APPROVAL FORM FOR RESEARCH ACTIVITIES INVOLVING COVID-19 CLINICAL SPECIMENS OR SARS-CoV-2-ASSOCIATED MATERIALS

This form should be completed before any research activity at Medical University of South Carolina (MUSC) involving clinical specimens from subjects known or strongly suspected to COVID-19 positive that could harbor a SARS-CoV-2 infection risk. **It is not intended for activities that require BSL-3 containment such as virus isolation or characterization.**

Please complete this form and submit it along with the following to the MUSC IBC Program Manager (smitmic@musc.edu)

- IRB protocol status documentation (if applicable)
- Standard Operating Procedures (SOPs) for tasks to be carried out with COVID-19/SARS-CoV-2 materials
- CDC permit (if applicable)
- Inactivation verification documentation (if applicable)

Please complete all check boxes and shaded fields below. Add lines to tables or expand text fields as necessary to provide detailed risk-assessment-relevant information for each question.

Principal Investigator Name:	MUSC IRB# and/or IBC#:
Form prepared by:	Date of preparation:
Email address:	Phone:

1. What kind of COVID-19 specimens/SARS-CoV-2 associated materials are you planning to acquire? Check all that apply.

☐ Purified RNA; please describe fully in the box below.

☐ Inactivated/fixed fluid or tissue specimen; please describe fully in the box, including inactivation method. If the inactivation method is covered under the IBC's Biological Inactivation of COVID-19/SARS-CoV-2 Specimens policy, please reference that. If the method inactivation method is not covered by the policy, please include a copy of the purification or inactivation procedure used and a literature reference that would support efficacy of SARS-CoV-2 inactivation.

☐ Body fluid or tissue specimen from patient with active infection; please describe fully in box below. Please include the corresponding IRB number for each specimen set described.

2. **Who and where (Name & Institution) are you planning to get the specimens or materials from? If this transfer required a CDC Import Permit or similar paperwork, send a copy of it to MUSC Risk Management with this form.**

3. **Where (Building and Room Numbers) do you intend to work with these specimens/materials?**

4. **Confirm by checking the boxes that the facilities above have the following:**

   ☐ A currently certified Class II biosafety cabinet
   ☐ A sink with an eyewash
   ☐ Secure storage for the samples
   ☐ Access to an autoclave
   ☐ Restricted access capable

5. **When do you expect to receive the specimens/materials? How will they be sent to you?**

6. **How long do you expect to work with the specimens/materials?** (In other words, is this a short-term project or will these specimens or material become a regular part of your research program?)

7. Work with COVID-19/SARS-CoV-2 associated materials needs to be carried out by personnel who are proficient at carrying out the technical procedures while adhering to all applicable biocontainment practices.
   Please submit a copy of your written procedures (SOPs) for the activities to be carried out along with this form. Additionally, please provide a brief but reasonably detailed explanation of how you plan to use these materials to support your research.

8. **What members of your lab staff will work with these specimens/materials?** Please fill out the table below to describe their technical and biosafety qualifications/proficiency for the procedures in the SOP. (We recommend that personnel be limited to as few as needed and that only the most experienced lab staff work with these specimens/materials.)

Name	**Procedures in SOP they will perform**	**Demonstrated proficiency in lab techniques (years performing procedures, specialized training, etc.)**	**BSL-2 training date**

PROFICIENCY ACKNOWLEDGMENT

I attest that the personnel above have satisfactorily completed all lab-specific procedural training. They have been observed to be proficient in carrying out all technical procedures they will perform in support of this project while adhering to all applicable biosafety practices.

Name of Project/Lab Manager Signature & Date

9. **Do you plan to transfer any portion of the specimens/materials to other collaborators?** If yes, list these here and provide succinct details regarding what will be transferred and for what purpose.

10. **Do you plan to use any MUSC shared resource (core) to support research work with these specimens/materials?** If yes, list these here and provide succinct details regarding which shared resource will be used, what materials will be submitted for analysis and for what purpose.

PRINCIPAL INVESTIGATOR ACKNOWLEDGMENT

I have reviewed this submission and acknowledge that the information provided is accurate. I will ensure that all biosafety and biosecurity practices specified for these activities will be followed. I will consult with MUSC Biosafety before:

- receiving specimens/materials that are not addressed in this submission;
- initiating procedures that are not captured in this submission;
- changing biosafety practices;
- transferring specimens/materials to collaborators not declared in this submission.

Principal Investigator Name Signature & Date

Please submit your completed form, along with planned technical procedures involving use of the agent, to the MUSC IBC.

Please contact the BSO, Dr. Chris Voelkel-Johnson (johnsocv@musc.edu; 843-792-3125) for assistance with form completion or risk assessment questions.