(20)30003-3 .

NOTE: Staff must be compliant with VHA Directive 1193, CORONAVIRUS DISEASE 2019 VACCINATION PROGRAM FOR VETERANS HEALTH ADMINISTRATION HEALTH CARE PERSONNEL, dated August 13, 2021, which can be found at:

https://dvagov.sharepoint.com/sites/VHACLEPH/2021-2022-Vaccine/GENERAL%20INFORMTION/VHA%20Directive%201193.pdf

b. Restricted space for research activities: To limit the transport of specimens with suspected or confirmed for SARS-CoV-2, research will be restricted to two designated locations at the VA NORTHEAST OHIO HEALTHCARE SYSTEM Louis Stokes Cleveland DVAMC. Research on specimens with suspected or confirmed for SARS-CoV-2 is restricted to PALMS and to the enhanced BSL-2+ laboratory space (B-D360) in Medical Research. Research on these specimens may also be conducted at the University affiliate, CWRU in their enhanced BSL-2+ laboratory. This stipulation is based on preliminary data found in the Rapid Expert Consultation Update on SARS-CoV-2 Surface Stability and Incubation for the SARS-COV-2 Pandemic (March 27, 2020) report from the National Academy of Sciences, Engineering and Medicine, available at http://nap.edu/25763, "Aerosol and surface distribution of severe acute respiratory syndrome coronavirus 2 in hospital wards, Wuhan, China, 2020." Emerg Infect Dis. 2020 Jul. https://doi.org/10.3201/eid2607.200885, "Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1." N Engl J Med. 2020 Apr 16;382(16):1564-1567. doi: 10.1056/NEJMc2004973, "Stability and Viability of SARS-CoV-2" NEJM April 13, 2020 Correspondence https://www.nejm.org/doi/full/10.1056/NEJMc2007942?query=recirc_curatedRelated_article, "Stability of SARS-CoV-2 in different environmental conditions." The Lancet Microbe. 2020 Apr https://doi.org/10.1016/S2666-5247(20)30003-3

Specimens with suspected or confirmed for SARS-CoV-2 with a high viral load (e.g., respiratory swabs, please see "Detection of SARS-CoV-2 in Different Types of Clinical Specimens." JAMA. 2020 Mar 11. doi: 10.1001/jama.2020.3786 and "Viral load of SARS-CoV-2 in clinical samples." The Lancet Infectious Diseases Volume 20, Issue 4, April 2020, Pages 411-412) must be inactivated using an SRS approved protocol prior to any additional downstream assays. Inactivation of respiratory swabs ONLY may be performed in PALMS, in the enhanced BSL-2+ lab within Medical Research Space (B-D360) or in the enhanced BSL-2+ lab at CWRU, the University affiliate. If high viral load samples (e.g., respiratory swabs, sputum, saliva, bronchoalveolar lavage fluid, and tissues) are collected and sealed in an impenetrable, decontaminated primary container on the wards and within a sealed biohazard bag, then they are permitted to be shipped out without inactivation. These samples may be shipped out of PALMs, the enhanced BSL-2+ lab within Medical Research Space (B-D360), or the enhanced BSL-2+ lab at CWRU, the University affiliate.

Specimens with suspected or confirmed for SARS-CoV-2 with an unknown or undetermined viral load (e.g., environmental swabs) must be inactivated using an SRS approved protocol prior to any further experimental procedures. Inactivation of environmental swabs ONLY may be performed in PALMS, in the enhanced BSL-2+ lab within Medical Research Space (B-D360) or in the enhanced BSL-2+ lab at CWRU, the University affiliate. If samples with unknown or undetermined viral load (e.g., environmental swabs) are collected and sealed in an impenetrable, decontaminated primary container on the wards and within a sealed biohazard bag, then they are permitted to be shipped out without inactivation. These samples may be shipped out of PALMs, the enhanced BSL-2+ lab within Medical Research Space (B-D360), or the enhanced BSL-2+ lab at CWRU, the University affiliate.

Specimens with suspected or confirmed for SARS-CoV-2 with a low viral load or low likelihood to cause infection (e.g., blood, feces, urine, rectal swabs, and cerebral spinal fluid) please see "Detection of SARS-CoV-2 in Different Types of Clinical Specimens." JAMA. 2020 Mar 11. doi: 10.1001/jama.2020.3786 and "Viral load of SARS-CoV-2 in clinical samples." The Lancet Infectious Diseases Volume 20, Issue 4, April 2020, Pages 411-412) may be directly taken in an impenetrable, decontaminated primary container and within a sealed biohazard bag to PALMs, the enhanced BSL-2+ lab within Medical Research Space (B-D360) or to the enhanced BSL-2+ lab at CWRU, the University affiliate for inactivation and

downstream assays. These samples may be shipped out of PALMs, the enhanced BSL-2+ lab within Medical Research Space (B-D360), or the enhanced BSL-2+ lab at CWRU, the University affiliate.

c. Shipping and receiving: If samples are to be shipped, samples with suspected or confirmed for SARS-CoV-2 are classified as Category B and the cultured virus is classified as Category A (as per Saf-T-Pak).

All SARS-CoV-2 samples must be shipped in a sealed container within an insulated shipping "shipper" container; triple containment for Category A and double containment for Category B.

Packaging would apply according to sample for transport on a public road, in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations. There are specific shipping containers for overnight delivery (on gel ice packs), which hold ten 10ml tubes, and for dry ice shipments, which hold eight 10ml tubes.

Personnel must be current in their Department of Transportation (DOT) training to pack and ship according to the regulations and in a manner that corresponds to their function-specific responsibilities. DOT Training must include both Category A and B Shipping, which will be confirmed by the Research Safety Coordinator.

Materials received by any laboratory containing SARS-CoV-2 or patient samples known or suspected of infection with SARS-CoV-2 must be sprayed with 70% ethanol or a 10% bleach solution and must opened inside of a BSC. Both the outer container and inner sample tubes must be fully decontaminated prior to starting your work.

The following specimens with suspected or confirmed for SARS-CoV-2 with a high or unknown/undetermined viral load that are collected and sealed in an impenetrable, decontaminated primary container on the wards and within a sealed biohazard bag are permitted to be shipped without *any* further manipulation: non-inactivated respiratory or environmental swabs, sputum, saliva, bronchoalveolar lavage fluid, and tissues. These samples may be shipped out of PALMS, the enhanced BSL-2+ lab within Medical Research Space (B-D360) or the enhanced BSL-2+ lab at CWRU, the University affiliate.

Other specimens with suspected or confirmed for SARS-CoV-2 with a low viral load or low likelihood to cause infection (e.g., blood, feces, urine, rectal swabs, and cerebral spinal fluid) may be shipped out of PALMs, the enhanced BSL-2+ within Medical Research Space (B-D360) or the enhanced BSL-2+ lab at CWRU, the University affiliate.

d. Scheduling and access: If investigators will be using PALMS to inactivate samples or for shipping, their SRS approved research studies must also be approved by the Chief of PALMS prior to initiation of work and a letter of support must be attached to the approved RPSS. The Research Safety Coordinator will serve as the conduit between PALMS and the principal investigators and their research team. Clinical samples specific to PALMS will always be the priority. All researchers must follow the rules and regulations set forth by PALMS. Research work in PALMS will be limited to 5pm-12am Monday through Friday and 7am-5pm on Saturday and Sunday. Christopher Paine, Lab/Medical Technologist, is the second shift supervisor who will be the point of contact for those times during this SARS-COV-2 crisis. When this crisis has ended, a PALMS staff member will be on-call. Access into PALMS by Research personnel will be coordinated by the Research Safety Coordinator.

All principal investigators with SRS approved research studies on specimens with suspected or confirmed SARS-CoV-2 must coordinate with the Research Safety Coordinator to obtain access and schedule time within the enhanced BSL-2+ lab within Medical Research Space (B-D360).

Any unauthorized access into the enhanced BSL-2+ lab within Medical Research Space (B-D360) or PALMS will automatically be a breech in security, which must be reported to the Office of Research Oversite. Improper use of the space (e.g. propping open doors) will also be considered a breach in security and may result in the termination or suspension of the study.

e. Exposures: Any researcher found to have an accidental exposure to SARS-CoV-2, and/or not adhere to the guidelines set forth in this policy, as well as those of PALMS, will be immediately/permanently removed from all protocols using specimens with suspected or confirmed for SARS-CoV-2 and no longer permitted to work on any study involving SARS-CoV-2. Personnel must also follow Medical Center Policy when exposed to SARS-COV-2 .

The primary routes of exposure are contact, droplet, and airborne.

Many routine laboratory procedures can potentially generate aerosols and droplets that are often undetectable. The following laboratory procedures have been associated with the generation of infectious aerosols and droplets: centrifugation, pipetting, vortexing, mixing, shaking, sonicating, ELISA plate washing, removing caps, decanting liquids, preparing smears, flaming slides, aliquoting and loading specimens, loading syringes, manipulating needles, syringes or sharps, aspirating and transferring blood and body fluids, sub-culturing blood culture bottles, spilling specimens, and cleaning up spills.

1) Contact transmission in the laboratory occurs via indirect contact. Indirect contact transmission occurs when infectious agents are transferred to a susceptible individual when the individual makes physical contact with contaminated items and surfaces (e.g. equipment, benchtops, door handles, etc.).

