

SARS-CoV-2 Laboratory and Research Guidelines

University of Pittsburgh Department of Environmental Health and Safety (EH&S) has developed guidelines for research activities with SARS-CoV-2 and/or clinical specimens from suspect or confirmed COVID-19 patients.

These guidelines address general principles regarding biosafety levels, however the biosafety level for specific lab activities and procedures can be altered by EH&S or relevant institutional oversight committees depending upon the precise scope of work. Investigators should note the following:

- An approved CDC import permit is required to obtain viral isolates or clinical samples from confirmed COVID-19 patients from countries outside the US. The import permit application process is now fully electronic.
- At present, SARS-CoV-2 is not regulated under the Federal Select Agent Program. Investigators should be aware that **SARS-COV-1 IS regulated as a Select Agent**, and Pitt is **NOT** currently registered for work with this agent. Therefore, any procurement of SARS-CoV-1 at the University of Pittsburgh must be pre-approved by EH&S and the Federal Select Agent Program.
- All research with SARS-CoV-2 or samples from COVID-19 patients must be described in research protocols approved by applicable institutional oversight committees (e.g. IBC, IRB, IACUC).
- For the purposes of these guidelines, specimens may include but are not limited to blood, serum, plasma, tissues, feces, urine, sputum, mucosal samples, bronchoalveolar lavage, and other respiratory secretions.

Research activities that must be performed at BSL-3/ABSL-3:

Current CDC and University of Pittsburgh Guidelines for SARS-CoV-2 require that any work involving isolation or propagation of virus, or infection of animal models, be performed at BSL-3/ABSL-3.

The University has a designated high containment facility that is currently approved for work with SARS-CoV-2. Investigators interested in performing work with SARS-CoV-2 cultures and/or infected animals should contact EH&S at biosafe@ehs.pitt.edu for more information regarding BSL-3/ABSL-3 work at Pitt.

Research activities that may be performed at BSL-2+:

In many cases, handling of clinical specimens from suspected or confirmed COVID-19 patients can be performed at BSL-2+, including some of the following types of work:

- Processing, aliquoting, or preparing specimens for downstream assays or storage,
- Chemical or heat fixation of specimens,
- Extraction of nucleic acids,
- Preparation of inactivated specimens,
- Performing diagnostic tests (e.g. serology) that do not involve potential propagation or concentration of virus.

Investigators should be aware of the following existing BSL-2+ requirements for lab facilities and work practices that must be met prior to handling SARS-CoV -2/COVID-19 clinical samples:

- All manipulation of potentially infectious materials **must** be performed in a certified biosafety cabinet (BSC) or other primary containment device (e.g. sealed biosafety centrifuge safety cups or rotors that are loaded and unloaded in the BSC).
- All rooms operating at BSL-2+ must be negatively pressurized in relation to all surrounding laboratory and/or common areas to ensure appropriate secondary containment via directional airflow.
- While work at BSL-2+ is in progress, there must be a way of limiting access for those not appropriately trained or authorized for the work. While EH&S prefers a dedicated room with a door, shared spaces with posting of “in use” signage can be acceptable for certain lab areas, upon the specific approval of EH&S.
- Appropriate EPA-registered disinfectants for coronavirus must be used to decontaminate work surfaces, and solid and liquid wastes.
- Enhanced personal protective equipment consisting of either a dedicated laboratory coat with a disposable liquid-resistant barrier (e.g. disposable apron), or a closed-front liquid barrier gown is required. Double gloves are also required. If proposed laboratory procedures cannot be performed inside a BSC, contact EH&S as additional work practices and/or PPE, or potential relocation of work to BSL-3 may be required.
- Personnel must possess proficiency in BSL-2 laboratory practices as well as comprehension of applicable occupational health information (e.g. monitoring for symptoms, exposure response, reporting symptoms consistent with COVID-19 to Employee Health Services regardless of whether there is a known exposure or not). Training of personnel must be **documented**. [The EH&S BSL-2+ biosafety manual template includes a section for personnel signature to document their review and understanding of lab-specific training prior to beginning work.]

Research activities that may be performed at BSL-2:

Work with appropriately inactivated or fixed specimens, and extracted nucleic acids may be performed at BSL-2 in most cases.

Registration of work, laboratory inspections, and biosafety manual review:

Investigators with currently approved BSL-2+ work areas and biosafety manuals should add proposed SARS-CoV-2/COVID-19 work to their manual and share with their EH&S Laboratory Safety Specialist via biosafe@ehs.pitt.edu.

Investigators with currently approved BSL-2 work areas that seek to add SARS-CoV-2 research that potentially requires BSL-2+ containment as described above must contact their EH&S Laboratory Safety Specialist via biosafe@ehs.pitt.edu for approval of the designated space at BSL-2+. If needed, EH&S can assist investigators with development of a research-specific biosafety manual. EH&S will prioritize a laboratory safety survey to ensure that all BSL-2+ requirements are met.