Questions & Answers about the Tufts University School of Medicine Arnold 8 Biosafety Laboratory

The Tufts University School of Medicine Arnold 8 Biosafety Laboratory will enable the School of Medicine, a world leader in infectious disease research, to develop innovative strategies to detect, prevent and treat many diseases that threaten human health worldwide.

Project Overview

What is the Arnold 8 Biosafety Laboratory?
The Arnold 8 Biosafety Laboratory is a research laboratory planned for part of the eighth floor of the Arnold Wing of the Biomedical Research and Public Health (BRPH) Building at the Tufts University School of Medicine. It would be located at 136 Harrison Avenue, at the corner of Kneeland Street and Harrison Avenue, in Boston. As a biosafety level 3 (BSL-3) facility, the proposed lab will provide a fully regulated, safe and secure environment in which our researchers can study microorganisms that cause serious but treatable infectious diseases -- such as tuberculosis -- which can be transmitted to people by breathing air that contains these organisms. The research conducted in this laboratory will advance understanding of the causes of these diseases and will help us detect, prevent and treat them. This knowledge can lead to important innovations such as the development of new vaccines, drugs or other ways to prevent or cure infection.

How large will the laboratory be?
The proposed laboratory will be approximately 1,700 square feet – about the size of a classroom. It represents less than 1 percent of the total space of the existing 260,000 square foot BRPH building where it will be located.

Are there any BSL-3 laboratories now operating in the Boston area?
Yes. The Boston Public Health Commission currently oversees permitting for 11 BSL-3 laboratories operating in the city of Boston. They include laboratories at Boston University, Brigham & Women's Hospital, Children's Hospital, Dana Farber Cancer Institute, and Harvard University. A number of other BSL-3 labs are located in Massachusetts and across the country.

Why is this laboratory needed?
Over the last several decades, a number of diseases previously under control have re-emerged as more severe or difficult- to-treat strains. Tuberculosis is an important example. Many of these diseases and the organisms that cause them can only be studied in a BSL-3 laboratory, which is specially designed with protective features that enable researchers to work with such organisms safely and effectively.

The Department of Molecular Biology and Microbiology at Tufts University School of Medicine has been at the forefront of infectious disease research for many years. For example, 45 years ago, the first chair of the department discovered how penicillin kills bacteria. More recently, we uncovered why HIV generates resistance to drugs so quickly, knowledge that is essential to how we treat HIV/AIDS today. Until now, our faculty have focused their research in areas that do not require BSL-3 facilities. Today, however, there is a growing and unmet need for research on diseases and pathogens that require a BSL-3 laboratory. Most other world-class microbiology departments already have such laboratories. Without such a lab, our School of Medicine researchers are increasingly limited in their ability to study important infectious diseases. This new research space will enable TUSM to recruit more top scientists to do vital research and allow current faculty to expand their efforts.

Could Tufts University School of Medicine Use an Existing BSL-3 Laboratory?
No. There are many reasons why we need to build a BSL-3 lab on our Boston campus. First, researchers working in the new laboratory will also need to perform important support experiments that do not directly involve BSL-3 pathogens but do require other department facilities close by. In fact, the relatively small Arnold 8 Biosafety Laboratory will be surrounded by a larger conventional microbiology laboratory so that researchers can perform such support experiments. In addition, the School of Medicine's mission is to teach as well as do research. Therefore, we need a biosafety lab that will give our faculty easy access to their students and teaching facilities. Our BSL-3 researchers will also need to work closely with and get advice from other researchers at our medical school in order to design the most effective experiments.

When would the Arnold 8 Biosafety Laboratory open?
Plans call for opening the proposed lab in 2013.

Will the community have input into the project?
The safety and well-being of our neighbors, as well as the Tufts community, is always of the utmost importance to the medical school and the university. We are committed to working very closely with our Chinatown neighbors and the city of Boston during development of the proposed facility and throughout its operation. To ensure accurate and timely communication, we are creating a Community Advisory Committee. The Committee members will represent a cross-section of the community. Through this Committee we will share information about the proposed project and receive feedback so that we can address any questions or concerns.

