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Submissions of Proposals for COVID-19 Related Research by Biological Safety Program

The COVID-19 pandemic has galvanized the scientific community, with researchers worldwide focusing their attention on the biology of SARS-CoV-2, the development of a vaccine and therapies for COVID-19, and efforts to understand the virus’s impact on our communities.

As this research ramps up across Columbia’s campuses, laboratories are reminded that all proposals to conduct essential COVID-19-related research project(s) using biological materials require review by a Biosafety Officer. Depending on the nature of the proposal, additional review may also be required by either the Institutional Biosafety Committee (IBC) or a Rapid Research Review Team (RRRT) sub-committee, which reviews work with human specimens. To address timely review of all proposals, the Institutional Biosafety Committee (IBC) is meeting on a modified schedule with increased frequency. Investigators wishing to perform essential COVID-19-related research should submit for each project:

1. A brief proposal (no more than one page; submit to biosafety@columbia.edu) that identifies the scope of research, locations and any aerosol generating procedures such as centrifugation or FACS, and very specifically the type of SARS-CoV-2 viral material employed (inactivated vs still active specimens).
2. An Appendix A in Rascal. See Appendix Guidance.
3. For clinical specimens, the Covid-19 Application to use Human Specimens.

In order to follow CDC guidance for any work with SARS-CoV-2 specimens, specific protocols must be developed, reviewed, approved and then trained on, and strictly followed in order to eliminate the primary mode of SARS-CoV-2 transmission: through direct or indirect contact of mucous membranes with infectious aerosols/droplets and possibly fomites. There are two helpful guidance documents on the EH&S website on how to work safely with specimens:

- Biosafety Precautions with Clinical Specimens from COVID-19 Patients
- BSL-2 Enhanced Work Practices for Specimen Processing and Cell Culture

Please reach out to biosafety@columbia.edu with any additional questions or requests.
The outbreak of SARS-CoV-2 has caused rapid changes in all aspects of our lives. This previously unknown enemy has instilled fear worldwide, and the cycle of fear and uncertainty has grown, especially on the internet, where both facts and fake news can spread like wildfire. To counter these fears, Environmental Health & Safety (EH&S) has provided information and evolving guidance throughout the crisis. An EH&S COVID-19 guidance page was created as a centralized platform for all safety related information: https://research.columbia.edu/ehs-covid-19-guidance.

A primary feature of the site has been EH&S’ Fact Sheets, which have been issued based on information from federal agencies, as well as New York State and City authorities. Topics have included an introduction to the SARS-CoV-2 virus and COVID-19, necessary precautions for mitigation of the spread, such as social/physical distancing, the use of face coverings when in public, and symptom monitoring before and during workhours for essential personnel – please see the left-hand side bar for access to the full list. It is important to note that the Fact Sheets were developed with input of various University stakeholders and are also currently posted on the Emergency Preparedness site and on the Executive Vice President of Research’s (EVPR) website.

In addition to the Fact Sheets, guidance pages were also created as often as needed to provide information and advisories for essential personnel and public safety workers, and collections of Frequently asked questions (FAQs) were developed for both laboratory personnel and Facilities staff on topics such as how to clean and disinfect workplace and high touch surfaces. An FAQ on the use of N95 respirators, surgical masks and other respirators complying with international standards (e.g., KN95 respirators) was also developed as a critical reference for healthcare personnel: https://research.columbia.edu/sites/default/files/content/EHS/COVID-19/COVID_FAQ-N95_KN95andSurgicalMask.pdf.

Together, these Fact Sheets, Advisories, and FAQ pages have become an important reference library.

Have a recommended topic for a new Fact Sheet, or a question that EH&S can address? Please reach out to labsafety@columbia.edu.

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**Facts Over Fear!**
by Parinita Sah, Senior Safety Advisor

COVID Fact Sheet #1: About COVID-19

COVID Fact Sheet #2: Precautions

COVID Fact Sheet #3: Social Distancing

COVID Fact Sheet #4: Face Coverings

COVID Fact Sheet #5: Face Covering and Symptom Monitoring

COVID Fact Sheet #6: Hygiene

More COVID-19 Resources

Centers for Disease Control and Prevention

New York City Department of Health

National Institutes of Health

CUIMC Coronavirus Resource Center
Laboratory research and the pursuit of scientific discovery is a 24/7/365 endeavor. Except when it isn’t. In the past, electrical blackouts, blizzards, hurricanes, heatwaves, and even earthquakes have all interrupted research at Columbia University. But these interruptions have been brief, and relatively insignificant, compared to the impact of the coronavirus pandemic.

