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Environmental Health & Safety

Safety Matters

Does my IRB Research Study on COVID-19 also Require Review by the IBC?

by Christopher Aston, Associate Director, Biological Safety Programs

In early 2020, as one of several pandemic safety contingencies, senior university administration required that research in Columbia University laboratories employing infectious materials capable of transmitting SARS-CoV-2 be reviewed by the Institutional Biosafety Committee (IBC). This policy is intended to ensure that research staff have received adequate training and have access to the appropriate facilities to safely handle potentially infectious material. Investigators conducting research with human subjects are aware that the Institutional Review Board (IRB) reviews such research. The following bullets clarify when concurrent IBC review is required, and is not required, in addition to standard IRB review. Review is solicited by attaching a hazardous materials Appendix A to the IRB protocol.

IBC review **is required:**

- **Only** for research employing subjects that have active COVID-19 infection. Research on subjects who are convalescent and have tested negative by PCR is not subject to IBC review. Nonetheless, strict adherence to universal precautions should be exercised in handling any clinical specimens.
- **Only** for research where COVID-19 specimens are processed in Columbia University laboratories, or for studies where COVID-19 specimens are packed and shipped to another facility for testing. Studies where COVID-19 specimens are processed solely in hospital labs, which are CLIA/CLEP-regulated, are exempt from IBC review. Investigators processing COVID-19 specimens must take Rascal training TC5500.
- For all types of specimens from subjects that have active COVID-19 infection (e.g., nasopharyngeal swab, saliva, blood).
- For studies where potentially infectious material is received from the University's COVID-19 Biobank, as well as directly from the study subjects.

IBC review **is not required** for studies that employ materials from subjects with COVID-19 disease that has been inactivated immediately following collection (i.e., at the bedside), inactivated in the University's COVID-19 Biobank, or inactivated by a collaborator. **However**, the Biosafety Office reviews all such research. Therefore, please email biosafety@columbia.edu to confirm that the inactivation procedure employs an approved method.

Other human subjects research that has **always required IBC review** includes:

- When recombinant DNA (e.g. COVID-19 mRNA vaccine) is administered to research subjects (Appendix M required).
- When infectious agents other than SARS-CoV-2 are cultured from research subject specimens in a Columbia University laboratory.
- When recombinant or non-recombinant infectious agents (e.g. live vaccines) are administered to research subjects.

Helpful resources include:

Guidance on attaching Appendix A to an IRB protocol https://research.columbia.edu/sites/default/files/content/EHS/BioSafety/Rascal%20Appendices/AppendicesandAttachtoIRBprotocol.pdf

The EVPR clinical research handbook (https://research.columbia.edu/sites/default/files/content/EVPR/Handbooks/Clinical%20Research%20Handbook%202020%20FINAL_0.pdf).

The biosafety office, who can be contacted at biosafety@columbia.edu.

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Soon Again to be Printed on Recycled Paper

When working in the laboratory: eating, drinking or applying cosmetics is prohibited.

Radiation, We Know It's Harmful, But Why?

by MacKenzie Hill, Health Physicist

Radiation: some fear it, some revere it, yet humans on earth interact with it EVERY SINGLE DAY. Ionizing radiation, specifically, can affect the body in numerous ways, as outlined below. In its state as high energy particles or waves - or a little of both - ionizing radiation has the ability to interact with a molecule and disrupt its chemical bonds. This concept of disrupting molecular bonds on the surface doesn't really seem that concerning, except for the fact that the human body is really just one big mass of very specialized molecules within cells. To be specific human DNA, or the "road map" to the body, is at its core a molecule.

So, what happens when those molecules are damaged? Sometimes the cells recognize the damage as too severe and shut down, sometimes the cell repairs the damage correctly and everything goes on as normal, and other times the cell attempts to repair the damage but flip-flops the DNA code around in the process. Unfortunately, the cell can't always tell the difference between a good repair and a bad repair. This is one of the main reasons radiation can be harmful to a living organism.