How does Tufts' facility differ from the laboratory built by Boston University?
The laboratory that Tufts plans is very different from the facility built by Boston University. Boston University constructed a 192,000 square foot, standalone building that includes a BSL-4 laboratory to study the most dangerous infectious diseases for which no treatments exist. Tufts is planning a 1,700 square foot BSL-3 laboratory within an existing building to study serious diseases, such as tuberculosis, that are treatable but for which new treatments are needed.

How are biosafety laboratories classified?
The U.S. Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) classify biosafety laboratories as level 1 through 4. Essentially, as the number gets higher, the agents (disease-causing microorganisms or toxins) being studied are more serious, and less likely to have existing vaccines, treatments or cures. In addition, as the BSL number increases, more protective features are required for the researchers and increased safety features are incorporated into the laboratory design and

operations. A BSL-3 lab studies serious infectious diseases for which some treatments already exist but for which more effective treatments or cures are needed. For example, treatments for TB exist but as new varieties of the disease emerge, new treatments are needed. In contrast, a BSL-4 laboratory, such as that built by Boston University, studies extremely serious infectious diseases that currently have no cure. Tufts has absolutely no intention of building a BSL-4 lab.

Does Tufts have experience operating a BSL-3 facility?
Yes. On our campus in Grafton, Mass., about 40 miles from Boston, Tufts' Cummings School of Veterinary Medicine operates two BSL-3 laboratories, including a Regional Biosafety Laboratory funded by the National Institutes of Health.

More about the Research

What diseases will be studied?
In the Arnold 8 Biosafety Laboratory we will study serious but treatable infectious diseases that pose risks to public health both in the U.S. and around the world. Those risks are increasing as new strains of pathogens emerge. The first priority will be to combat tuberculosis (TB), caused by a bacterium that infects as much as a third of the world's population, according to the World Health Organization. TB is a serious health issue in Boston and the Chinatown community. In fact, the Boston Public Health Commission estimates that TB is about 20 times more common among Asians in Boston than among Caucasians. A better understanding of the bacterium that causes TB has the potential to help save millions of lives. Depending on future health needs and the research specialties of our faculty, we may also study additional important infectious agents.

How serious are these diseases?
Although treatments exist for all of the infectious agents that we will study in our proposed BSL-3 facility, diseases caused by these organisms, when untreated, can be very serious, even life-threatening. The organisms that cause these diseases are transmitted by breathing in air that is contaminated with them. The potential seriousness of these infections is the main reason why Tufts needs to develop active research programs to combat their spread and health impacts.

Will the laboratory work with select agents or select toxins?
We are not seeking approval to study any select agents or toxins. The laboratory's highest priority will be the bacterium that causes tuberculosis, which is not classified as a select agent. Select agents and toxins are a specific category of viruses, bacteria, fungi, and other disease-causing substances identified by the CDC or U.S. Department of Agriculture as potentially posing a severe threat to public health and safety. Our current plans do not include study of select agents. However, the Arnold 8 Biosafety Laboratory will be designed to safely accommodate such research. If in the future we want to study select agents or toxins, we will have to apply for and receive approval from the Boston Public Health Commission and also obtain approval from the CDC. We would share such plans with the community, working closely with the Community Advisory Committee throughout the permitting process.

How many people will work in the lab?

Approximately 25 to 30 Tufts researchers will be authorized to access the lab. Five to six people would work in the lab at one time. They will include faculty, postdoctoral fellows, laboratory technicians and graduate students, all of whom will be thoroughly trained and tested to ensure their own safety and the safety of others.

Will they undergo background checks?
Yes. Tufts will allow Arnold 8 Biosafety Laboratory access to only a limited number of trustworthy individuals who are screened and qualified to do such research.