2) Droplet transmission can occur during routine laboratory manipulations, e.g. the preparation of cultures. Transmission occurs when droplets are generated and come into direct contact with the mucosal surfaces of the eyes, nose, or mouth of a susceptible individual.

3) Airborne transmission occurs through very small particles or droplet nuclei that contain infectious agents and can remain suspended in air for extended periods of time. When they are inhaled by a susceptible individual, they enter the respiratory tract and can cause infection.

Personnel must wash epidermis (hands, forearms, open wound, etc.) when suspected of an exposure:

Follow these five CDC steps every time.

1) Wet the affected area with clean, running water (warm or cold), turn off the tap, and apply soap.
2) Lather the affected surface with the soap. If hands are suspected of being contaminated, lather the backs of hands, between fingers, and under nails.

3) Scrub affected area for at least 20 seconds.
4) Rinse affected area well under clean, running water.
5) Dry affected area using a clean towel.

Exposures that occur to the eyes, nose, or mouth must be deluged immediately using an emergency eyewash for a minimum of fifteen minutes.

Following washing of epidermis/deluging of eyes, nose, or mouth, personnel must report to Personnel Health immediately for treatment; after-hours, personnel must report to the Emergency Department.

Exposures must be reported to PALMS Staff, Personnel Health, the Principal Investigator of the study, and Research Administration (the Research Safety Coordinator, Administrative Officer for Research, Associate Chief of Staff for Research, and Chairperson of the Subcommittee on Research Safety).

Note: In the event of any suspected exposure, an employee must be quarantined at home for a period of 14 days.

f. Communication: Until more information becomes available, precautions should be taken in handling specimens that are suspected or confirmed for SARS-CoV-2. Timely communication between clinical and laboratory staff is essential to minimize the risk incurred in handling specimens from persons with possible SARS-CoV-2 infection or surrounding environmental samples. Such specimens should be labeled accordingly, and all personnel should be alerted to ensure proper specimen handling.

g. Permitted experiments:
i) The following experiments/procedures using specimens with suspected or confirmed SARS-CoV-2 must be conducted using **enhanced BSL-2+** precautions in PALMS, the enhanced BSL-2+ lab within Medical Research Space (B-D360) or the enhanced BSL-2+ lab at CWRU, the University affiliate (see Section 5h):
    1) Processing, aliquoting or preparing specimens for research use and storage
    2) Inoculating bacterial or mycological culture media
    3) Performing diagnostic tests that do not involve propagation of viral agents in vitro or in vivo
    4) Nucleic acid extraction procedures involving potentially infected specimens
    5) Preparation and chemical- or heat-fixing of smears for microscopic analysis
    6) Any experiment that may generate an aerosol (centrifugation, pipetting, vortexing, mixing, shaking, sonicating, ELISA plate washing, removing caps, decanting liquids, preparing smears, flaming slides, aliquoting and loading specimens, loading syringes, manipulating needles, syringes or sharps, aspirating and transferring blood and body fluids, sub-culturing blood culture bottles, spilling specimens, and cleaning up spills
    7) Inactivation of respiratory or environmental swabs
    8) Processing of blood for shipment
    9) Shipment of non-inactivated respiratory swabs, sputum, saliva, bronchoalveolar lavage fluid, tissues, feces, urine, rectal swabs, and cerebral spinal fluid. Specimens must sealed in an impenetrable, decontaminated primary container on the wards and within a sealed biohazard bag and cannot be further manipulated.

ii) The following experiments/procedures using specimens with suspected or confirmed SARS-CoV-2 are permitted to be conducted using **BSL-2** precautions (PPE: surgical mask, single gloves, gown/lab coat, eye protection). It is recommended that a PAPR is worn when working with inactivated samples due to the limitation listed above in Section 3c and that a Biological Safety Cabinet is used when feasible. All aerosol-generating procedures must be conducted in a Biosafety Cabinet.

1) Using automated instruments and analyzers
2) Staining and microscopic analysis of fixed smears
3) Examination of bacterial cultures
4) Pathologic examination and processing of formalin-fixed or otherwise inactivated tissues
5) Molecular analysis of extracted nucleic acid preparations
6) Final packaging of specimens for transport that were collected, packaged, and ***sealed in the shipping container*** on the wards to laboratories for additional testing (specimens should already be in a sealed, decontaminated primary container)
7) Using certain inactivated specimens that were approved by SRS:
   a. Flow cytometry of fixed samples
   b. ELISA plate reading of inactivated samples
8) Performing electron microscopic studies with glutaraldehyde-fixed grids

Note: Any deviation from an approved RPSS involving SARS-CoV-2 will result in an automatic suspension of all activities.

h. Enhanced BSL-2+ Precautions: Enhanced biosafety level-2+ (BSL-2+) precautions include the following biosafety level-3 (BSL-3) enhancements, please see Appendix A for detailed procedures:
   1) All procedures will be performed in a certified Class II A2 Biological Safety Cabinet (BSC). BSC must be decontaminated with an EPA approved disinfectant for coronavirus, see Section 5n for decontamination.
   2) Standard (Universal) Precautions must be used, ALL personnel present during the procedures outlined in Section 5h will wear the following PPE until samples have been inactivated, see Section 5j. Research Service will supply PPE.
      a. A closed impervious front gown OR disposable lab coat with disposable impervious sleeve covers
      b. Double pair of gloves
      c. PAPR.
   3) Centrifugation of specimens must be performed using sealed centrifuge rotors (or sample cups) or housed in a BSC.
   4) The use of sharps should be eliminated wherever possible.
   5) Surface decontamination at every step with an EPA approved disinfectant for coronavirus will be performed, see Section 5n for decontamination.
   6) Use Good (Standard) Microbiological Practices.

i. Administrative controls: The following administrative controls must be in place:
   1) Scheduled time for handling SARS-CoV-2 samples (best practice).
   2) Minimization of withdrawing hands from BSC is required: it is recommended to have two employees present to prevent exposure, e.g. handing supplies to an employee working within a BSC.
   3) Training and competency verification on donning and doffing required PPE. For work at CWRU, training must be documented by the Department of Occupational and Environmental Safety at CWRU. For work at the VA, training must be

documented by a VA employee who is proficient in enhanced BSL-2+ practices, and whose own training in these procedures has been documented and approved by the SRS. On the VA network, go to "W: Public drive" and navigate to "Medical Center Information folder", then to "Town Hall" folder, and then to "PPE videos" to see videos on donning and doffing PPE properly.

4) Mandatory reporting of laboratory exposures to PALMS Staff, Personnel Health, the Principal Investigator of the study, and Research Administration (the Research Safety Coordinator, Administrative Officer for Research, Associate Chief of Staff for Research, and Chairperson of the Subcommittee on Research Safety), see Section 5e.
5) Demonstrated competency on working in a BSC.
6) Laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures.
7) Note: Experiments that will be generating genetically modified SARS-CoV-2 are NOT included in this policy and must be reviewed and approved by the local Institution Biosafety Committee (IBC) prior to initiation.

j. Inactivated samples: The use of inactivated specimens must be completely free of live virus. It must be documented who will be inactivating samples. If it will be PALMS, a letter of support will be needed. Specific protocols for inactivation must be reviewed/approved by the SRS. Please see "Evaluation of heating and chemical protocols for inactivating SARS-CoV-2." https://www.biorxiv.org/content/10.1101/2020.04.11.036855v1.full.pdf and "Stability of SARS-CoV-2 in different environmental conditions." The Lancet Microbe. 2020 Apr https://doi.org/10.1016/S2666-5247(20)30003-3

Once samples are inactivated using an approved inactivation protocol and inactivation process has been verified (if possible, see Section 5k), the samples may be processed further maintaining the use of BSL-2+ precautions, as stated above, within the enhanced BSL-2+ lab within Medical Research Space (B-D360) or a BSL-2+ lab at CWRU, the University affiliate. Experiments/procedures under Section 5gii are permitted at BSL-2. The SRS must approve the work to be conducted prior to initiation of work.

k. Problems with inactivation and/or verification: If low titer samples (blood, urine, or feces) are not able to be inactivated due to interference with downstream assays, then enhanced BSL-2 precautions must be maintained throughout the duration of the experiments, see Section 5h. Verification of inactivation may not able to be completed due to the low viral load present in the sample, which can result from the following possible scenarios: 1. The data obtained from a plaque assay or PCR not falling within the limits of detection to measure any difference in viral load before or after inactivation. 2. Residual viral RNA present may interfere with verification methods as inactivation only removes live virus and not RNA. If it is not possible to verify an inactivation protocol, then primary literature that shows that the inactivation is effective on either SARS-CoV-1, MERS-CoV, or SARS-CoV-2 must be provided. At this time, it cannot be confirmed that inactivation procedures for SARS-CoV-2 are 100% effective at VANEOHS, as these experiments must be conducted under BSL-3. Research personnel are recommended to use an abundance of caution when working with inactivated samples. It is recommended that a PAPR is worn when working with inactivated samples due to the limitation listed above and that a Biological Safety Cabinet is used when feasible. All aerosol generating procedures must be conducted in a Biosafety Cabinet.

