Research Lab Re-Entry Requirements and Guidelines
- Compliance Monitoring & Reporting

Michelle MacLeod
Lab Safety Advisor, EH&S, Harvard University

Noman Siddiqi, PhD
Chair, Lab and Biosafety Focus Forum
Leader, COVID-19 Oversight Team

Delia Wolf Christiani, MD, JD
Associate Dean, Regulatory Affairs & Research Compliance
Leader, COVID-19 Oversight Team
COVID-19 Lab Training

Crimson Clear

Baseline Viral Testing

Lab Visitors

Compliance & Reporting

Questions & Answers

*Disclaimer: the contents of this presentation refer to information known to the date above and is subject to change. -6/17/20202
Must be taken prior to returning to campus and prior to self-screening with Crimson Clear.

Can be assigned in HTP.

Takes about 30 minutes to complete, Accessed via Harvard Training Portal (HTP).

You can refer back to the training through HTP if needed/desired.
Crimson Clear

- Self-reporting screening certification for laboratory personnel

- Crimson Clear is a url (not an app) that is available here: https://crimsonclear.harvard.edu/

- Used daily, before leaving your home and prior to entering Harvard property, to generate clearances to access University buildings and facilities

- If your training is NOT complete, you cannot self-screen

- Expires after 12 hours
Baseline Viral Testing

• All personnel who are returning to the labs should have baseline viral testing within 14 days of their return to campus.

• Harvard University Health Services (HUHS) will administer the test at no cost to the individual.

• Schedule an appointment via Harvard University Health Services' COVID-19 Testing Registration Form. The site will be updated as additional appointment dates are released.

• HUHS will conduct follow-up on positive test results and conduct contact tracing.
• Research Lab Visitors Sign-off document on EHS Website, https://www.ehs.harvard.edu/node/8513.
• Applies to vendors/contractors (e.g. equipment technicians).
• Describes expectations for entering Harvard buildings and conducting work in a laboratory setting.
• Labs should check that the document has been signed.
• Labs do not need to collect or retain the signed document.
Surface Disinfectants

- You should continue to use whatever disinfectant was advised prior for disinfecting lab surfaces, including BSCs (i.e. disinfectant that is effective for your research biologicals and biohazards).
  - If you are unsure if it is effective against SARS-CoV-2, please reach out.
  - For example, alcohol is still not considered an acceptable disinfectant against bloodborne pathogens (so all human materials work), non-enveloped viruses, and bacteria/fungi that produce spores/biofilms.
- New safety and procurement guide for disinfectants: https://www.ehs.harvard.edu/secure/node/8519
- For equipment that wasn’t previously disinfected, a lot of manufactures are now providing guidance (ex. Leica, https://www.leica-microsystems.com/science-lab/how-to-sanitize-a-microscope/).
- Oxivir TB will be provided for use on high touch surfaces such as door knobs, light switches, etc... If disinfecting lab areas or equipment not traditionally disinfected, you must assess for compatibility. Disinfectants can react with research materials and/or equipment components to produce hazardous byproducts and/or damage equipment.
  - Provided disinfectant user guide: Oxivir TB
  - If you have any questions about how to use this disinfectant, please let me know.
Supplies Available Upon Request

Mask and Disinfectant Request Form: https://hsph.me/operations-forms-ppe-request
Reminders

• All work relating to COVID-19 must be reviewed by EHS Biosafety, regardless if it falls under COMS. Please contact biosafety@harvard.edu or your specific biosafety officer for details. A matrix has also been developed to help you understand expectations around your work: https://www.ehs.harvard.edu/system/files/covid_19_sars_c cov_2_laboratory_research_biosafety_matrix_cd045b_2020_05_19.pdf
• Flush eye washes weekly.
• Wear long pants or other garments that cover one’s legs and shoes that cover the entire foot while in lab.
Research Laboratory Reopening Planning
Compliance Requirements

• Harvard University Laboratory Reopening Planning Committee
  • Research Laboratory Re-Entry Plan
• Harvard Chan Research Planning Committee
• Office of Regulatory Affairs and Research Compliance (ORARC)
• COVID-19 Oversight Team (COT)
• COVID-19 Safety Officer
• Develop School-specific requirements
• Approve initial lab re-entry plans
• Review compliance reports from the COVID-19 Oversight Team and make determinations on serious and continuing non-compliance
Harvard Chan Research Planning Committee - Membership

