

## **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](mailto: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:**

EH&S recognizes the importance of supporting SARS-CoV-2/COVID-19 related research. In order to avoid duplicative registrations, EH&S will collaborate with the Clinical and Translational Science Institute (CTSI; <https://covid19research.pitt.edu>) and the Office of Research Protections to obtain project information and prioritize risk assessments.

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](mailto: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](mailto: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.