When/if the minimum infectious dose of SARS-CoV-2 in humans is published in a peer-reviewed journal, further consideration for inactivation/verification of specimens with suspected or confirmed for SARS-CoV-2 with a high or unknown or undetermined viral load will be considered by the SRS. This consideration includes the verification of an inactivation protocol (using identical sample types, protocols, and equipment as on the PI's RPSS) for samples with SARS-CoV-2 by a registered BSL-3 Facility. The BSL-3 Facility must demonstrate that the number of viral particles is below the minimum infectious dose in humans via experimental evidence (plaque forming units (PFUs), viral genome copies/PFU, and viral particle:PFU ratio). If approved by the SRS, future samples can be inactivated in PALMs or an enhanced BSL-2+ lab and processed further in a BSL-2 laboratory. Prior to this taking place, the BSL-3 Facility must provide documentation of their most recent certification, a letter of verification that the inactivated samples possess a number of viral particles that is below the minimum infectious dose in humans, including their experimental evidence. Work with these samples may only begin once these documents have been reviewed and approved by the SRS.

l. Equipment: All equipment to be used must be located within PALMS or the enhanced BSL2 laboratory within Research space. Equipment cannot be moved-in and out of this space. Equipment will have restricted use to the approved SARS-CoV-2 protocol. When a new piece of equipment is introduced to the research protocol, the SRS must be notified. Also, when new equipment is introduced to the inactivation of SARS-CoV-2, the verification procedure in Section 3, Responsibility, part b, must be repeated. When work with SARS-CoV-2 is completed by an investigator and their team, the investigator may remove their equipment, *however*, it must be decontaminated with a 10% bleach solution that has been made that same day *or* any EPA-listed disinfectant for SARS-CoV-2.

Note: See Section 5c, Packaging and shipping of specimens with suspected or confirmed SARS-CoV-2 sealed in an impenetrable, decontaminated primary container on the wards and within a sealed biohazard bag is permitted. However, these samples must be packaged and shipped out of PALMs, the enhanced BSL-2+ lab within Medical Research Space (B-D360), or the BSL-2+ lab at the University affiliate, unless they are packaged and sealed in the final shipping container on the wards.

m. Sharps Safety: Refer to Medical Center Policy Bloodborne Pathogen Exposure Control Plan, which notes, "In the event of a needle stick or other sharps injury, mucous membrane splash, or cutaneous exposure, [employees must] report immediately to Personnel Health".

n. Disinfection: Decontamination of work areas involving infectious agents is mandatory. The following procedures must be followed:

Research personnel working with SARS-CoV-2 must decontaminate work surfaces, including high-touch surfaces, i.e., door handles, etc. and equipment with appropriate disinfectants Use EPA-registered hospital disinfectants with label claims to be effective against SARS-CoV-2 and follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling., as described in the Research Protocol Safety Survey (VA Form 10-0398), which is associated with the Principal Investigator's research plan, when work with infectious agents takes place. Please see, https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2

70% ethanol and 10% bleach may be used, as per PALMS guidance for work. Bleach solutions degrade rapidly over time, therefore a 500ml bottle of 10% bleach should always be prepared *fresh each* day prior to starting experiments and kept within easy reach so that in the event of a spill, there is enough to cover the area.

o. Waste disposal:

Solid waste should be placed into primary biohazard bag within the BSC and the bag should be sealed and decontaminated with EPA-registered hospital disinfectants with a label that claims to be effective against SARS-CoV-2 and follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling. The primary biohazard bags will then be removed from the BSC and placed within a secondary biohazard bag outside the BSC. The secondary biohazard bag will then be sealed and decontaminated fully prior to removal from the enhanced BSL-2 space placed into an appropriate biohazard container for pick up by Environmental Management Service (EMS). PPE using during research on SARS-CoV-2 must be disposed of as solid waste.

Liquid waste must be autoclaved must be disinfected/deactivated with a final volume of 10% bleach or approved EPA-registered hospital disinfectants with a label that claims to be effective against SARS-CoV-2 and follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling. Liquid waste should also be labelled with name and date if it requires extended periods of decontamination. Once contact time has been met (20 minutes) decontaminated liquid waste can be disposed down the drain followed by at least 2 volumes of water.

Sharps waste should be placed into puncture-resistance containers provided by EarthSmart within the BSC. The container should be decontaminated with an EPA-registered hospital disinfectant with a label that claims to be effective against SARS-CoV-2 and follow manufacturer's recommendations for use, such as dilution, contact time, and safe handling placed into an appropriate location for pick up by EarthSmart.

p. Enhanced BSL-2+ laboratory in Medical Research must:
1) Have negative room pressure to the corridor.
2) Have two sinks. One for lab work; one for personnel to wash-up prior to leaving lab.
3) Have a Proximity Card Reader, which monitors/limits personnel who enter this lab.
4) Have all required PPE available.
5) Have red hard sided sharps boxes and red biohazard receptacles in place.
6) Have a specific "clean" area designated in the lab.
7) Have a designated workflow so as not to contaminate "clean" areas of the lab.
8) Have a nearby spill kit.

q. Documentation of Decontamination in PALMS: Workstations, equipment, floors, etc. must be disinfected. There is a log in PALMS documenting decontamination procedures; each employee initials/dates that they have decontaminated their workspace.

r. Spill Procedure: For spills that occur within a Research Laboratory, See Appendix B. For a spill in PALMS, refer to the PALMS Infection Control Plan, See Appendix C. When attending to a spill, personnel must wear the same PPE as described on page 11, Personal Protective Equipment.

Note: PPE required to attend to a SARS-CoV-2 related spill will be provided by Research Service, whether the spill in in PALMS or a SARS-CoV-2 designated Research Laboratory.

s. Post-approval Monitoring

Post-approval monitoring of personnel working in the BSL-2+ enhanced laboratory will be conducted and documented by the RSC.

Monitoring will be performed to ensure that work areas are visibly clean, i.e. all disposable PPE is placed into a red biohazard receptacle, sharps (pipette tips, needles, etc.) are disposed of into a red hard sided sharps box, and all "soft" waste (paper towels, absorbent pads, etc.) is placed into a red biohazard receptacle.

Anyone found out of compliance with this policy who is working directly with SARS-Cov-2 will permanently lose the privilege of working with SARS-CoV-2 on this and any other study where the individual is working directly with this material.

6. **REFERENCES:**

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c. Rapid Expert Consultation Update on SARS-CoV-2 Surface Stability and Incubation for the SARS-COV-2 Pandemic (March 27, 2020) report from the National Academy of Sciences, Engineering and Medicine
d. The Association on Biosafety and Biosecurity International: SARS-CoV-2/SARS-COV-2 TOOLBOX
e. Duke University: SARS-CoV-2 (SARS-COV-2) Research Laboratory Biosafety Guidelines
f. Boris Pastorino, Franck Touret, Magali Gilles, Xavier de Lamballerie, Remi N. Charrel. "Evaluation of heating and chemical protocols for inactivating SARS-CoV-2." https://www.biorxiv.org/content/10.1101/2020.04.11.036855v1.full.pdf
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l. Yang Pan, Daitao Zhang, Peng Yang, Leo L M Poon, and Quanyi Wang. "Viral load of SARS-CoV-2 in clinical samples." The Lancet Infectious Diseases Volume 20, Issue 4, April 2020, Pages 411-412

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7. **RESCISSION:**

The rescission date of this policy is February 13, 2024.

8. **FOLLOW-UP**: Research Safety Coordinator/Chemical Hygiene Officer.

9. APPENDICES:

- Appendix A: Case Western Reserve University Enhanced BSL2 Practices and Guidelines for Work with SARS-CoV2 Clinical Specimens Prepared by the Biosafety Working Group of the Cleveland SARS-CoV-2 Task Force April 10, 2020 Version 4
- Appendix B: SARS-CoV-2 Spill Procedures in Medical Research
- Appendix C: Pathology and Laboratory Medicine Service Infection Control Policy No. 113-2
- Appendix D: Examples of inactivation and verification protocols required are attached as well as primary literature supporting both.

APPENDIX A – Case Western Reserve University

Enhanced BSL2 Practices and Guidelines for Work with SARS-CoV2 Clinical Specimens
Prepared by the Biosafety Working Group of the Cleveland SARS-CoV-2 Task Force
Feb. 15, 2022 ver 5

Please note this is a living document and will be updated as new data and recommendations come forth. SARS-CoV2 is an incompletely characterized virus and as such this document aims to provide risk management guidelines that extend beyond current recommendations of the CDC based on knowledge that has been made available over this short period of time.