What kind of safety training will lab workers receive?
No one will be allowed to work in the lab until he or she has been thoroughly trained by Tufts' Environmental Health and Safety Department. The Boston Public Health Commission requires that Tufts submit our training plan to the Commission before we can receive a permit to operate the laboratory. Training includes proper use and handling of the specific kinds of biological samples personnel will be working with, as well as extensive instruction on the proper use of protective clothing and equipment. Workers will be tested on their understanding of biosecurity, containment protocols, appropriate actions in case of different emergencies, and proper recordkeeping. We will review the training program each year to ensure that it reflects best practices and provide refresher training as needed.

Who is in charge of assuring that research at Tufts School of Medicine is conducted safely?
Several groups at Tufts take an active role in ensuring that all research is conducted safely and that Tufts employees and students as well as the greater community are protected. The primary responsibility for maintaining safety in our laboratories rests with the biosafety and laboratory safety professionals in Tufts University Environmental Health and Safety Department. They work very closely with researchers across the university to ensure the safety of ongoing work with infectious agents. They review research protocols, provide training and conduct routine audits of all laboratory and research facilities at Tufts. Specific protocols and procedures are carefully documented and approved before research can be conducted.

In addition, the Tufts University/Tufts Medical Center Institutional Biosafety Committee (IBC) is responsible for making sure that research involving infectious agents is conducted to meet all regulations and with proper attention to research personnel, the environment and the community. The IBC includes both community and Tufts representatives. Every experiment proposed for the Arnold 8 Biosafety Laboratory will be submitted to the IBC for prior review; that submittal must include a risk assessment by the Biosafety Officer for the School of Medicine and the scientists involved. The IBC is required to provide a yearly report to the Boston Public Health Commission. That report must document efforts undertaken to ensure and enhance safe and effective laboratory operation and include minutes of its meetings.

The Tufts Boston Laboratory Safety Committee, a committee appointed by the Dean of the School of Medicine, meets regularly to review all laboratory inspection findings and any incident or accident that occurs in any School of Medicine laboratory. This committee includes faculty and administrators from both the School of Medicine and Tufts Medical Center.

The Boston Public Health Commission and Boston Fire Department will inspect the facility at least once a year, as they do all of the other BSL-3 laboratories in Boston. The BPHC inspection includes review of

policies, procedures and on-site documentation; staff interviews; and physical observation and assessment of the laboratory. BPHC regulations require that each final inspection report be available to the public.

Facility Design & Operation

What kinds of equipment and facilities will the Arnold 8 Biosafety Laboratory contain?
This laboratory will be self-contained and fully equipped with everything needed to study the biology of specific disease-causing microorganisms and how they interact with human cells to cause disease. The laboratory will include refrigerators and freezers, autoclaves to sterilize equipment and waste through high-pressure steam, incubators to grow cell cultures, centrifuges that spin substances in order to separate individual components, and biosafety cabinets. Biosafety cabinets provide a physical barrier between disease-causing organisms and the researchers and also pull air that might be exposed to the organisms away from researchers.

Will workers wear protective clothing?
Yes. Before going into the part of the facility where research is done, BSL-3 workers will remove their usual clothing and put on pants and shirt (sometimes referred to as "scrubs") and shoes that will be worn only in the laboratory. They will also wear a disposable, protective coverall that completely covers the scrubs and foot protection that covers their lab shoes. Additional protective clothing may be worn if needed, to meet federal Occupational Safety and Health Administration (OSHA) requirements. Personal respiratory and eye protective devices will also be worn. Finally, many types of protective gloves will be worn, depending on the task. All personnel wearing personal protective equipment will be trained on its proper use in accordance with OSHA regulations.

Before leaving the lab, workers will remove their scrubs, laboratory shoes and all protective clothing and equipment. The protective clothes, which include the coverall, shoe coverings and gloves, and protective equipment, will be sterilized by high-pressure steam in an autoclave before being incinerated offsite. Scrubs are always covered by protective clothing, so they are not exposed to contamination. However, as a precaution, scrubs will also be sterilized and then washed at high temperatures before they can be worn again. Depending on research procedures, lab workers may shower before donning their own clothing.