The severity and scale of this damage strongly relate to the amount and rate of radiation that interacted with the living cells. Sporadic cell damage in the long term is usually not very harmful, cells are resilient and can repair themselves. This is probably best exemplified by the risk humans experience on earth being exposed to small amounts of radiation every day, or the nearly unmeasurable effects from a single small radiographic exam, like a DEXA scan.

Next, consider a moderately large radiation exposure all at once, an acute exposure. In this scenario, the body can repair a good amount of the cellular damage, but perhaps a small collection of cells escapes proper repair, and then damaged DNA propagates. This is how radiation-induced cancer can occur, and an example of this might be individuals who were distantly involved in a nuclear event.

Finally, consider the scenario of individuals who were exposed to a large amount of radiation in a very short amount of time during a large, acute exposure. In this example, so many cells are damaged throughout the whole body that the repair systems simply cannot keep up, and body systems start to fail. An example or scenario could be a person who was very closely involved in a nuclear event.

In conclusion, ionizing radiation has the ability to damage a living organism on its most basic level, its molecules/cells. Yet it is important to recall cells are not completely helpless, they have a number of repair mechanisms that protect them from all sorts of damage and not just the damage caused by radiation interactions. Finally, the scale of damage determines the repair response. If this simple breakdown of radiation-cellular interactions sparks an interest, the field of radiation biology may be something to explore further! As always, contact Radiation Safety at rso-ehrs@columbia.edu, with any specific questions.

Proper work attire (e.g., long pants, closed toe shoes) and PPE (e.g., laboratory coat, gloves and eye protection) must be worn when working in the laboratory.

Remember to periodically flush your laboratory cup sinks and floor drains with water to prevent odors from migrating into your laboratory.

For Lab Fire Safety Prevention tips, check out FDN(wh)Y Me https://research.columbia.edu/content/fdnwhy-me

Compressed Gas Safety Program Star Spotlight: Hydrogen

by Lauren Kelly, PM Safety & Regulatory Affairs and Sunipa Pramanik, Senior Safety Advisor

Hydrogen, a diatomic gas, is the most abundant element in the universe. While it makes up only a tiny fraction of the earth's atmosphere, hydrogen is found in everything from the sun, to hydrocarbons in the earth's surface, and water. Important applications of hydrogen gas in laboratories include its use in hydrogenation reactions, fuel for gas chromatography equipment and other apparatuses, and in cyclotron instruments. With its extremely low flash point of –259°C, and wide range of flammability when mixed in air (4%-74%) it presents significant hazards when not managed safely.

The safe management of hydrogen gas in laboratories is dependent on multiple factors, including:

- The number and volume of tanks
- The percentage of hydrogen in each tank and other mixture constituents
- The location of the laboratory (above or below grade)
- Whether the laboratory has an overheard fire-suppression or sprinkler system
- The flow rate of hydrogen in the lines of each set-up in the laboratory
- Whether there is a manual or automatic shut-off device in the laboratory

Based on the above, there are storage quantity limits in laboratories, and in certain cases, specialized gas cabinets may be required for storage. Additionally, flash arrestors and leak detection sensors should always be used. In summary, regulatory requirements for the handling, storage and use of hydrogen include:

- **Separation of incompatible gases:** Incompatible gases such as hydrogen (flammable gas) and oxygen (oxidizing gas) should be segregated by a distance of at least 20 ft. If adequate separation cannot be achieved, a noncombustible partition of at least 5ft (1.5m) high with a fire-resistant rating of one-half hour should be installed between the incompatible gas cylinders.
- **Backflow prevention or check valves:** These devices which prevent the reverse flow of gas into a system or container, are recommended at the source of the gas in addition to the point of use. Required when the backflow of hazardous materials could create a hazardous condition or cause the unauthorized discharge of hazardous materials, per FDNY 2703.2.2.1.5. A closed valve is not equivalent to a backflow preventer.
- **Gas detection and alarm systems (including audible and visual alarms):** Required if the pressure of hydrogen in laboratory gas lines is above 15 psi, per NYC fire code requirements.
- **Storage:** Maximum amount of hydrogen permitted to be stored in an area varies depending on whether the area has sprinklers or not and if a gas cabinet or exhausted enclosure (ex. certified chemical fume hood) is in use for storage. The table below from Airgas, which references NFPA requirements and mirrors FDNY requirements, summarizes the limits for hydrogen and other flammable gases. Note, storage limits decrease when the laboratory area is located below grade.