*Please note the following:

1. This document only covers guidelines for work with standard clinical patient specimens being processed for routine diagnostic testing or similar assays (please see Appendix A). This document does not cover work involving virus isolation, virus propagation, nor recombinant molecular virology work. Please see the Appendix, and contact Safety OfficerI you have any questions regarding the classification of specific workflows. We have adapted this document from Duke University's guidelines for Biosafety Level classification to provide additional guidance on how work should be performed and including work that may be performed in a BSL2 space using standard practices.
2. This guidance does not replace the need for each laboratory to have an ECP that includes all workflows with SARS-CoV2 that is fully approved by EHS prior to work with any potentially infected samples. The space must be approved for enhanced BSL2 work by EHS, to ensure that specific facility requirements such as negative airflow, locked door to restrict access to workspace, and a sink for handwashing/eyewashing and spill cleanup are all available within the space. Every laboratory's space, equipment and sample and assay workflow is unique and must be assessed and approved independently. Each laboratory's ECP must clearly state the specific types of samples that will be processed with specific assays, and when new sample types or assays are added these must be approved and integrated into a revised ECP and approved by EHS prior to beginning work on these sample types and/or performance of these assays.
3. All individuals working with infectious or potentially infectious samples must be trained by the PI or their laboratory designate who is highly experienced in enhanced BSL2 work. In the absence of suitable trainers, please contact Andrew Young at aby3@case.edu to request assistance in training.
4. All work with SARS-CoV2 falls under the standard CWRU biosafety regulations and compliance. This document provides additional guidance in practices to facilitate rapid ECP preparation and submission, but does not replace or usurp CWRU's biosafety regulations in any way.
5. The PI of each lab is responsible for ensuring that their lab has safety protocols in place and approved, that their laboratory personnel and trainees are fully trained prior to starting work, and that their laboratory space is approved for Covid-19 work. The PI is ultimately responsible for the safety and oversight of work with SARS-CoV2 virus.

In addition to complying with standard BSL2 practices as outlined in the BMBL (5th Ed.) and according to CWRU's IBC and EHS policies, the following additional practices and procedures must be conducted when working with materials that are known to be or potentially infected with SARS-Cov2 at Enhanced BSL2. These guidelines are not meant to address every aspect of every project. This is general guidance that has been compiled from the recommendations provided by the CDC, the American Biological Safety Association, as well as other research institutional guidelines and protocols. Each research group will need to review their aims and experimental procedures and perform an independent risk assessment that analyzes the specific risks and the safety precautions required to mitigate those risks.

Disinfection/Deactivation:

Researchers must ensure that all solid and liquid Enhanced BSL2 waste is dealt with appropriately upon the completion of each experiment.

- Solid waste should be placed into sealed biohazard bags in an autoclavable container and autoclaved the same day, following autoclave procedures. Primary biohazard bags located within the BSC are sealed and decontaminated, followed by removal and placement within a secondary biohazard bag outside the BSC. The secondary biohazard bag will then be sealed and decontaminated fully prior to removal from the enhanced BSL2 space for autoclaving.
- Liquid waste must be disinfected/deactivated with a final volume of 10% bleach or approved liquid decontaminated for SARS-CoV2 (see approved EPA list at https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2). Liquid waste should also be labelled with name and date if it requires extended periods of decontamination. Once contact time has been met (5 minutes) decontaminated liquid waste can be disposed down the drain followed by at least 2 volumes of water.
- Bleach solutions degrade rapidly over time, therefore A 500ml bottle of 10% bleach should always be prepared *fresh each* day prior to starting experiments, and kept within easy reach so that in the event of a spill, there is a sufficient quantity to cover the area. A spill kit with absorbent materials must also be placed in a convenient and obvious location. Additional clothing (i.e. scrubs) should be stored near the spill kit so that in the event of clothing contamination, the worker is able to remove contaminated clothing and place contaminated clothing into a biohazard bag and sealed for decontamination. Both the PI and Biosafety Officer, Andrew Young, must be notified immediately of any spills, potential or suspected exposures.

Personal Protective Equipment:

- Back closing disposable gowns, front-zipped Tyvek suits, or similar PPE that provides liquid impermeable protection of the front and arms, should be worn, if available, while working with Enhanced BSL2 materials and must be disposed of with Enhanced BSL2 waste. They may be reused if not contaminated, with a name written clearly and hung carefully within the room. Disposable gowns and soiled lab coats must never be worn outside of the lab. Soiled lab clothes (scrubs or street clothes) should be decontaminated (i.e. soaked in disinfectant or autoclaved) prior to laundering.

- Eye protection must be worn to protect the eyes at all times. If performing any manipulations where there is the possibility that splashes or sprays of infectious or other hazardous materials may be generated and contamination to the face (eye, nose, or mouth) can be anticipated, full face protection (faceshield) must be used. Obviously, this type of manipulation should be avoided if at all possible.
- Two pairs of gloves must be worn while working with Enhanced BSL2 materials. The outside glove must be removed before leaving the biosafety cabinet and carefully disposed of in the biohazard bag inside the cabinet. The inner glove may then be removed outside of the cabinet and disposed of as biohazardous waste in the biohazard container outside of the BSC, but within the lab. Gloves must be immediately disposed of when contaminated, replaced frequently, and removed when work with potentially infectious materials is completed or when leaving the area. Gloves must not be reused, nor sprayed with alcohol to "wash" (this degrades glove material and results in pinholes). Gloves must be removed before handling common non-lab equipment such as phones, desks, and door knobs. Gloves that fit over the sleeves of the lab gown are recommended. Hands must be washed immediately at the lab sink with soap and water after removing PPE.
- Disposable sleeve covers are recommended to help protect the disposable lab coat from contamination and excessive wear. These should be removed within the BSC along with the second, outer pair of gloves.
- Respiratory protection is not currently required for enhanced BSL2 work with blood samples, however use of N95 masks will be necessary for work with certain other specimen types as outlined in each laboratory's approved ECP. Each lab's ECP must clearly state the specific types of samples that will be processed with specific assay details, and will specifically outline the use of respiratory protection accordingly.
- N95 masks will be required for enhanced BSL2 work with standard small volume (<2ml) clinical lab respiratory specimens such as nasopharyngeal swabs, sputum, and saliva as well as other sample types which potentially have high titers of virus. All people working in that laboratory space during the time that these specimens are processed must also wear N95 masks, as the masks are used to protect personnel in the event of a spill outside the biosafety cabinet which would potentially expose all personnel within that working space. A note to all other users must be posted on the door to the space and on equipment and lab space schedules so that all users are aware that work with samples requiring respiratory protection and know to don N95 masks upon entry. Verbal notification by the person processing samples requiring N95 masks must also be made to all others entering the room.
- When doffing PPE the outer pair of gloves should be removed with the sleeve cover (if wearing) within the biosafety cabinet. Remove the disposable lab coat and hang up if not contaminated. Remove goggles. Remove inner gloves and wash hands.

Manipulations of Enhanced BSL2 agents

- All manipulations of Enhanced BSL2 materials must be performed in a properly maintained and certified biological safety cabinet (BSC) Class II A2. No Enhanced BSL2 work will be conducted on the open bench top. This includes opening containers of potentially infectious materials, pipetting, vortexing, transfer operations, plating, grinding, blending, drying, sonicating, etc. with the exception noted below.
- Vortexing must be performed within the BSC. The vortexer should be placed within the BSC while in use and decontaminated after use if removed. Sonicating may be performed outside the BSC but only when the infectious sample is completely sealed in a screw top tube that has been decontaminated prior to removal from the BSC, and inspected carefully to ensure there are no cracks or defects in the plastic. No sharps are to be used when conducting Enhanced BSL2 work if this is experimentally avoidable, and if unavoidable as always one should never recap, bend or break sharps. Note that glass is not always considered a sharp (if it is not broken), but the use of glass of any kind should be avoided by using plastic substitutes (disposable hemacytometers, etc.). If use of a glass hemacytometer is the only option, one must be sure to fully and carefully decontaminate the slide and cover after and between uses.
- Enhanced BSL2 materials can be thawed in the water bath if they are kept in a sealed and water tight containers or tubes.
- When Enhanced BSL2 material is pipetted using disposable pipettes in the biosafety cabinet, care should be taken to avoid aerosolization, i.e. do not rapidly or forcefully expel fluids into tubes. All pipettes (and pipet tips) should also be filtered, unless being used for aspiration directly into a disinfectant (bleach or iodine-based solution). When filtered pipets are not avalailble non filtered may be used with pipets dedicated to SARS-CoV-2 work are utilized.
- Avoid generating aerosols when pipetting. Decontaminate all pipettes by pipetting fresh 1:10 bleach waste solution up and down in the bleach container within the BSC prior to placing into the biohazard container within the BSC. After soaking, the pipettes should be carefully drained in the sink with excess water before disposal as autoclave waste. Pipettes and tips used while working with SARS-CoV2 clinical specimens using enhanced BSL2 practices will be first decontaminated in the BSC with 10% bleach for 5 minutes, then drained and placed in a sealed biohazard bag within a suitable hard plastic autoclave container and autoclaved. After autoclaving the pipettes and tips will be placed within a cardboard box which is sealed and labelled as “biohazardous sharp waste”. All decontaminated biohazard waste should still be handled and removed as biohazardous wastes. The personnel that are dealing with waste have requested that the waste be decontaminated multiple times and labelled as such out of an abundance of caution.
- Pipette tips should be soaked in the bleach solution in the biosafety cabinet for at least 5 minutes prior to placing in a suitable hard plastic sealable sharps container for autoclaving.