Over the last several weeks, many extraordinary measures have been enacted in order to “flatten the curve” of the spread of SARS-CoV-2 and the illness it causes, COVID-19. Among these measures has been the abrupt, indefinite suspension of all but essential research activity at Columbia University, an unimaginable development only weeks ago. The research community deserves high praise for the safe, orderly and efficient manner in which laboratories were ramped down; to do so involved the cooperation of thousands of researchers in hundreds of University laboratories.

The suspension of research has been an incredible challenge for those who have had to stay away from their life’s work. But these necessary efforts are paying dividends: while still painfully high, new COVID-19 cases, hospitalizations and fatalities have indeed flattened and begun to trend significantly downward in the New York City area, and there are signs that certain elements of academic life may be able to resume.

Laboratories are complex places of business. Just as tremendous effort and cooperation were required to safely “ramp down”, the same and more will be needed as research prepares to “ramp up”. EH&S prepared and distributed informational checklists and guidance documents to help ensure that researchers addressed the many potential hazards within their laboratories before departure. Similarly, a careful approach will be needed prior to the resumption of research, including:

- Thorough examination of laboratory facilities, systems, instruments, controls, chemical stocks, and safety equipment upon arrival at the laboratory and before resuming any experimental work.
- Re-stocking of personal protective equipment and other supplies. Many laboratories generously donated PPE to the hospital, which will need to be replenished. It may be a challenge to procure some items due to strained global supply chains, so plan in advance.
- A strategy to ensure that effective physical distancing can be maintained by workers, as well as a sustainable approach to cleaning and disinfection of high-contact and shared surfaces, in order to continue to limit potential infection. While the apex of the coronavirus infection curve may have passed, adjustments to the practice of laboratory research will be necessary in the context of an ongoing pandemic.

EH&S is here again to help. All laboratories are strongly encouraged to review and utilize the new guidance and training materials available at https://research.columbia.edu/ehs-covid-19-guidance to prepare themselves for the resumption of research.

With patience, thoughtfulness, and a resolve similar to that which has been shown over the last two months of the ramp down, the research ramp up can also be accomplished safely. Please feel free to reach out to EH&S for assistance at labsafety@columbia.edu.
EH&S is delighted to recognize and thank Principal Investigators Charles Zuker Ph.D., Rudy Behnia, Ph.D., and post-doctoral researchers Alvaro Sanz Diez, Ph.D. and Jose Cánovas Schalchli, Ph.D., for donating their time, expertise, and chemical reagents to provide New York Presbyterian Hospital with fit-testing solutions.

Health care workers must be fit-tested in order to safely utilize N95 respirators in a clinical setting. As the name "fit testing" implies, this procedure is used to verify which size of respirator a worker may need, or whether a different make or model are more effective in achieving a proper seal for each user. The global shortage of N95 respirators has been widely documented. Additionally, due to the global pandemic, certain chemical solutions that are required for the fit testing procedure are also currently in high demand and short supply. New York Presbyterian sent out a call asking for help and EH&S reached out to the research community. The Zuker and Behnia laboratories had the appropriate ingredients and knowledge to assist.

The fit-testing solutions of Bitrex and saccharin were prepared by the laboratories in accordance with the OSHA Standard for Respiratory Protection (29 CFR 1910.134, Appendix A). Qualitative fit testing is a pass/fail test that uses one's sense of taste or smell, or one’s reaction to an irritant, in order to detect leakage into the respirator facepiece. During a fit-test, a bitter Bitrex (denatonium benzoate) or a sweet saccharin solution is aerosolized in a user's breathing zone before and after donning a respirator. If the subject cannot detect the taste of the testing solution while wearing a respirator, the fit is satisfactory, verifying a tight seal between the user’s face and the N95 respirator. In addition to an initial and annual fit-test, an N95 user must also undergo a medical evaluation to ensure they have the capability of wearing this important piece of equipment.

By providing the fit-testing solutions, the Zuker and Behnia laboratories secured the ability for NewYork Presbyterian (NYP) healthcare personnel to safely and securely wear their respirators to protect against the spread of the coronavirus. EH&S thanks them for their donations and assistance!

Not All Respirators Are Equal
by Ritu Pandit, Health and Safety Specialist II

An N95 respirator, which filters at least 95% of particles that are 0.3 microns or larger, is a filtering face-piece respirator that protects against SARS-CoV-2. As these critical items of personal protective equipment became scarce across the world, frontline healthcare workers were in dire need of a solution to this supply chain problem.