Table 2. Maximum Allowable Quantity (MAQ) of Gas per Control Area

		Unsprinklered Area		Sprinklered Area	
Gas Hazard Type	Phase	No gas cabinet, gas room or exhausted enclosure	Gas cabinet, gas room or exhausted enclosure	No gas cabinet, gas room or exhausted enclosure	Gas cabinet, gas room or exhausted enclosure
Flammable	*Liquefied* *Non-liquefied*	150 lbs. 1,000 ft³	300 lbs. 2,000 ft³	300 lbs. 2,000 ft³	600 lbs. 4,000 ft³

Airgas, *Guide To Gas Cabinet Safety and Code Conformance*/NFPA 55 Table 6.3.1.1

Continued on Page 4

Hydrogen Gas Continued

Other best management practices include:

- **Hands-on training:** The PI, laboratory manager or their designee should train new users on how to hook up and change hydrogen tanks from laboratory equipment.
- **SOPs:** Written documents that include how to set up, change and disconnect hydrogen tanks from equipment.
- **Spark resistant tools:** To be used for changing tanks and regulators.
- **Compatible regulators:** Designed to be fitted directly to the cylinder valve. No other fittings, connections, lubricants or Teflon tape should be used to connect a regulator to a gas cylinder valve.
- **Flash arrestors:** Should always be installed on lines that carry flammable gases to minimize potential for reverse flow and reduce the possibly of high pressure back up, which can over-pressurize upstream equipment at lower pressure.

For more information about compressed gas safety, EH&S has developed a comprehensive Compressed Gas Safety Program website including a technical manual, a safety training module (RASCAL TC5450), and a variety of other technical resources including compatibility guides and references.

Flash Arrestors: What are they and why are they needed?

- Prevent the entry of air or oxygen into the distribution line or single cylinders.
- Provide positive shut-off of gas and checks the reverse flow of gas.
- Prevent flashbacks which are the rapid propagation of a flame down the hose, by closing up and extinguishing the flame inside the device.
- Prevent further gas flow in the event of a burnback.

Team EH&S Recertifies CPR/AED/Naloxone skills

This February EH&S leadership provided free CPR/AED/Naloxone training through the American Heart Association. The training is provided to team members on a biennial basis and is open for all EH&S personnel that wishes to be certified. Groups of two and three took the course in a large conference room, while observing proper social distancing and PPE protocols. This year, due to the pandemic, the instruction was web-based and performed remotely by a proctor. Also, to be as safe as possible, masks were required to remain on and rescue breathing was simulated rather than performed. For more information on how you can become certified, please visit https://cpr.heart.org/en.

Remember:

Photo Courtesy of the American Heart Association

Photo: Pam Shively

Meet the EH&S Staff

Carmen Hoepelman has lived in New York City her entire life. Her first job was sweeping and beautifying the parks of NYC in the Summer Youth Employment Program. Even though she loves NYC, she would enjoy living in Alaska (Anchorage or Fairbanks) where people are easy going and life moves at a slower pace. Carmen also loves the idea of a Midnight Sun!