Biosafety Cabinet (BSC) Use

- A beaker or container containing **fresh** 1:10 dilution of bleach or other validated decontamination solution should be used inside the biosafety cabinet to collect/disinfect pipettes and pipet tips prior to removal from the BSC. We must allow for a minimum of 5 minutes contact time with bleach before removal from the BSC, or appropriate time if using another approved disinfectant.
- Prior to starting work within the BSC, set up a small, biohazard bag-lined waste container within the cabinet securely to collect solid biohazard waste (eppendorf tubes, gloves, etc.) inside the BSC.
- An impermeable hard plastic biohazard sharps container should be available to collect sharps inside the BSC once they have been decontaminated with bleach. A spray bottle containing approved disinfectant should be kept at each BSC for full decontamination of work surfaces before and after each work session. Any use of bleach as a routine surface disinfectant (or just for spills) should be eventually followed by wiping with 70% ethanol (after sufficient bleach contact time) to remove any bleach residue that would cause corrosion of the metal surfaces.
- All biohazardous materials should be transferred out from the biosafety cabinet for storage in a sealed leakproof container that has been tightly closed and decontaminated by spraying the outside with 70% ethanol, a 1:10 dilution of bleach, or other appropriate disinfectant (approved by the safety working group). The fridge or freezer the equipment is stored in must be clearly labelled with a biosafety sticker.

Centrifugation

- All samples must be processed in capped tubes and aerosol-containing canisters must be used (safety cups) or sealed top centrifuge buckets. The outside surfaces of the tubes must be wiped down with 70% ethanol before placing into safety canisters or buckets to prevent contamination of the inner surfaces of the bucket. The outer surfaces of the centrifuge bucket must be decontaminated prior to removal from the BSC. After centrifugation, open the safety canisters or buckets inside the BSC. The centrifuge must be clearly marked with a biohazard sticker.
- If there has been any possibility of leakage from the buckets into the centrifuge chamber during centrifugation, this must be reported immediately to the Principal Investigator and Andrew Young and considered a biohazardous spill with a potential for droplet contamination. The inner walls of the centrifuge and the rotor must be decontaminated.

Vacuum Lines and Traps

- The protocol for use of and need for vacuum lines and traps must be discussed with and approved by Biosafety Officer. If approved, vacuum lines must be protected with secondary traps and in-line hydrophobic filters. Traps must contain either fresh 1:10 bleach (for final concentration or approved decontamination solution. Liquid trap waste should be decontaminated for a minimum of 5 minutes before drain disposal with excess water. Disinfection of the vacuum line with 10% bleach, if the vacuum line was used, before leaving the BSC is often overlooked if not incorporated as part of the

training. The exposed end of the vacuum line should also be disinfected by this process before storage. Filters must be replaced every 6 months or when they become clogged (which must be avoided by regular inspection prior to beginning work).

Laboratory Doors:

- The laboratory door must be kept closed at all times during experimentation with a notice stating "Experiment in Progress" "Authorized Personnel Only". Doors should be locked when laboratory is unattended. Doors must have an EHS sign identifying the hazards in the lab, including the universal biohazard symbol, and all emergency contact information.

Labeling:

- Equipment used for Enhanced BSL2 work must be labeled with the universal biohazard symbol and marked "Enhanced BSL2" or "BSL2+". Labeling should include the identity of the material.

Housekeeping:

- Custodial staff should not have access to the laboratory space. Maintenance staff will not be given access to the immediate areas in which the experiment is being conducted while experiments are being carried out. Otherwise, service and maintenance staff should conduct themselves according to institutional policy.
- Every researcher should wipe down 'high touch' areas, such as door knobs, faucet handles, BSC sashes, etc. before leaving the laboratory.

Transport of ENHANCED BSL2 material:

- The transport of Enhanced BSL2 material between laboratory spaces will be for storage purposes only and will be done only in sealed, biohazard labeled containers such as a Tupperware box with a locking lid, clearly identified with biohazard stickers, and only in approved, locked locations by Biosafety Officer, in equipment clearly labelled with biohazard stickers. All containers used for transport must be clearly labeled with name, date and identity of the material. Double biohazard bagged if large frozen samples racks of boxed samples. Enhanced BSL2 materials may not be transported to another lab or research area that is not registered and approved for Enhanced BSL2 work. Any exceptions require EHS and/or IBC approval. All materials transported by vehicle, between campuses, or between buildings must be packaged in accordance with IATA/DOT packaging instructions.

Shipping and receiving of ENHANCED BSL2 materials:

- All personnel shipping SARS-CoV2 infected samples or related hazardous biological materials must be trained in DOT hazardous materials transport (contact Andrew Young at aby3@case.edu for more information).

- Materials received by the laboratory containing SARS-CoV-2 or patient samples known or suspected of infection with SARS-CoV-2 must be sprayed with 70% ethanol or a 10% bleach solution and must opened inside of a BSC. Both the outer container and inner sample tubes must be fully decontaminated prior to starting your work.

Appendix:

BSL-3/ABSL33
Storage and laboratory work with seed stocks, working stocks or specimens with the intent to grow or use live virus.
Virus isolation, characterization and/or expansion
Viral cultures or isolates should be transported as Category A, UN2814, "infectious substance, affecting humans"
Use of live SARS-CoV-2 virus in functional assays:
Plaque/Focus Forming Unit assays
Serologic virus capture/binding assays
Therapeutic MIC assays
Live cell sorting with intact virus
Processing, aliquoting or preparing specimens of high titer virus in volumes larger than 2ml
Research laboratory processing, manipulating or preparing unfixed autopsy specimens from Covid+ donors
Use of live SARS-CoV-2 virus in animal models
BSL-2 with enhancements
Processing, aliquoting or preparing specimens for research use and storage
Preparation of chemical- or heat-fixed specimens for microscopic analysis
Nucleic acid extraction of specimens for molecular analysis
Preparation of inactivated specimens for other laboratory assessments
Performing diagnostic tests (e.g. serology) that do not involve activities with the potential to propagate virus
Inoculating bacterial or mycological culture media
BSL-2
Molecular analysis of already extracted nucleic acid preparations
Analysis of specimens that have been inactivated by a method approved by EHS
Final packaging of specimens already in a sealed, decontaminated container for transport to collaborating laboratories for additional analyses
Specimens from suspected or confirmed cases should be transported as UN3373, "Biological Substance, Category B
Pathologic/microscopic examination of fixed specimens (e.g. formalin-fixed tissues or glutaraldehyde-fixed grids).
Routine staining and microscopic analysis of fixed smears
Routine examination of bacterial and mycotic cultures
***Specimens are defined as, but not limited to, blood, serum, plasma, tissues, feces, urine, sputum, mucosal swabs or washes/secretions collected from any species.**

Virus Isolation

Virus isolation in cell culture and initial characterization of viral agents recovered in cultures of SARS-CoV-2 specimens should only be conducted in a Biosafety Level 3 (BSL-3) laboratory using BSL-3 practices which are covered in a separate set of guidelines. Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs.

Guidance Derived from the Following Resources:

- https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html
- https://absa.org/covid19toolbox/
- https://ehs.yale.edu/sites/default/files/files/biosafety-manual.pdf
- http://www.dartmouth.edu/ehs/biological/biosafety_docs/150_1_ibcenhancedbsl2policy18.pdf
- ibc-policy-bsl2-enhanced-practices_vumc.pdf
- https://www.safety.duke.edu/sites/default/files/SARS-CoV-2%20(COVID-19)%20Biosafety%20Guidelines.pdf

APPENDIX B. SARS-CoV-2 Spill Procedures in Medical Research

(1) Laboratories working with SARS-CoV-2 must have access to a basic Biological Spill Kit. A Biological Spill Kit must be housed within the laboratory where work will be performed, which is easily accessible.

Biological Spill Kit Includes:

1. Disposable coveralls (bunny suit)
2. Scrubs (for use only if clothes are contaminated)
3. De-con boots
4. Gloves
5. Goggles
6. Face Shield
7. EPA-registered hospital disinfectant with label claims to be effective against SARS-CoV-2 (follow manufacturer's recommendations for use).
8. Bleach wipes (environmental surfaces only)
9. Absorbent
10. Disposable spatulas

(2) The following procedures are provided as a guideline to the clean-up of a biohazardous spill:

A. All Spills

1. Take appropriate measures to prevent the spread of the contamination (e.g., drips, tracking on shoes, etc.) to additional surfaces (e.g., floors, outside the lab, etc.).

2. Use a two-step cleaning/disinfection process of first removing contents of the spill or contaminated area with an initial bleach wipe/solution, then clean/disinfect with a new wipe to prevent cross contamination.

B. Spill Inside a Centrifuge

1. Remove all personnel from the room. Wait 30 minutes for any potential biological aerosol to settle before attempting to clean-up the spill.

2. Personal Protective Equipment (PPE):

   For all spills within a centrifuge, wear disposable coveralls, de-con boots, goggles, PAPR, and gloves during clean-up.

3. Remove rotors and buckets to the nearest biological safety cabinet using a secondary container to prevent drips.

4. Thoroughly disinfect inside of centrifuge, rotors, and buckets using disposable towels and 10% bleach, or bleach wipes using the two-step cleaning process. Place all contaminated wipes and paper towels into solid biohazardous waste containers for further processing by Environmental Management Service.

5. Remove contaminated debris, including PPE (disposable coveralls, de-con boots, and gloves) after disinfection, place into solid biohazardous waste containers for further processing by Environmental Management Service, and wash hands. Autoclave any reusable items (i.e., centrifuge tubes) after they are initially cleaned with bleach.

6. Remove and discard PPE at point of use and wash hands.

C. Spill Inside the Laboratory

1. Remove all personnel from the room. Wait 30 minutes for any potential biological aerosol to settle before entering the spill area.

2. Remove any contaminated clothing and footwear and place into a biohazard bag and sequester, then contact the RSC for further assessment on measures to take. Change into scrubs and/or de-con boots.

