

Yale Environmental Health & Safety

Application checklist for laboratories requesting approval for COVID-19 related research

First Step: Register your work with Yale EHS

Yale is requiring all PIs to register their COVID-19 related laboratory research with EHS through their online registration system. You must complete a COVID-19 EHS registration if your laboratory is planning to handle or receive clinical specimens from COVID-19 patients, SARS-CoV-2 RNA, or environmental samples to be tested for SARS-CoV-2. This includes collection, storage, transport, RNA extraction, PCR and sequencing procedures. **Please note if you are working with respiratory samples such as lung exudates and secretion samples, these samples present a much higher risk. The COVID-19 registration must also be submitted if you are planning to work with non-infectious material from SARS-CoV-2 such as lysed material, fixed tissues, cDNA etc.**

In addition to the COVID-19 registration:

*If you are planning **recombinant work** with SARS-CoV-2 genetic material, please submit an rDNA registration.*

*If you are planning to work with **infectious SARS-CoV-2 virus**, please update your Bio General registration and submit or update your Infectious Agent registration.*

*If you are receiving **human tissues (especially from the Yale Morgue)** please forward us your Yale HIC (IRB) registration for the use of human tissue and other human materials.*

*If your project involves **testing of samples for providing information to a medical professional, laboratory, study subject or other group**, please provide us with the date your laboratory has passed a state of CT CLIA inspection.*

*If your project is **at a Yale Medicine clinic, or in a space managed by Yale leased properties**, please provide confirmation that Yale leased properties has approved the research in this location.*

Please follow these steps to register your COVID-19 work prior to initiation:

1. Go to our EHS Integrator homepage: <https://ehsis.yale.edu/EHSIntegrator>
2. Sign in by using your NetID and password.

Please note that you must be signed in to VPN to access EHS Integrator if you are not using Yale Wi-Fi.

3. Click on 'Registration' tab on the left side of the page.

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4. Select the type of registration that applies to your work e.g. 'COVID-19 research' tab on the right side of the page (under 'New Registrations')
If you want to update a current authorized registration, please select the 'amend' button.
5. Fill out the required answers and follow the step by step instructions through all sub-tabs.
6. After each sub-tab click on 'save & continue' to move to the next sub-tab.
7. To expedite EHS review, please provide as much information as possible.
 - **Please ensure that you provide a description of the proposed work, especially if there is any potential for the propagation or amplification of the virus. We are also concerned about procedures that may generate aerosols, like high speed cell sorting, centrifugation, or any equipment that is capable of generating splash or splatter.**
 - **Make sure all research locations are listed, including any collaborating laboratories.**
 - **Include all locations where the specimens, samples, and RNA will be handled and stored.**
 - **You can upload your SOPs to your registration.**
8. Once the form is submitted to EHS for review the registration would appear in the "EHS Approval or Close Pending" list
9. If the registration has been filled out by a laboratory contact, as designated in EHS Integrator, on behalf of the PI, the PI must review and approve the registration for accuracy.

Important note:

Yale Undergraduates or visiting undergraduates are not allowed to work on COVID-19 related research projects!

Second Step: Develop site-specific SOPs

Develop a site-specific biosafety standard operating procedure (SOP) for your proposed work using the 'Biosafety Precautions with Clinical Specimens due to COVID-19' document, our BSL2 enhanced reference documents, your existing State of CT Department of Public Health human pathogen biosafety work practices protocol, or other document that provides researchers performing the work a blueprint for their own protection.

Please note that any work with human material requires a disinfectant that complies with the OSHA bloodborne pathogens standard. You need to use a tuberculocidal disinfectant such as 10% bleach to disinfect any waste as well as items coming out of the biosafety cabinet.

Remember to emphasize these points when drafting your SOPs:

- Use screw top cap tubes in place of snap cap Eppendorf tubes to minimize aerosol generation and create better primary containment.

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- Safety buckets are required when centrifuging higher risk materials. Safety buckets need to be loaded and unloaded inside the biosafety cabinet.
- If you use a microcentrifuge, please use this device inside the biosafety cabinet.
- If you are planning to use a vortex, please use this device inside the biosafety cabinet.
- Provide step-by-step instructions and identify where each step will be performed. (Mention if you will be using a kit to e.g. extract RNA; if so you can list the manufactures instructions)
- Mentioned when and how are you inactivating the virus. Will this be done directly after receiving the samples or will you receive already inactivated material?
- Provide information on sample transportation and storage.
- List PPE all personnel will be wearing and how it will be disinfected.
- Describe how you will collect and disinfect waste inside the biosafety cabinet

Third Step: (Virtual) Onsite visit from EHS

Schedule a meeting with EHS to review the proposed research space by contacting your Safety Advisor. This meeting may be a virtual (e.g. FaceTime) meeting depending on the status of the outbreak and required social distancing requirements.

EHS Biosafety is scheduling a meeting with each laboratory working on COVID-19 related research to review BSL-2 enhanced work practices for handling live specimens and the BSL-2 practices for handling SARS-CoV-2 RNA on the bench. Ensure that all members of the laboratory involved in the COVID-19 research project participate in the work practices review. This may also be in the form of a virtual meeting.

EHS Biosafety is also providing labs with the following items (while supplies remain in stock):

- 1 Transport container
- 1 face shield / person (maximum 5 per lab; labs are asked to re-use them by wiping them down with 70% Ethanol)
- BSL-2 enhanced work practices handouts
- Safety equipment and supplies ordering information

Fourth Step: Inform your colleagues

Prior to EHS approval, please confirm that you have notified everyone in your laboratory that you are initiating this work. Allow them to express any of their concerns privately about any discomfort they may have regarding the proposed new work. We have identified that this has been a significant area of contention. Also discuss the routes of exposure of the virus and signs and symptoms of the disease (COVID-19).

Please also confirm that any neighboring laboratories are aware of your proposed COVID-19 related research and explain your safety protocols and how you have implemented safety measures to prevent

them from any exposure. **This is most critical if you are sharing any equipment or laboratory space with other groups.**

**If the proposed space is a university properties or leased properties space, please confirm that you have received approval from either of these two groups and the landlord that the clinical research can proceed.

Fifth Step: Documentation

Provide EHS with your SOPs and confirmation that all of your staff and neighboring research groups have been notified of your proposed COVID-19 related research.

After receipt of these two items and following the successful start-up inspection, EHS will issue approval to initiate the research.

EHS has averaged 4 days for this process once all information is received. As the number of requests increases approvals may take a bit longer.