Felix the Cat, Carmen's favorite cartoon character

Carmen has been at Columbia University for over 31 years. Prior to joining EH&S, Carmen worked in the Institutional Review Board (IRB) office for seven years as Senior Secretary. Her first position at EH&S was as an Administrative Assistant, and through the years she has worked her way up the ladder to her current position as the Senior Manager for EH&S Administration and HR. Her patience and understanding of others are crucial assets in this important role. She sees herself as relating to an owl, both possessing great wisdom and a quiet demeanor. Carmen is motivated when someone breathes a sigh of relief as she helps them work through a complex issue.

A true New Yorker, Carmen supports the Yankees, Knicks, and Giants, and as a resident of Washington Heights, enjoyed seeing "In the Heights" filmed in her neighborhood during the summer of 2019. She takes time to reflect on her walks home from work and spends as much time with her family as possible. Dian Fossey, the Primatologist who studied mountain gorilla groups until her death in 1985, was an inspiration for Carmen. She experiences the world by collecting global magnets, which family and friends bring to her from their travels. Her wish for changing the world is to eliminate cancer forever, especially in children. The best professional advice Carmen has ever received, "don't take certain situations personal, most times it's how the other person is feeling or something they are going through" are words that can benefit everyone.

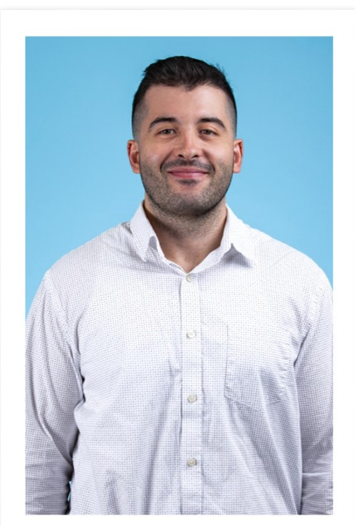


Photo: Jon Paul Aponte

Vincent Vagnone grew up in Wantagh, NY, on Long Island, the "Gateway to Jones Beach". He shares his hometown with many interesting characters, including Richard Nixon's dog, Checkers, that is buried in the town, a high school classmate who is dating Katie Holmes, and several residents who have appeared in major reality shows (Survivor, Ultimate Fighter, Real World/The Challenge, American Idol). Vincent would enjoy living in Dublin, Ireland a city where he found great comfort during a past visit.

Vincent has been an EH&S team member for four years, and currently holds the position of Senior Safety Advisor. His knowledge of Columbia University began when working for Veolia Environmental Services, the University's hazardous waste vendor, where Vincent provided exceptional service to the research community collecting laboratory chemical waste and assisting EH&S with the management of central accumulation areas. He is motivated by people underestimating him, and the best work advice he has received is "be honest and be yourself".

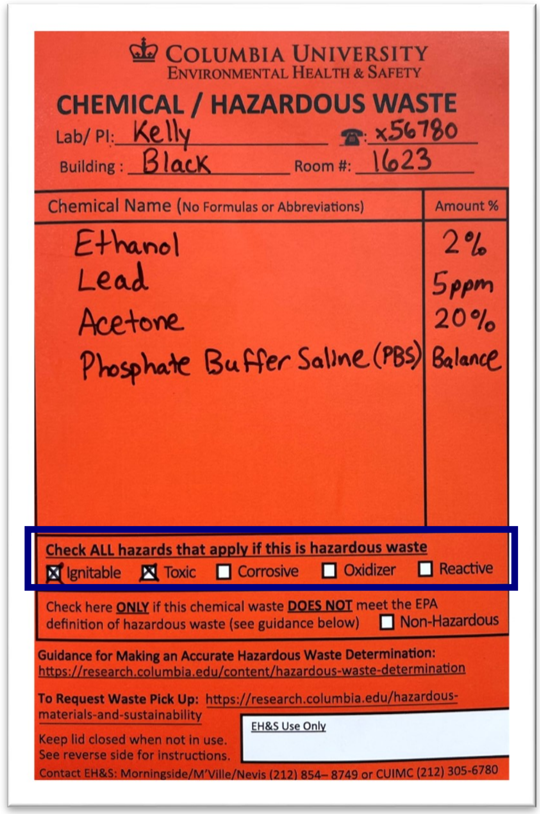
When Vincent is not working, he enjoys spending time with his family and two dogs. As a dog lover, he identifies with the Australian Shepard because they are loyal, active, and hard working. Although it has been challenging recently, he enjoys working out to wind down after a long day at EH&S. He also enjoys watching his favorite team, the New York Yankees, while making memories with his family going to games and enjoying the team's multiple World Series championships. He would like to learn more about investing in the stock market. Vincent's other favorite hobbies include homebrewing beer, recreational sports, and weightlifting.