3. If the spill made any contact with the person's skin, even thru clothing, first wipe the affected area thoroughly with a disposable towel, soap and water to remove any excess contamination, dry, then wipe with Chlorhexidine Gluconate wipes and allow to air dry to ensure germicidal action of disinfectant. Dispose all towels/wipes into solid biohazardous waste containers for further processing by Environmental Management Service.

4. PPE:

   For all spills within the laboratory, wear disposable coveralls, de-con boots, goggles, PAPR, and gloves during clean-up.

5. Clean-up:

   a. For large spills (>100 mL), cover and encircle the spill with absorbent and use a disposable spatula to scoop up waste into a biohazard bag, being careful to minimize aerosolization, and dispose into solid biohazardous waste containers for further processing by Environmental Management Service.
   b. For smaller spills (<100 mL), cover and encircle the spill with paper towels being careful to minimize aerosolization, and dispose into solid biohazardous waste containers for further processing by Environmental Management Service.

6. All items that were contaminated must be removed from the spill area; wiping each item thoroughly with bleach wipes using the two-step cleaning process. Autoclave any

reusable items (i.e., centrifuge tubes, porous materials) after they initially cleaned with bleach. Broken glassware must be picked-up with forceps and disposed into a red hard-sided sharps box.

Note: *Do not pick up any contaminated sharp object with your hands*.

7. Wipe equipment with bleach wipes for designated contact time and rinse with water, if necessary, using two-step cleaning process. Dispose of all wipes into solid biohazardous waste containers for further processing by Environmental Management Service.

8. Wipe off any residual spilled material, and clean/disinfect with the area, including the floor, with a new bleach wipe, using two-step cleaning process. Dispose of all wipes into solid biohazardous waste containers for further processing by Environmental Management Service.

9. Remove and discard PPE at point of use and wash hands.

10. Re-open lab when decontamination is complete.

D. Spill Outside the Laboratory

1. Always transport biohazardous materials in an unbreakable well-sealed primary container placed inside a leak-proof, closed and unbreakable secondary container, labeled with the biohazard symbol (plastic cooler, bio-specimen pack, etc.).

2. Should a spill occur outside the laboratory, secure the area to ensure that the spill remains contained.

3. Contact the RSC at ext. 4263.

4. Do not attempt to clean up the spill without the proper PPE and spill clean-up materials.

E. After a Spill

1. Inform lab personnel, laboratory supervisor, the Principal Investigator, and the RSC about the spill and the decontamination process that took place.

2. Determine the root cause of the spill and propose a method to prevent this from happening in the future. This information must also be shared with lab personnel, laboratory supervisor, the Principal Investigator, and the RSC.

APPENDIX C:

PATHOLOGY AND LABORATORY MEDICINE SERVICE INFECTION CONTROL POLICY NO. 113-2

1) **PURPOSE**: To establish guidelines and practices to prevent transmission of infectious diseases to patients and laboratory employees.

2) **POLICY**: All PALMS Personnel are required to comply with this policy.

3) **RESPONSIBILITY**:
   A) All employees will receive an initial orientation as well as annual updates in infection control and are responsible for compliance with this policy and all Infection Control Medical Center Policies
   B) Supervisor of the area will periodically monitor compliance with this policy. Compliance will be reflected in employee performance appraisals.

4) **GENERAL PROCEDURES**:
   A) All employees are required to be familiar with and comply with Infection Control Medical Center Policies, including the following:
      1) Isolation and Infection Control Precautions, MCP 011-056
      2) Tuberculosis Control Program, MCP 011-031
      3) Bloodborne Pathogen Exposure Control Plan
      4) Personnel Health Infection Control Policy, COPS-002
   B) Bloodborne, Body Fluid or Tissue Pathogens General Procedures: Bloodborne Pathogens are real occupational hazards to all laboratory employees. All available precautions should be taken to avoid direct contact of skin with blood, blood products, secretions, excretions or tissues. The medical center has adopted Standard Precautions, which means that body substances of all patients are considered potentially infectious. Laboratory workers will use protective barriers such as gloves, gowns, masks, and protective eyewear to reduce the risk of exposure of skin or mucous membranes to potentially infectious materials. To minimize the risk of infection, it is important that all employees read and observe the following policies:
      1) Infection may be acquired by several routes:
         (a) Ingestion
         (b) Direct inoculation through damaged skin or mucosal membrane
         (c) Airborne droplets and aerosols
      2) General Precautions:
         (a) Treat all specimens as contaminated
         (b) Disposable laboratory coats or gowns are provided, laundered, and maintained by the hospital laundry. They must be worn when working with potentially infectious material and are NOT to be worn outside assigned work areas. Laboratory coats worn in the Laboratory must not be worn to perform phlebotomies. Laboratory coats are not to be removed from the institution.
         (c) Handwashing:
            (i) Patient care area - Hands will be decontaminated with alcohol-based waterless hand rub (foam), or hospital supplied antimicrobial soap and water before and after each patient contact, after contact with the patient's environment, and before invasive

procedures. Hands must be washed with antimicrobial soap or plain soap followed by alcohol-based hand rub after visible soiling of hands or contact with a patient with Clostridium difficile.

(ii) Laboratory area - Handwashing is essential and must be done frequently and thoroughly after handling specimens, removing gloves, leaving the work area, prior to eating, drinking, smoking, applying cosmetics/lip balm, or handling contact lenses, and with an anti-microbial handwashing agent in Microbiology and Autopsy areas of the laboratory.

(iii) Handwashing sinks are not to be used for disposal of specimens, reagents or any contaminated items and must be identified as a "clean sink". Sinks shall always be kept free of all debris. If slides or paper accidentally drop into sink(s), remove at once with forceps and discard into the proper containers.

(d) In accordance with MCP 011-056, fingernails should be clean, well-manicured, and not interfere with job performance. Short (1/4" or less), unpolished nails are recommended. Artificial nails (includes overlays, acrylic, wraps, nail jewelry, etc.), extenders and chipped nail polish are prohibited among healthcare workers who provide direct, hands-on care to patients, even on an occasional basis, or have contact with biohazardous materials. Long or ragged nails, artificial nails, and chipped nail polish harbor a great number of infectious bacteria.

(e) Do not put pencils, pens or other work utensils in your mouth.

(f) Do not eat, drink, smoke, apply cosmetics/lip balm, or handle contact lenses in laboratory work areas.

(g) Do not store food or beverages in refrigerator containing biologics, laboratory reagents, media, or specimens.

3) Regulated Infectious Waste Disposal:

(a) All blood and body fluids (except urines), cultures, stocks, and tissue specimens are to be double-bagged, placed in biohazard containers, picked up and transported to the Sani-Pak machine at Wade Park.

(b) Needles, knife blades and blood gas syringes are disposed of in sharps containers. As one of our Green initiatives the Medical Center has converted from disposable sharps containers to reusable sharps containers. Sharps containers are exchanged on a weekly basis by a contractor at site of collection. Sharps are removed and properly disposed of after treatment at the contractor's plant. Containers are then sanitized prior to reuse.

(c) Urine is disposed of by carefully pouring into a sink not designed for handwashing, followed by flushing with copious amounts of water. Urine cups are to be rinsed as part of this process prior to disposal in the designated green recycling container which is then shredded by EMS to destroy all identifiable patient information before placing into a recycling container for offsite recycling. Alternatively, they may be discarded as infectious waste in a closed container.

4) Spills Clean Up Procedures:

(a) Wear protective clothing, such as gloves, gowns, and masks (if significant formation of aerosol is suspected).

(b) Cover area with absorbent material.

(c) Flood area with 10% bleach for at least 30 minutes.

(d) Wipe up spill with disposable absorbent (paper towel); wipe from edges to center of spill.

(e) Dispose of all contaminated material in a biohazard container

5) Equipment Repair and Decontamination:
   (a) Decontaminate and thoroughly clean specified equipment parts with 10% bleach or disinfectant recommended by the manufacturer before release to engineer or service representative or before transporting equipment to manufacturer for repair. Follow manufacturer's instructions for disinfection and cleaning.
   (b) If necessary, provide appropriate personal protective barriers to engineer or service representative at his/her request.
6) Environment:
   (a) The disinfectant of choice is a 10% solution of commercial bleach kept in a closed container. This disinfectant must be prepared daily (1:10 solution of bleach water), or a self-mixing dispenser may be used.
   (b) Work benches are cleaned daily with 10% bleach or other hospital approved disinfectant (HAD). When using a HAD, the manufacturer's instruction must be followed, including recommended contact time. Documentation of decontamination is required.
   (c) Telephones in the laboratory area must be wiped down daily with a 10% bleach solution or other HAD.
   (d) Spills of serum or biological samples are flooded immediately with 10% bleach solution and wiped up with disposable absorbent pads or towels
   (e) Biohazard specimens - contaminated specimens are placed in Biohazard bags and transported by EMS to the Sani-Pak machine at Wade Park. Manifests are kept by Environmental Management Service (EMS) staff. If the waste receptacle becomes contaminated through see page, it must be disinfected with detergent, hot water, and 10% bleach.
7) Plan for Reduction of Biohazardous Materials:
   (a) All contaminated materials (soiled) will be discarded in the Biohazard waste container. Do not place non-contaminated materials in biohazard containers.
   (b) All used protective barriers, disposable laboratory devices, and other materials such as paper, towels, gowns, gloves, etc., must be discarded in a regular waste receptacle if they are not grossly soiled with blood, body fluids or tissues.
   (c) In the Biosafety level 2 (BL-2) or higher labs, personal protective equipment that is contaminated with biohazardous material is to be discarded into a designated infectious waste container.
   (d) The number and size of blood tubes drawn per patient will be re-evaluated as technology/instrumentation changes occur.
8) Reportable diseases testing:
   (a) Except as noted below, all reportable infectious diseases are reported to the Infection Control office for reporting to the appropriate public health authorities.
   (b) New positive HIV antibody and confirmatory results are reported to the HIV Coordinator, who will report them to the appropriate public health authority.
   (c) All new Hepatitis C cases will be reported by to Infection Control office for reporting to the appropriate public health authorities.

