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CHANCELLORS
DIRECTOR ALIVISATOS
MEDICAL CENTER CHIEF EXECUTIVE OFFICERS

Dear Colleagues:

The use of biohazardous materials is an indispensable part of the University of California's teaching, research, and health-care mission. The University conducts ground-breaking research on a broad range of human, animal, and plant pathogens and toxins that is critical to understanding, evaluating, and designing countermeasures to emerging infectious diseases that can threaten human health and agriculture. In addition, our Medical Centers provide some of the most advanced and up-to-date care on emerging infectious diseases. Effective biosafety and biosecurity practices, as well as effective oversight, are key components of this research and medical enterprise.

Biosafety and biosecurity have recently come under increased scrutiny nationwide. This scrutiny has resulted largely from well-publicized incidents involving biohazardous materials, particularly two that occurred at federal laboratories in 2014. These incidents, as well as others, have led to heightened public awareness of research using biohazardous material, Congressional hearings, and directives from the White House and the National Institutes of Health (NIH). The latter include recommendations that institutions conducting federally-funded research, like UC campuses, re-examine their inventories of biohazardous material and re-assess their practices toward the goal of enhanced stewardship of biohazards and improved individual and public safety.

In partial response to these considerations, I convened a *Task Force on Biosafety and Biosecurity*. The Task Force was asked to identify UC's facilities and practices for the use of infectious agents and toxins, with an emphasis on Biosafety Level 3 (BSL-3)¹ laboratories.

¹BSL-3: Facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure and requires special engineering and design features.

In January, I met with members of the Biosafety and Biosecurity Task Force to discuss their findings and recommendations. Based upon the discussion with the Task Force Chairs and subsequent discussion at our Council of Chancellors' meeting, I am instructing campuses to implement the following objectives in line with the major recommendations produced by the Task Force:

1. Each campus that operates or is actively planning recommissioning or construction of a high-containment facility (BSL-3 and Select Agent or Toxin²) should create and fund a *High-Containment Laboratory Director* position within its current biosafety program. Appointments should be made by June 1, 2015, or planned for at the appropriate time in the new program's budget, if applicable.

The candidate should be properly qualified, trained, and empowered to be responsible for oversight of all aspects of the high-containment facility operations and management on that campus, including oversight of facility design, construction, maintenance, certification, performance verification, and provision of validated training programs. The individual should possess relevant background, experience, and training in high-containment facilities and biosafety issues.

In consultation with campus leadership, the Office of the President's (UCOP) Office of Risk Services is in the process of evaluating the cost for seed-funding for staffing and training the *High-Containment Laboratory Director* position on facility improvements and laboratory validations.

2. A site visit team, led by UC Irvine's BSL-3 Training and Development Program Director, will gather additional information from the system's high-containment facilities regarding their operations, testing and verification, and personnel training needs.
 - a. UCI will establish a team of experts for this purpose.
 - b. Visits will be initiated by May 15, 2015, with a target completion date of December 31, 2015.
3. Campuses shall use the UCI National Biocontainment Training Center³ to conduct initial and refresher training of the *High-Containment Laboratory*

² Select Agent or Toxin (SAT): A pathogenic organism or toxin which has been listed by the U.S. Department of Health and Human Services or by the U.S. Department of Agriculture to have the "potential to pose a severe threat to public health and safety."

³ The UCI program was established through funding support from the NIH-Regional Centers of Excellence program and has provided integrated training to over 900 people from across the U.S. and internationally including personnel from academic, public health, government, military, and corporate sectors.

4. *Directors*. Ultimately, all high-containment and SAT facility personnel groups should receive appropriate integrated cross-training.
 - a. The initial training should commence by May 15, 2015, with a target completion date of October 31, 2015.

5. Each campus should establish a *High-Containment Laboratory Oversight Group* (Group) to coordinate laboratory operations, including preventative maintenance, testing and verification, and planning of modification to existing and proposed high-containment facilities, emergency management planning, and implementation of training for all laboratory-associated personnel groups.
 - a. Because high-containment facilities are extremely complex to build and operate, this Group should include expertise from a cross-section of campus divisions, including Research, Facilities, Finance, Police, and Construction, and Planning and Administration. A campus may designate an existing committee to serve this function, as long as it includes representation from the appropriate areas, as specified.
 - b. The Group's activities should be coordinated with the existing Institutional Biosafety Committee (IBC) and Environment Health and Safety (EH&S) Biosafety unit by including representatives of same. For campuses with a Medical Center or School of Medicine, representatives from these enterprises should be part of the Group. It is strongly encouraged that campuses also consider appointing, at least initially, representatives from their campus who were part of the systemwide Task Force. This would provide continuity between the Task Force recommendations and the initial activities of the campus High-Containment Laboratory Oversight Group.
 - c. Campus Oversight Groups should be convened no later than July 31, 2015.

6. UCOP will establish and facilitate a systemwide committee composed of Chairs and representatives of each campus's *High Containment Laboratory Oversight Group* to enable sharing of best practices and development of policies and guidance. The intent is to strengthen consistency in practices within the high-containment facilities and to provide a conduit for addressing ongoing BSL-3 issues to the President's Office.
 - a. The systemwide committee should convene before August 31, 2015.

7. All campuses should conduct an inventory of their infectious agents that incorporates positive Principal Investigator (PI) attestation that he or she has reviewed their inventory of biohazardous agents, that the inventory is consistent

Chancellors, et al.

March 4, 2015

Page 4

with list of agents declared on their Biohazard Use Authorization (BUA), and that they are either aware or unaware of any unaccounted-for freezers or laboratory space in which unidentified biohazards might be suspected.

8. This survey should be sent to the broadest scope of PIs and faculty who have assigned laboratory space on each campus to ensure that all potential users are queried, regardless of whether they have a current BUA. Campuses that have not yet done so should use the UCSD survey or a similar instrument to document a review of their inventories in a manner that provides PI attestation.

The University must continue to be a leader in research and patient care with respect to infectious disease. By implementing the practices and recommendations outlined above, we will better enable research using biohazardous materials to be performed with minimal risk to the researchers, operations and support staff, the general public, and the environment. By strengthening our abilities to conduct this research safely, we are continuing UC's tradition of excellence within the state and nationwide.

Yours very truly,



Janet Napolitano
President

Enclosure

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