Is My Chemical Waste a Hazardous Waste?

by Kathy Somers, Senior Manager of Research Safety and Hazardous Materials Programs

After researching the literature, studying the technique, vetting it with your Principal Investigator (PI) and writing up your protocol, you're finally at the bench and running your experiment. In addition to the adjustments that come out of your first few runs, now you're faced with yet another catch – what do I do with the chemical waste I collected from my research? Is it a hazardous waste or a nonhazardous waste? Can it go down the drain?

Hazardous waste regulations are enforced by the Environmental Protection Agency (EPA) through the Resource Conservation and Recovery Act (RCRA) of 1976. With a few amendments along the way, and some state-specific variations in its implementation, the RCRA definition of a hazardous waste can be summarized as any chemical meeting any of four characteristics , or appearing as a listed waste. Pictured at left is the Columbia University Chemical / Hazardous Waste label. In the blue box there is a row of six checkboxes: Ignitable, Toxic, Corrosive, Oxidizer, Reactive, and Nonhazardous. The job of all researchers is to write down all of the contents (and percentages or quantities) of the waste and check the box(es) that best match the chemicals that are added to the container. The result is then evaluated by trained professionals in EH&S and the University's hazardous waste contractor in order to make a final waste determination. And with that, researchers are spared the nuances (and many lists) of RCRA law!



A properly styled waste label. *Photo: Jon Paul Aponte*

When deciding which boxes to check, it's best to err on the side of caution and, for example, mark "ignitable" if any flammable contents are added to the container and written on the label. In the case of a weak acid or base mixture, it is a good suggestion to take a quick pH prior to checking the "corrosive" box, as a large container with only a few milliliters of an acid often will not result in an acidic mixture. If a pH test is performed, write the result on the label as this information is helpful to making a proper determination. The hardest decision often lies with whether or not to check "nonhazardous". Nonhazardous is appropriate to check when none of the other five categories describe the contents of the waste, and the material was ineligible for drain disposal. Below are listed some EH&S resources including an index of common nonhazardous wastes, and the short list of materials suitable for drain disposal.

EH&S provides chemical waste management services to the research and teaching community at Columbia, and performs the physical chemical waste pick-up and delivery of labels and empty containers. The department also aids laboratories in the proper labeling and classification of chemical waste. As always, EH&S is happy to help with any individual questions at hazmat@columbia.edu.

Resources:
Columbia University EH&S Drain Disposal Policy: https://research.columbia.edu/content/policy-drain-disposal-chemicals
A list of Common Nonhazardous Waste Types at Columbia: https://research.columbia.edu/sites/default/files/content/EHS/Waste_Hazmat/NHWList.pdf
A fuller definition of Hazardous Waste:
https://research.columbia.edu/content/hazardous-chemical-waste-management-guidelines
A comprehensive CU EH&S handbook, Chapter IV. Hazardous Waste Management and Disposal:
https://research.columbia.edu/sites/default/files/content/EHS%20Handbook%202020%20FINAL.pdf
Form to Request a Waste Pick up or Supply Drop off: https://research.columbia.edu/chemical-waste-pick-up-request.
How to Prep Chemical Waste for Pick up, AKA the 5Ls Poster: https://research.columbia.edu/sites/default/files/content/EHS/Waste_Hazmat/5Ls.pdf

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