**Protocol for Research Activity Related to SARS-CoV2**

**Conducted on the Campus of**

**The University of Alabama In Huntsville**

# Effective: 2 April 2021

**Purpose:** The purpose of this protocol is to guide research activity that supports the inclusion of deactivated SARS-CoV2 (virus causing COVID-19). The following guidelines pertain to all SARS-CoV2 related research activities that do not concern the propagation and handling of active SARS-CoV2 conducted on the campus of The University of Alabama in Huntsville.

**Required facility:** Any treatment or storage of biological samples containing deactivated SARS- CoV2 must performed in a Biosafety Level (BSL)-2 level facility.

# Basic requirements of BSL- 2 facility

The lab must be equipped with the following:

* + A minimum of one certified biosafety cabinet.
	+ An operable sink, eyewash and a door(s) that can be closed to restrict access.
	+ An autoclave accessible for treatment of solid or liquid waste: Autoclaved samples must have an autoclave labeling tape to validate the sterilizing conditions.
	+ Work areas with limited access. Doors must be closed while working with research materials (Make sure there is sufficient ventilation).
	+ An operating rule of no food or liquid consumption in the laboratory.
	+ Biohazard warning signs are posted at laboratory entry points, equipment, workbenches or common areas that are exposed to potentially infectious materials.
	+ Approved disinfecting agents to decontaminate work surfaces at least once a day.

In the designated laboratory area where deactivated SARS-CoV2 are being handled, one must comply to the following rules:

* + Never mouth pipette.
	+ Use sharps only when no alternatives (e.g., safety devices or non-sharps) exist.
	+ Take extreme precautions when sharps must be used. Dispose sharps carefully and properly.
	+ Conduct procedures likely to create splashes, sprays, or aerosols within a biological safety cabinet that is certified annually.
	+ Decontaminate work surfaces with approved disinfectants at least daily.
	+ Decontaminate waste materials by autoclave treatment before disposal.
	+ Wear a BUTTONED lab coat to protect street clothes.
	+ Wear gloves when hands may contact potentially infectious materials, contaminated surfaces, or equipment.
	+ Wear eye/face protection if splashes or sprays are anticipated during work outside a biological safety cabinet.
	+ Transport materials outside of the laboratory using secondary containment and a cart. Avoid public areas during transport.
	+ Wash hands after handling biological materials, removing gloves, or before leaving work area.
	+ Transfer materials to and from the UAH campus according to federal and international regulations.
	+ Be familiar with written instructions for laboratory procedures and proper responses to emergencies.
	+ Report spills, exposures, illnesses, and injuries immediately.

# Notification and approval of deactivated SARS-CoV2 usage

UAH office of Health and Environmental Safety (OHES) should be notified and the UAH biosafety committee should approve the study prior to bringing known deactivated SARS- CoV2 into the research lab. Transportation of materials should go directly to the laboratory containing the designated workspace as described above. Kristi Dendy will be the point of contact from OHES who should be notified.

# Risk assessment

* + Risk assessment will be conducted by the investigator describing the type of samples used for analysis, procedures and protocol, equipment and containment need - for example, loading and unloading of sealed centrifuge cups, grinding, blending, vigorous shaking or mixing, sonic disruption, opening of containers of infectious materials.
	+ All equipment used for research analysis will be included in the risk assessment.
	+ Competence level requirements of lab personnel handling biological samples shall be described. These include students, technicians and research assistants (i.e. postdoctoral fellows, visiting interns etc.)
	+ As per NIH guidelines, any recombinant DNA/RNA must be approved by the full IBC committee. This applies to any new BUA and BUA amendments.

# Deactivation protocol

All samples potentially containing SARS-CoV2 must be deactivated in one of the following ways described below before arriving to UAH. Bio-samples to be deactivated of SARS-CoV2 should not exceed 2.0 mL per containment. In other words, sample volumes should be contained in laboratory grade containment tubes not to exceed 1.5ml each (the size of a 2ml Eppendorf tube or smaller). A maximum of 10ml of biosamples (i.e. 5 X 2.0ml tubes) shall be transported at a time.

All biosamples must be deactivated by one of the following methods:

1. Heat inactivation- Bio-samples (in 2ml or less Eppendorf tubes) are boiled in a 100C water bath for at least 15min.
2. Detergent treatment - Bio-samples are mixed to a final concentration of

0.5% sodium dodecyl sulfate [SDS], 0.5% Triton X-100, 0.5% Tween 20, or 0.5% NP-40 to incubate at room temperature for at least 30min.