(d) Reportable infectious diseases are stipulated by Ohio law and as recommended by the Centers for Disease Control and Prevention (CDC).

5) **SPECIFIC PROCEDURES RELATED TO PaLMS**:

A) Specimen Collection and Transport General Procedures:

1) All phlebotomists must wear properly fitting gloves while performing venipunctures. Gloves must be changed between each patient contact and hands decontaminated either with antimicrobial soap and water or an alcohol-based hand rub between changes. Random spot checks may be performed to assure that this policy is being followed. The outcome of these spot checks will be reflected on the employee's annual performance appraisal. Failure to adhere to this policy will result in disciplinary action.

2) Long sleeved scrub jackets may be worn for phlebotomy to prevent soiling of personal clothing and to prevent direct skin contact with blood specimen or other body fluids, as well as from potentially contaminated surfaces, materials, or objects.

3) Take extreme care to avoid accidental "needle stick" injuries. Do not place needles back in their original sheaths, since this is a common cause of injury. Needles are to be disposed of in a needle disposal container without bending, breaking, recapping, or other manual manipulation of needles. Sharps safety devices should be used whenever they are available. All contaminated needles are to be disposed of in a needle disposal container after activating safety device. Notify Environmental Management when containers are ¾ full.

4) Clean blood spills and/or blood on the outside of Vacutainer tubes promptly with isopropyl alcohol. Replace barcode label if necessary.

5) Place the specimen in a biohazard labeled leak-proof plastic bag or container for transport to the laboratory. Specimen bags are not to be reused and must be disposed of in a bio-hazardous waste container.

6) Conform to any posted isolation precautions (as applicable, including the wearing of particulate respirators and gowns). All personnel required to enter rooms of patients on AIRBORNE PRECAUTIONS must use a powered air purifying respirator (PAPR), after having been cleared by Personnel Health to wear a PAPR and then trained by the Facility Safety Office.

7) Decontaminate hands after removing gloves (and gowns, if worn) and before leaving patient room.

B) Specimen Handling General Procedures:

1) When handling specimens in the laboratory, wear disposable gloves and long-sleeved laboratory coat to prevent soiling of personal clothing and to prevent direct skin contact with blood specimen or other body fluids, as well as from potentially contaminated surfaces, materials, or objects. Safety goggles and/or face shields shall be worn when there is a possible of a splash or the generation of aerosols.

2) Perform all procedures and manipulations of potentially infectious material carefully to minimize the creation of droplets and aerosols.

(a) All biological specimens are covered, capped, or plugged, except while being collected or in the process of separation or analysis.

(b) Uncap all (screw cap) tubes away from the body.

(c) Remove stoppers behind a shield or by placing a gauze pad over the stopper.

(d) Cap all specimens during centrifugation.

(e) Mixing, shaking or vortexing should be done only when necessary and with extreme caution. Tubes must be capped or stoppered. Use a biologic safety cabinet (BSC) or primary containment device for these procedures.

(f) Dispense contaminated sera as closely to the bottom of any vessel as possible to minimize "splatter."

3) Mouth pipetting is strictly prohibited. Mechanical pipetting devices are to be used for the manipulation of all liquids in the laboratory.

4) Cover work areas (except within BSC) with absorbent material when working with any specimens. Decontaminate work surfaces with 10% bleach or hospital approved disinfectant following any spill and at the completion of each work shift. Decontamination of the work surface must be documented daily.

5) Follow manufacturer's instructions for cleaning instrument probes and other parts that may be contaminated with blood or biohazardous material.

6) All tissue specimens for histologic examination will be fixed in 10% formalin (4% formaldehyde) prior to dissection except as noted below. Large specimens are fixed overnight or longer, small specimens are fixed for at least ½ hour prior to dissection. Brain biopsy material will be fixed in formalin followed by formic acid if a prion disease is suspected.

C) Blood Bank General Procedures:

1) Screening of donors for infectious diseases:

(a) All blood and blood components from the American Red Cross have been tested by FDA - licensed tests and found to be nonreactive for antibodies to human immunodeficiency virus (anti-HIV-1/2), hepatitis C virus (anti-HCV), human T-cell lymphotropic virus (anti-HTLV-I/II), and hepatitis B core antigen (anti-HBc), and negative for hepatitis B surface antigen (HBsAg). Licensed nucleic acid testing (NAT) for hepatitis B virus (HBV) deoxyribonucleic acid (DNA), HCV ribonucleic acid (RNA), HIV-1 RNA, West Nile virus RNA and Zika virus RNA has been performed and found to be nonreactive. A serologic test for syphilis is also performed and found to be nonreactive.

2) Blood preservation and quality control:

(a) Refer to Blood Bank Procedure Manual for blood preservation and quality control procedures.

(b) Recipient follow-up of possible transfusion transmitted diseases:

(i) Transfusion histories will be reviewed for all patients. The Blood Bank Medical Director will notify the American Red Cross, Northern Ohio Region of all involved units if transmission by transfusion is confirmed or probable. The same information will be reported to the hospital Infection Control office.

(ii) Work up on bacterial contamination of blood and blood products:

(1) Blood culturing will be done when inspection of blood reveals suspicious-appearing blood or contaminants, or when patients suffer adverse transfusion reactions suspected to have resulted from contaminated donor blood(s).

(2) The Microbiology unit will perform the test by standard blood culture techniques.

(3) The supervisor of the Blood Bank and the Infection Control office will be notified of all positive Blood Bank cultures.

D) Microbiology

1) General Procedures:

(a) Broken culture tubes or plates must be covered with paper towels and flooded with 10% bleach. To prevent dried particles from becoming airborne, area must be kept wet with the disinfectant and the material allowed to stand for 30 minutes before handling.
(b) Screw caps of culture tubes must be loosened or removed before autoclaving to allow for steam penetration.
(c) Safety pipetting devices or automated equipment, not mouth pipetting, must be used in the Microbiology Laboratory.
(d) Grossly contaminated specimen containers must not be accepted. To dispose of them, the container must be placed in a biohazard bag and autoclaved.
(e) Media for all specimens and slides for direct examination must be inoculated within the BSC.

2) Special Procedures for Mycology and Mycobacteriology
(a) In the event of gross contamination (i.e., breakage of tuberculosis culture tube), no one is permitted to enter until the entire area has been decontaminated by personnel within the area. Spills must be flooded with 10% bleach and allowed to stand for one-half to one hour before wiping. Wipe from periphery, moving toward center of the spill.
(b) PAPRs will be available for use in the event of BSC failure or spill outside of a BSC. Annual fit testing for PRs is required and done by OHS.
(c) The Mycobacteriology laboratory is at negative air pressure. The room will be checked by the technologist on the days it is in use and recorded on form SAF 2.0 (See Attachment A). Engineering is to be notified if the room is not operational.
(d) Biohazardous specimens from the Mycology/Mycobacteriology lab are autoclaved prior to transport to the Sani-Pak machine.

3) Procedures for specimens, pipettes, slides, media, etc. disposal:
(a) After processing, all specimen containers will be placed in biohazardous waste receptacles lined with plastic autoclave bag.
(b) If necessary to decant supernatant fluid after centrifugation, pour the supernatant fluid into receptacle containing disinfectant and autoclave prior to disposal.
(c) Agar plates, tubed media and plastic-based disposables are placed in biohazard bags and handled as biohazardous waste.
(d) Glass-tubed media, all broken glass, and disposable glass pipettes are placed in sharps containers.
(e) Used slides will be placed into jars of phenolic disinfectant which are kept on the workbench. When the jar is full, the disinfectant should be drained off and the slides discarded into a sharps container.

E) Histology and Cytology General Procedures:
1) Gloves should be worn for handling all specimens, including fresh and fixed tissues.
2) All specimens will be placed in appropriate fixative prior to handling.
3) Discard formalin into appropriate container, neutralize, and pour neutralized formalin down drain, followed by copious amounts of water.
4) Tissues (brain) from patients with prion disease will be sent to the prion lab at University Hospitals.

5) The Grossing Room laboratory is at negative air pressure. The room will be checked by the technologist on the days it is in use and recorded on form SAF 2.0 (See Attachment A). Engineering is to be notified if the room is not operational.

F) Autopsy Pathology General Procedures:

1) Only authorized individuals may attend the autopsy examinations. Professional and paramedical personnel are encouraged to observe the autopsy examinations; however, others may attend only when the pathologist approves their attendance.