• Jane Kim, Dean for Academic Affairs (Chair)
• Katie Hope, Executive Dean for Administration
• Delia Wolf Christiani, Associate Dean for Regulatory Affairs and Research Compliance
• Robert Farese, Chair, Department of Molecular Metabolism
• Sarah Fortune, Chair, Department of Immunology and Infectious Diseases
• Russ Hauser, Chair, Department of Environmental Health
• Frank Hu, Chair, Department of Nutrition
• Marie Richard, Director of Administration, Department of Immunology and Infectious Diseases
• Katrina Soriano, Executive Director of Administration,
  Departments of Nutrition & Molecular Metabolism
• Glenn Stern, Director of Administration, Department of Environmental Health
• Brian Frederick, Research Operations Manager, Department of Molecular Metabolism
• Noman Siddiqi, Director of Research Operations, Department of Immunology and Infectious Diseases;
• Alex Machaiek, Senior Director of Operations
• Danny Beaudoin, Deputy Director of Operations,
• Shawna Marquis, Associate Director of Lab Safety Services, Harvard University EH&S
• Marissa Cardwell, Associate Director of Biosafety, Harvard University EH&S
ORARC

- Office of Regulatory Affairs & Research Compliance is responsible for a broad range of regulatory affairs and research compliance functions:
  - Laboratory and biological safety
    - Coordinating functions of the COVID-19 Oversight Team (COT)
  - Human subjects research (IRB)
  - Research misconduct
  - Review of institution collaboration agreements/Memorandums of Understanding (MOUs)
  - Providing training and support to the research community
COVID-19 Oversight Committee (COT)

• COT is responsible for
  • Monitoring compliance with individual laboratory plans and institutional guidance
  • Reviewing and approving changes to individual laboratory plans
  • Reviewing deviation and/or non-compliance reports
  • Identifying common findings of non-compliance
  • Collecting and providing information relevant to any changes in policies and/or procedures to COVID-19 Safety Officers and PIs
  • Reporting serious and continuing non-compliance issues to the Chan School Research Planning Committee
COVID-19 Safety Officer

43 Officers at Chan School appointed by their PIs

Special title, additional responsibilities

- Serve as liaisons between research lab community and COT
- Work with researchers to develop re-entry plans and train lab members on best practices, including infection control practices
- Ensure adherence to University and Chan School Lab Re-Entry requirements
- Report non-compliance events/incidents to COT via ORARC website: https://www.hsph.harvard.edu/regulatory-affairs-and-research-compliance/covid-oversight-team/
- Submit lab plan modification to COT for review and approval
- Work with Operations/FMO to establish best practices in getting the lab/equipment set up and running
Reporting/Reviewing Step-By-Step

1. Submitter completes report via ORARC website at: [https://harvard.az1.qualtrics.com/jfe/form/SV_3K09J60aSwXzMgJ](https://harvard.az1.qualtrics.com/jfe/form/SV_3K09J60aSwXzMgJ)
   - There are 9 Reporting/Requesting Categories
   - If you are submitting a new lab/office reentry plan, you will be directed to the final step – upload your proposed plan
2. Submitter receives a PDF version of the report via email
3. COT Co-Leader (Dr. Noman Siddiqi) reviews the report within 24 hours and consult with relevant reviewers, if necessary
4. Notification will be sent to:
   - Submitter, PI, and copy department chair, department administrator, and COT co-chairs
5. If the request is to add lab members to the plan, ORARC updates the master list and security has access to the list for granting access to the building
Report/Request Update

• We have received a total of 15 reports since June 6, 2020
  • Seven plan modifications
  • Eight non-compliance issues/concerns (2 reported anonymously)
  • There has been no serious or continuing non-compliance incident
  • Corrective actions have been re-training and education/clarification
- Ombuds Office
- Environmental Health & Safety
- Human Resources
- Harvard Union of Clerical and Technical Workers
- Harvard University Anonymous Hotline