1. Chaotropic chemical treatment - Bio-samples are mixed with Trizol or other chaotropic reagent in a 1:4 ratio of biosample:Trizol reagent, which is to be mixed and incubated at room temperature for 5 minutes.
2. Deactivated samples must be stored in a dedicated storage area, such as in a freezer or refrigerator with at least 3 levels of containment.
3. The investigator must sign an attestation of deactivation form stating the biosamples being investigated have been treated by one of the deactivation methods indicated above.

# Occupational Health Considerations

Personnel working with the deactivated virus or samples potentially containing the virus should be trained by the principal investigator of the laboratory on standard training for BSL- 2 labs. This will include reviewing symptoms of SARS-CoV infection and counseled to report any fever or respiratory symptoms to their supervisor immediately. Research teams performing work with the deactivated SARS-CoV or handling specimens should implement a specific occupational medical plan to contain at a minimum, the procedures for managing:

* + identifiable breaks in laboratory procedures
	+ exposed workers without symptoms
	+ exposed workers who develop symptoms within ten days of an exposure, and
	+ symptomatic laboratory workers with no recognized exposure.

Further information and guidance regarding the development of a personnel exposure response plan is available from the CDC.95 Laboratory workers who are believed to have had a laboratory exposure to live SARS-CoV should be evaluated, counseled about the risk of SARS-CoV transmission to others, and monitored for fever or lower respiratory symptoms as well as for any of the following: sore throat, rhinorrhea, chills, rigors, myalgia, headache, and diarrhea. UAH health and safety should be promptly notified of laboratory exposures and illness in exposed laboratory workers.

# Clean-up and maintenance

All laboratory area shall be wiped with any of the commonly used disinfectants with a minimum contact time of 5 mins:

* + Bleach: Liquid sodium hypochlorite (5.25%) - 20 ml bleach to 980 ml water
	+ Accelerated Hydrogen Peroxide 2'0.5%

Commonly used agents for cleaning with a minimum contact time of 1 min after disinfecting are:

* + Ethanol 70-90% (not recommended as a disinfectant)
	+ Chlorine-based products (e.g., sodium hypochlorite at min. of 0.5% )

All materials and waste associated with the biosamples must be sterilized by standard autoclaving protocols prior to disposal.

**PLEASE READ THE FOLLOWING TERMS & CONDITIONS OF THIS RELEASE CAREFULLY BEFORE PARTICIPATING IN A RESEARCH ACTIVITY INVOLVING DEACTIVATED SAR-CoV2:**

1. I acknowledge that the terms and conditions of this Release stated herein refers to my participation in a research activity involving deactivated SARS-CoV2, the virus causing COVID-19 (individually a "**Research Activity**") at The University of Alabama in Huntsville ("**UAH**").
2. I will comply with all applicable federal, state, local, and UAH laws, orders, directives, policies, protocols, procedures, and guidelines related to the Research Activity, and specifically the "Protocol for research activity related to SARS-CoV2 conducted on the campus of The University of Alabama in Huntsville." I will also follow all instructions, recommendations, and cautions of UAH officials, supervisors, and employees related to my participation in the Research Activity.
3. I understand and acknowledge that my participation in the Research Activity carries with it certain inherent risks that cannot be eliminated regardless of the care taken to avoid injuries. The specific risks include, but are not limited to: contracting COVID-19; injury; illness; permanent disability; paralysis; and death. I voluntarily and freely assume all the risks that may arise from my participation in the Research Activity.
4. I understand that this Research Activity involves the inclusion of deactivated SARS-CoV2. For each Research Activity under this Release, UAH will receive deactivated SARS-CoV-2 samples from an outside third-party source. Although UAH will receive deactivated SARS-CoV-2 samples, there are risks that these SARS-CoV-2 samples could be active due to an error in the deactivation process completed by the third-party source or any other error caused by the third-party source. I understand that while UAH has implemented measures to reduce the risk of injury from the Research Activity and spread of COVID-19, UAH cannot guarantee that I will not be injured or become infected with Covid-19 due to my participation in the Research Activity and that engaging in the Research Activity may increase my risk of contracting COVID-19. I am aware of the contagious nature of COVID-19 and the risk that I may be exposed to or contract COVID-19 by engaging in the Research Activity, which may result in serious illness or death. NOTWITHSTANDING THESE RISKS, I ACKNOWLEDGE THAT I AM VOLUNTARILY TO PARTICIPATING IN THE RESEARCH ACTIVITY WITH KNOWLEDGE OF THE RISKS INVOLVED. I HEREBY AGREE TO ACCEPT AND ASSUME ALL RISKS OF INJURY, ILLNESS, DISABILITY, AND DEATH ARISING FROM MY ENGAGING IN THE RESEARCH ACTIVITY, WHETHER CAUSED BY THE ORDINARY NEGLIGENCE OF UAH OR OTHERWISE.
5. **I do hereby release absolutely, forever discharge, and covenant not to sue The Board of Trustees of The University of Alabama and its officers, employees, and agents of the said Board and/or The University of Alabama in Huntsville and all their officers,**

