

Yale Environmental Health & Safety

Checklist for laboratories requesting review of work with unfixed human materials collected post January 1, 2020*(for SARS-CoV-2 concerns)

First Step: Risk assessment of your human materials

Please note that if you are working with human materials that have been tested for and found negative for COVID-19, you may continue to use OSHA Bloodborne Pathogens Universal Precautions (BSL-2 biocontainment) as you were prior to the pandemic.

Where possible, aerosol generating procedures should be performed in the biosafety cabinet with these materials. If not possible, additional personal protective equipment such as eye, nose and mouth protection, lab coats and gloves that protect personal clothing and skin in the wrist area, along with engineering controls shall be utilized for work on the bench. Please contact Yale EHS Biosafety for assistance with verification of your biosafety practices if you have any questions.

Note that a risk assessment for other pathogens that could be present (such as respiratory pathogens in lung specimens) must also be considered as part of your risk assessment.

Second Step: Register your work with human materials with Yale EHS

Yale is requiring all PIs to register their work with human materials (fixed and/or unfixed) with EHS through their online registration system. You must complete or update your Biological General registration if your laboratory is handling, storing and/or receiving any kind of human materials. Due to the concerns for SARS-CoV-2 in human materials collected after January 1st of 2020* (November 1st, 2019 for samples collected in China), all samples have to be treated as potentially COVID-19 positive if the status of the samples is unknown. This includes but is not limited to unfixed tissues, swabs, respiratory samples, secretion materials, or environmental samples. **Please note if you are working with respiratory samples such as lung exudates and secretion samples, these samples present a much higher risk for potential SARS-CoV-2 viral load.**

*** : Due to the start of the SARS-CoV-2 outbreak the collection date refer to as following:**

Human samples collected after November 1, 2019 in China or samples collected after January 1, 2020 outside of China (including the US).

In addition to the update of your EHS Biological General registration:

*If you are receiving **human tissues from known COVID-19 positive patients or research subjects**, please forward us your Yale HIC (IRB) registration for the use of human tissue and other human materials and alert EHS for an updated evaluation of your work.*

*If your project involves **testing of human 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 Connecticut Clinical Laboratory Improvement Amendments of 1988 (CLIA) inspection.*

*If your project involves **COVID-19 positive samples and 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 work with post January 1, 2020 human samples prior to initiation:

1. Go to our EHS Integrator registration page: <https://ehsis.yale.edu/EHSIntegrator/Registration>
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.
4. Select the type of registration that applies to your work e.g. 'Biological General' Registration tab on the right side of the page (under 'New Registrations').
 - *If you want to update a currently authorized Biological General registration, please select the 'amend' button.*
 - *If you want to update your currently 'pending' Biological General registration (which means under EHS review), you need to contact your Safety Advisor before you can modify your Biological General registration.*
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. For the work with unfixed human materials where the status of the COVID-19 is positive or unknown, a SOP is required (see step 3 for more details).
 - **Please ensure that you provide a description of the proposed work with unfixed human materials, especially if you are planning to culture or propagate human materials since this would be required to be performed inside a BSL-3 facility. We are also concerned about procedures that may generate aerosols, like high speed cell sorting, centrifugation, or any equipment that can generate splash or splatter with unfixed human materials.**

- **Make sure all research locations are listed, including any collaborating laboratories.**
 - **Include all locations where the unfixed human materials will be handled and stored.**
 - **You can upload your SOPs for your work with unfixed human materials to your Biological General registration.**
8. Once the registration is submitted to EHS for review, it would appear in the “EHS Approval or Close Pending” list.

Third Step: Develop site-specific SOPs for your work with unfixed human materials if the status of the sample is COVID-19 positive or unknown

Develop a site-specific biosafety standard operating procedure (SOP) for your proposed work with unfixed human materials using the ‘Biosafety Precautions with unfixed human materials’ document, the BSL-2 enhanced work practices reference documents, your existing State of CT Department of Public Health human pathogen biosafety work practices protocol (if applicable), or other document that provides researchers performing the work a blueprint for their own protection.

Please note: A site-specific SOP is not required for your work with fixed human materials or if the sample has been tested for and found negative for COVID-19.

Please note that any work with human materials requires a disinfectant that complies with the OSHA bloodborne pathogens standard. This also is mandatory when you work with established human cell lines. You must use a tuberculocidal disinfectant such as 10% bleach to disinfect any waste inside the biosafety cabinet as well as all items coming out of the biosafety cabinet.

Remember to emphasize these points when drafting your SOPs for your work with unfixed human materials:

- Use screw cap tubes in place of snap cap Eppendorf tubes to minimize aerosol generation and create better primary containment.
- Safety buckets are required when centrifuging higher risk materials. Safety buckets need to be loaded and unloaded inside the biosafety cabinet and the exterior of the safety bucket decontaminated before removing from 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 (e.g. in the biosafety cabinet). If you will be using a kit (e.g. RNA extraction kit); if so you can list the manufacturer’s instructions and add where the step will be performed.
- Mention when and how you are 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 or discarded.
- Describe how you will collect and disinfect waste inside the biosafety cabinet.

Please note: EHS has amassed a library of SOPs for common laboratory procedures and can provide, upon request, an example SOP for guidance in developing your own site-specific laboratory SOPs for your work with unfixed human materials.

Fourth Step: (Virtual) laboratory inspection for your work with unfixed human materials if the status of the sample is COVID-19 positive or unknown

Schedule a meeting with EHS to review the proposed research space for your work with unfixed human materials 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. At the time of this update, EHS is beginning live site visits attempting to maintain 6-foot distance requirements while wearing a mask to inspect laboratory sites.

Fifth Step: (Virtual) BSL-2 enhanced work practices training for your work with unfixed human materials if the status of the sample is COVID-19 positive or unknown

The EHS Biosafety group is scheduling live zoom meetings each week for laboratories working with unfixed human materials if the status of the sample is COVID-19 positive or unknown to review BSL-2 enhanced work practices until further notice. Ensure that all members of the laboratory involved in the research project with human materials participate in the BSL-2 enhanced work practices training. You can sign up for a training class through TMS:

https://bmsweb-h.yale.edu/ords/tms/tms_enrollments.offerings?p_crs_id=7265&p_std_id=

Sixth Step: Approval of your work with unfixed human materials

Once site-specific SOPs for your work with unfixed human materials are finalized, a successful laboratory inspection is completed, and all required trainings are taken and up to date (for example bloodborne pathogens training is an annual requirement per OSHA), EHS will approve the Biological General registration (or the amendment of the Biological General registration) to initiate the research with unfixed human materials.