How will the laboratory be built to ensure safety?
The laboratory will be designed and built to prevent any release of potentially infectious agents and to protect workers, the community and the environment. It will meet or exceed all applicable codes and regulations set by the City of Boston and Commonwealth of Massachusetts. It will also be designed in accordance with the National Institutes of Health (NIH) and Centers for Disease Control (CDC) guidelines published in *Biosafety in Microbiological and Biological Laboratories* (BMBL), which is the most widely accepted foundation of good biosafety policy and practice.

Multiple safety features will include doors that self-close and lock as well as sealed floors, walls, ceilings and windows made from materials that are easily cleaned. The air pressure in the lab will be lower than the air pressure outside the lab in order to prevent air leaks. Air will be cleaned by special high efficiency particulate air (HEPA) filters that meet federal standards before it is vented from the building in which the lab is located. A continuous automatic monitoring system will ensure that the ventilation system is operating properly. If a problem occurs, the system will immediately alert trained personnel who will

address the situation. In addition, outside firms will test the air handling system each year to be sure it is working properly. In the event the regular power system is interrupted, a backup generating system will provide electricity so that all safety systems continue to operate.

How will liquid and solid waste be managed?
Research will be carefully planned to minimize creation of waste materials. All solid waste that might be contaminated will be disinfected within the BSL-3 facility before being removed. This will be done in an autoclave that exposes the material to high-pressure steam, or through chemicals that destroy harmful organisms. Each system will be tested to verify that it works properly. As an extra precaution, a licensed medical waste disposal company will remove all decontaminated material for incineration. Such waste will never come into contact with normal trash. Liquids exposed to BSL-3 agents will be either autoclaved or treated with disinfecting chemicals to ensure that they are safe before entering the sewer.

How will infectious agents and materials be moved into and out of the facility?
We will follow all requirements set by the U.S. Department of Transportation (DOT) for transporting, receiving, monitoring, and inventorying bio hazardous materials used in a BSL-3 facility. The DOT and the International Air Transport Association (IATA) require that such materials be packaged in three layers of protective containers that are able to prevent leaks of harmful agents even if the package is badly damaged. All packages will be shipped by commercial freight and transportation firms with training and experience in handling hazardous materials. Staff working in the laboratory will be trained in these requirements and will be responsible for ensuring that we meet all safety protocols. Because the planned lab is small, we expect there will be on average no more than one shipment to or from the lab per month.

What kind of emergency plan will be in place in case of an accident?
Every day, biosafety laboratories across Boston and Massachusetts conduct important research safely and securely. The well-being of our personnel, the community and the environment is Tufts' top priority as we plan the Arnold 8 Biosafety Laboratory, and we will be fully prepared in the unlikely event of an accident. The university has in place a general emergency operations plan, reflecting best practices of the National Incident Management System, which addresses how we respond and coordinate with local and state agencies. Tufts will also prepare an Incident Response Plan for the proposed laboratory that anticipates both natural and manmade incidents that might occur at the lab and identifies specific procedures to follow in the event of each such incident. These include fire, smoke, chemical releases, flood, vandalism, spills, power interruption, and other similar events. Every year, Tufts will conduct at least one exercise that simulates one or more of these events and requires the participation of all persons who have a role in responding to incidents. In addition, the City of Boston has detailed emergency response plans. Tufts will work closely with Boston public safety agencies should action be needed.

Will the lab be able to withstand severe storms and natural disasters?
The Arnold 8 Biosafety Laboratory will be built within a large, existing industrial grade building that has already withstood some of the most severe storms on record in Boston, including Hurricane Bob in 1991 and Hurricane Carol in 1954. It will not be directly exposed to the effects of severe weather, such as rain, wind or blowing objects. The facility will be designed to remain secure during all storms and expected natural disasters, based on 400 years of recorded history for Boston. The laboratory will meet the seismic, wind load and structural requirements outlined in appropriate building codes. In the event of a power loss, standby power will continue to operate security and safety systems, including air handling, freezers, elevators, fire alarms and fire protection controls. Security doors will automatically lock to prevent unauthorized access.