 **employees, agents, and members ("University Parties"), from and concerning all liability, losses, claims, demands, actions, debts, and expenses of every name and nature for personal or bodily injury (including any resulting in death) or other damages which I, or a third person, may sustain from whatever cause during, arising out of, or as a result of such Research Activity participation or any of activity reasonably connected with my participation in the Research Activity.** It is my intention to include the negligence of the University Parties within the scope of this Release and to except, by express limitation here stated, only wanton or willful misconduct by the same.

1. I do further agree to indemnify and hold harmless the University Parties for any and all claims related to my participation in the Research Activity.
2. I hereby consent to receive medical treatment deemed necessary if I am injured or requires medical attention during my participation in the Research Activity. I understand that UAH is not responsible for providing coverage for medical expenses if I am injured during my participation in the Research Activity. I understand that I will not be covered under any insurance policies held by UAH in the event that I am injured during the Research Activity. I hereby release, forever discharge, and hold harmless University Parties from any claim based on such treatment or other medical services.
3. This Release constitutes the agreement of UAH and me with respect to the subject matter contained herein and supersedes all prior contemporaneous understandings, agreements, representations, and warranties, both written and oral, with respect to such subject matter. All matters arising out of or relating to this Release shall be governed by and construed in accordance with the laws of the State of Alabama.

**I, the undersigned, have read and understand these terms and conditions and realize it relates to the surrender and release of valuable legal rights, and I do so freely and voluntarily.**

**SIGNATURE**

**DATE**

**Attestation of deactivated SARS-Cov2 biosamples**

I, (name of personnel who are handling the biological samples) attest that the contained biological samples (not to exceed 2.0 milliliters) have been deactivated of any live SARS-Cov2 particles using at least one of the following deactivation procedures:

* 1. Heat inactivation- Bio-samples (in 2ml or less Eppendorf tubes) are boiled in a 100C water bath for at least 15min.
	2. Detergent treatment – Bio-samples are mixed to a final concentration of

0.5% sodium dodecyl sulfate [SDS], 0.5% Triton X-100, 0.5% Tween 20, or 0.5% NP-40 to incubate at room temperature for at least 30min.

* 1. Chaotropic chemical treatment – Bio-samples are mixed with Trizol or other chaotropic reagent in a 1:4 ratio of biosample:Trizol reagent, which is to be mixed and incubated at room temperature for 5 minutes.

**Disclaimer Statement:** UAH has received the deactivated SARS-CoV-2 biological samples from an outside third-party source. While it has been attested that the biological samples have been deactivated using a specified deactivation procedure, there are risks that the SARS-CoV-2 samples could be active due to an error in the deactivation process completed by the third-party source or any other error caused by the third-party source. While UAH has implemented measures to reduce the risk of injury from the research activity and spread of COVID-19, UAH makes no guarantee that the SARS-CoV-2 biological samples will be completely deactivated and that the research participant will not be injured or become infected with COVID-19 due to their participation in the research activity. Notwithstanding these risks, by participating in a deactivated SARS-CoV-2 research activity, the research participant acknowledges that they are voluntarily participating in the research activity with knowledge of the risks involved. If there are any questions, contact the UAH Office of Health and Environmental Safety.

By my signature below, I attest that the information provided above is true and correct. I have also read and understand the disclaimer statement.

Name (First and Last)

Affiliation

Signature

Date