To ease the demand, the United States Food and Drug Administration (F.D.A) issued an Emergency Use Authorization (EUA) to allow the import of a similar type of respirator, KN95 respirators. Unlike N95 respirators, that are tested and certified by the National Institute for Occupational Safety and Health (NIOSH), a Centers for Disease Control and Prevention (CDC) research agency, KN95 masks are regulated by the Chinese government.
Adapting Clinical Radiation Safety Procedures During the COVID-19 Pandemic

by Clinical Radiation Safety Team

One of the most important services that the EH&S Clinical Radiation Safety Program provides, is the support of all procedures that involve the use of radioactive materials (RAM) for cancer treatments at New York Presbyterian (NYP). The COVID-19 public health crisis caused NYP and hospitals throughout the state to postpone elective procedures. Practically, cancer treatment is truly not an elective procedure. Some cases may be able to be delayed for a period, but others are considered more urgent.

For cases that had to move forward, circumstances are far from normal, and the Clinical Radiation Team needed to consider adjustments to usual procedures. For example, in eye-plaque brachytherapy procedures, the common practice is to admit the patient to the hospital for three consecutive days during their therapy. However, due to the pandemic, many in-patient areas in the hospital are currently occupied by COVID-19 patients. Considering both the risk of COVID infection and psychological factors, the team instead determined the feasibility of allowing patients to return home for the three day treatment period. Based on pre-therapy interviews with patients to assess their living conditions, transportation and caregiver assistance needs, calculations were performed to determine that the radiation dose to family members and others interacting with the patient would be below regulatory limits. Additionally, instructions were provided to each patient to ensure that radiation doses to others stayed as low as reasonably achievable.

During the pandemic, the old conclusions balancing risks and benefits may no longer be the right ones. This is just one example of how all members of the clinical and research communities need to remain nimble and adapt to changing conditions, without sacrificing the safety of patients or the public.

Respirators continued from page 4

NewYork Presbyterian/Columbia Doctors received large donations of N95 and imported KN95 respirators from many companies and organizations. Although there are generally only minor differences between N95 and KN95 respirators, determining the authenticity of a KN95 respirator due to the lack of verifiable information from their manufacturers has been a challenge. The EH&S Occupational Safety Team has collaborated with NYP/Columbia Doctors to test these respirators before distribution to patient-facing healthcare workers. Together, the teams cross-check the NIOSH approved list and the F.D.A EUA list to authenticate the donated respirators, and have quantitatively tested 20 different types for fit on different face sizes. Modifications were also developed to replicate the current real-life use of the respirators to improve the fit, for example, the use of a surgical mask worn on top of the respirators. Unfortunately, a majority of donated KN95 respirators have failed the quantitative fit test with or without modifications; these masks should not be worn in a healthcare setting.

It is highly recommended that Columbia or NYP workers validate the authenticity of new/donated non-NIOSH-approved respirators via an EH&S quantitative fit test (using an instrument to measure actual leakage into the respirator). This way healthcare professionals treating COVID-19 patients as well as researchers involved in SARS-CoV-2 and COVID-19 related research are sure to be protected.
While essential laboratories continue to perform research during these challenging times, EH&S provides active support to the Columbia Research Community. In terms of waste disposal, the following services remain available:

Chemical/Hazardous Waste Pick-Up (Morningside, CUIMC and Manhattanville):
Please submit a pick-up request via the online form at https://research.columbia.edu/hazardous-materials-and-sustainability. Labs can request containers and labels using the same link.
As a reminder, containers must be appropriately prepared according to the Five L’s of Hazardous Waste Management: Collect, Label, Lid, Locate, and Leaks. For more details, visit this link: https://research.columbia.edu/sites/default/files/content/EHS/Waste_Hazmat/5Ls.pdf

Regulated Medical Waste (RMW):
- **Morningside**: EH&S is currently providing weekly pick-up service, upon request. Until further notice, Regulated Medical Waste pick-up requests must be submitted using the same online form as for Chemical/Hazardous Waste; note that the request is for RMW using the Comments/Special Instructions section. After placing the request, the waste container must be left outside of the laboratory on Monday or Thursday evenings. Please tie the red bag and close the container properly.
- **CUIMC**: Contact Facilities 212-305-4357 (305-HELP), ext.3.
- **Manhattanville**: Contact the Facilities Service Center at 212-854-2222.

**E-waste:**
- **Morningside**: Personal electronics can be recycled on campus by calling the Facilities Service Center at 212-854-2222 to arrange a pick-up, or items can be dropped off in the electronic waste collection area in the courtyard, known as “The Grove”.
- **CUIMC**: Please contact Facilities 212-305-4357 (305-HELP), ext.3.
- **Manhattanville**: Please contact the Facilities Service Center at 212-854-2222.

For the E-waste, remove all sensitive data from the hard drive before disposing of the equipment. For recycling or disposal of laboratory electronics please contact labsafety@columbia.edu and follow the steps for equipment clearance https://research.columbia.edu/system/files/EHS/Forms/ClearanceRequestForm.pdf.

For any emergency pick-up request or questions regarding waste management, please contact hazmat@columbia.edu.

**Keep Calm and Wash Your Hands**