Will animal research be conducted in this laboratory?
No animal research will be conducted in this laboratory.

Who will be in charge of the facility?
As chair of the Department of Molecular Biology and Microbiology, John Leong will have primary responsibility for the Arnold 8 Biosafety Laboratory. He will have the support of Tufts' Vice Provost Peggy Newell, Dean of the School of Medicine Harris Berman, chair of the Institutional Biosafety Committee Cheleste Thorpe, and Steve Larson, the head of the Environmental Health and Safety Department at the University.

How will Tufts prevent unauthorized access to the Arnold 8 Biosafety Laboratory?
Multiple security measures will ensure that only authorized personnel have access to the lab. The main building is accessible only through a lobby staffed 24 hours a day by Tufts University Public Safety personnel and with an identification card. Devices that identify people by scanning their hands will ensure that only authorized persons enter the BSL-3 laboratory. These systems will also provide a record of dates and times of entry. The TUSM Biosafety Officer will check the records regularly. In addition, video security systems will provide further protection.

Project Development Process

What is the development process for the project?
Tufts is in the initial stages of project development, and we will work closely with the community throughout this process.

We have hired the Boston-based architectural firm of Payette to design the laboratory. Payette has designed more than 20 other BSL-3 laboratories across the country. In the summer of 2012, we expect to submit our application to operate a BSL-3 laboratory to the Boston Public Health Commission (BPHC). Our application will include detailed plans for all aspects of the laboratory as required by the BPHC. For example, these plans will cover procedures for working safely with biological agents and chemicals, laboratory startup and closure, decontamination procedures, emergency response planning, laboratory inspection, monitoring worker health, risk management, security, training, transportation of samples, and waste disposal. The BPHC will review the application thoroughly. We will also be applying for a building permit from the city of Boston. We hope to begin construction in 2012, with operation in 2013.

To ensure that community views are heard, we are planning to meet with neighborhood organizations, including the Chinatown Residents' Association, Neighborhood Council, CCBA, Safety Committee and Chinatown Coalition to share our plans. We will continue to meet with them as plans develop. We will be pleased to meet with additional groups that are interested in learning more about the project. We are also creating a Community Advisory Committee.

What role will the Community Advisory Committee have in this process?
The Arnold 8 Biosafety Laboratory Community Advisory Committee (CAC) will be thoroughly informed about all aspects of the proposed laboratory, so that members have a full understanding of the project. Our goal is for committee members to be well prepared to receive feedback from the community and share

questions or concerns. We hope the Committee members will represent a cross-section of Chinatown and reflect a variety of perspectives and interests. We are extending invitations to individual members of the community and welcome others who may want to participate. We expect the Committee will meet regularly to consider all aspects of our plan during the permitting process and may continue to provide an ongoing voice for the community.

How active is Tufts in the community?
Tufts tries hard to be a good neighbor to the communities in which we are located. For example, our School of Dental Medicine provides free care to all the children at the Josiah Quincy Elementary School in Chinatown. Our students provide free medical and dental care at the Sharewood Clinic and a Girls' Values Program at the Boston Chinatown Neighborhood Center (BCNC). We encourage and support many such partnerships and contribute to many local organizations. Our $2.2 million community benefit allowed the Wang YMCA to be built. Almost 30 years ago, we donated $100,000 to CCBA to fund scholarships to Tufts for Chinatown area students. We also partnered with Tufts Medical Center to buy the building at 50 Herald Square and donate it to the Chinese Consolidated Benevolent Association.

How much will the Arnold 8 Biosafety Laboratory cost?
The cost will be approximately $3.5 million, all of which will be paid by Tufts. There will be no public funding.

How can members of the public get more information about the project?
Information is available at medicine.tufts.edu/Research/Arnold8BiosafetyLab or from our Community Relations office, telephone: 617-627-3780 or by email: communityrelations@tufts.edu.