2) Autopsy Room Rules:
   (a) No drinking, smoking, application of cosmetics, lip balm, handling of contact lenses, or eating is permitted in the Autopsy Room.
   (b) Do not touch the gross specimens, fixed or unfixed, with bare hands. Gloves must be worn for palpating organs.
   (c) Hands must be washed thoroughly with an antimicrobial handwash before leaving the autopsy area.

3) Dissecting Instruments:
   (a) Autopsy Assistants will provide instruments which are necessary for one autopsy case only. Too many instruments on the working table can create unexpected accidents, such as cutting and puncturing fingers.

4) Cleaning Autopsy Area:
   (a) All prosectors are cautioned to avoid spilling blood, fluid, or dropping tissue on the floor during dissection. If this occurs, the floor must be cleaned and disinfected immediately by flooding the area with 10% bleach prior to clean up.
   (b) Autopsy Assistants must disinfect all dissecting tables thoroughly with 10% bleach each time after completing an autopsy examination.
   (c) Instruments will be soaked in 10% bleach before cleaning between uses
   (d) Prosectors are requested to dissect fresh organs only on the dissecting table.
   (e) Camera must be handled with clean hands
   (f) To discard formalinized organs and tissue, drain formalin into appropriate container, neutralize, and pour down sink drain with copious amounts of water. Place organs or tissues in biohazard trash for pickup and incineration.
   (g) Autopsy Assistants will clean the floor in the autopsy suite after each case.

5) Handling Contaminated Infectious Cases:
   (a) All cases are considered potentially infectious. For all cases the following PPE must be worn: double gloves, protective eye covering, mask, cap and gown, waterproof apron, and shoe covering. If the patient had active tuberculosis, a PAPR should be used.
   (b) Specially designed electric saws will be used for dissecting bones.
   (c) Cultures, if necessary, may be obtained during the dissection. The prosectors decide how far to dissect organs based on the he prosectors' best judgement or after consultation with staff pathologists.
   (d) Proper thin tissue blocks are made from each organ at the time of the autopsy and fixed thoroughly in a bottle with an ample amount of fixative. Any retained tissue not submitted in blocks will be stored in an appropriate container with an ample amount of fixative.

6) In case of Accidental Injury in the Autopsy Room:

(a) Wash the affected skin area with antimicrobial soap and water, or flush mucous membrane exposures with ample amounts of water or saline. Apply first aid if necessary.
(b) Immediately proceed to the Personnel Health Clinic or Emergency Department for further treatment.
(c) Notify supervisor and complete an accident report.

G) Ancillary Testing and Satellite Facilities General Procedures:

1) For capillary glucose testing, only house staff, staff physicians, physician assistants, nurse practitioners, nurse clinicians and health technicians who have been trained on the glucose meter by a certified laboratory-approved Abbott trainer may perform the test.
2) Employees who are exposed to blood or potentially contaminated body fluids by needlestick or other sharps injuries, mucous membrane splashes, etc. must follow the Bloodborne Pathogen Exposure Control Plan, Medical Center Policy 011-039. The physician in charge of Personnel Health at the CBOC must complete, with the assistance of the employee, a "Federal Employees Notice of Traumatic Injury Claim for Continuation of Pay/Compensation Form" (Form CA-1) using E-COMP Program.
3) For patients in isolation, the Abbott Freestyle isolation bags are a special transparent isolation sleeve that is used for the Abbott Precision Xceed Pro Glucose Meters. The disposable sleeve is used once and disposed of properly by following OSHA and EPA guidelines. Alternatively, contact isolation plastic transfer pipettes may be used. The same standard precautions recommended by the Centers for Disease Control and Prevention should be followed (MCP 011-056 Isolation Precautions). All specimens should be treated as potentially infectious.
4) The same general laboratory guidelines to prevent the transmission of infectious diseases to patient and laboratory employees (Policy No. 113-2) apply to all Ancillary Testing and CBOC staff.
5) The Abbott Precision Xceed Pro Glucose meters must be cleaned after each use and between each patient with Sterile Processing Service supplied cavi-wipes. Do not use 70% alcohol or bleach products.

6) **REFERENCES**:

Louis Stokes Cleveland VA Medical Center Medical Center Policy 011-056, Isolation and Infection Control Precautions Policy, January 2017

Northeast Ohio VA Healthcare System Medical Center Policy 011-031, Tuberculosis Control Plan, April 2016

Infection Prevention and Control Bloodborne Pathogen Exposure Control Plan, April 2018

Louis Stokes Cleveland VA Medical Center Medical Center Policy COPS-002, Personnel Health Infection Prevention and Control policy, Attachment F, Bloodborne Pathogen Exposure Control Plan, September 2016

Northeast Ohio VA Healthcare System Medical Center Policy 011-084, Human Immunodeficiency Virus Diagnostic Testing, October 2018

Louis Stokes Cleveland VA Medical Center Medical Center Policy 137-011, Refuse and infectious Waste Management Program, March 2017

Ohio Administrative Codes 3701.23 Reporting contagious or infectious diseases, illnesses, health condition, or unusual infectious agents or biological toxins.

Clinical and Laboratory Standards Institute, May 2014. Protection of Laboratory Workers from Occupationally Acquired Infections: Approved Guideline, 4th edition, M29-A4. CLSI, Wayne PA

Clinical and Laboratory Standards Institute, June 2012. Clinical Laboratory Safety; Approved Guideline, 3th edition, GP17-A3, CLSI, Wayne PA

Clinical and Laboratory Standards Institute, January 2011. Clinical Laboratory Waste Management; Approved Guideline, 3rd edition, GP05-A3, CLSI, Wayne, PA

Circular of Information for the Use of Human Blood and Blood components, American Association of Blood Banks, American Red Cross, America's Blood Centers, and the Armed Services Blood Program circular

7) **RESCISSION**: PALMS Infection Control Policy 113-2 dated January 27, 2016. The date of rescission of this policy is March 27, 2022.

SUSAN BRINK MT (AMT), MLT (ASCP)
P&LMS Safety Officer

MOHAMMAD ANSARI, MDF
Chief, Pathology and Laboratory Medicine Service

CURTIS DONSKEY, MD
Chairman, Infection Prevention Committee

APPENDIX D

Inactivation protocol EXAMPLE:

Before going to the PaLMs lab:
1. Prepare 560uL buffer AVL in a lysis tube (one for each sample).
2. Collect the following to bring with you to the PaLMs lab:
a. Qiagen DSP kit
b. P1000 pipette, P200 pipette, and appropriate tips (disinfect with 70% ethanol)
c. Vortex (disinfect with 70% ethanol)
d. Centrifuge (disinfect with 70% ethanol)
e. marker (disinfect with 70% ethanol)
f. RNAse free molecular biology grade H2O
g. 100% molecular biology grade ETOH

At the PaLMs lab:
1. Turn on BSC, put on appropriate PPE (impervious gown, goggles, double gloves, and PAPR.
2. All the below steps to be completed in the BSC
3. Vortex swab in viral transport medium 1 minute
4. Use long pipette tips to pull off 140uL from each specimen and add to corresponding lysis tube containing buffer AVL
a. If sample volume is less than 140uL, add enough PBS to balance
5. **Heat 60°C for 30 minutes**
6. **Virus is now inactivated**
7. Disinfect BSC and equipment with 70% ethanol or 10% sodium hypochlorite as appropriate
8. Alternatively to steps 1-9, 200ul of sample could be inactivated by use of heat at 56°C for 30 minutes in a heat block before moving on to RNA purification

Reference for heat inactivation of coronavirus:
https://www.journalofhospitalinfection.com/article/S0195-6701(20)30124-9/fulltext

Verification protocol EXAMPLE

Validation of inactivation protocol:
In a laboratory setting, inactivation methods were tested against surrogate virus *Pseudomonas* phage Φ6 (HER102) (a double-stranded RNA enveloped virus) to simulate inactivation of SARS-CoV-2 (a single-stranded RNA enveloped virus).

Method:
1. Bacteriophage was suspended in sterile water or lysis buffer AVL and heated at 60°C for 30 minutes* in a heat block.

2. Surviving virus was cultured using a top agar overlay method with host strain *Pseudomonas syringae* var. phaseolicola (HER1102).

3. Virus presence was observed via lysis of host bacteria and the formation of plaques.

4. Test samples were compared against untreated controls.

*60°C for 30 minutes was chosen as per attached review of inactivation methods for coronaviruses using heat (Journal of Hospital Infection by Kampf et al.), this method was most effective to reduce viral load by >4 log10 PFU.

Results:
5.5log10 PFU reduction of *Pseudomonas* phage Φ6 by heating method and heat + AVL.

Limitations:
As, currently, the VA does not possess the capability to test live SARS-CoV-2 inactivation methods, *Pseudomonas* phage Φ6 was chosen as a surrogate. However, based on the attached Environmental Science and Technology publication by Aquino de Carvalho et al., *Pseudomonas* phage Φ6 may not be a good surrogate for all viruses, thus even after the virus is inactivated; samples will continue to be handled with BSL-2+ with the knowledge that they may actually contain live virus.

Reference for heat inactivation of coronavirus:
https://www.journalofhospitalinfection.com/article/S0195-6701(20)30124-9/fulltext

Reference for use of *Pseudomonas* phage Φ6 (HER102) as a surrogate:
https://pubs.acs.org/doi/10.1021/acs.est.7b01296