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Subject: FW: [cogr-l] Government-wide Biosafety Stand-Down

From: cogr-l-request@usc.edu [cogr-l-request@usc.edu] on behalf of COGR [cogr@usc.edu]
Sent: Wednesday, August 27, 2014 8:08 AM
To: cogr-l@usc.edu
Subject: [cogr-l] Government-wide Biosafety Stand-Down

There has been a lot of speculation about a government-wide biosafety "stand down" following the Department of Veterans Affairs sending notices to its own research institutions on the topic. Our colleagues at the Association of American Universities (AAU) discussed the subject with senior Administration officials on Tuesday, August 26, and received permission to provide additional information to clarify the issue under consideration by the Federal government for the research community. Please note: the following Q&A is not an official communications from the government but based on notes from the discussion with AAU staff.

- **What is the stand-down**? Essentially, what the government will request is a short term – on the order of 24 hours – suspension of research involving high-consequence pathogens in order to allow institutional lab personnel to take stock of what pathogens they have stored in freezers, cold rooms, etc. This is prompted by some recent, high profile biohazard stories, such as the discovery of smallpox in cold storage at NIH. This would apply to research conducted by and funded by federal research agencies. With the focus on high-consequence pathogens the impact, nonetheless, should be focused on a known group of labs.

- **Where does this directive come from**? The directive would come from the Office of Science and Technology Policy (OSTP), through the research agencies, via a memorandum. OSTP had anticipated issuing the memorandum last week but that action is delayed to allow for additional consultation with the Federal agencies. OSTP anticipates the memo will be released soon, at which point labs and institutions may be contacted by multiple agencies about the stand-down. In light of the likely multiple calls for a stand-down, we encourage institutions to coordinate the activity on campus to avoid miscommunications.

- **Does this only apply to Select Agents**? No, because all institutions using Select Agents and Toxins should already be keeping track of those pathogens. Ideally, the federal agencies would ask institutions to take stock of all pathogens stored in laboratories. However, they are giving latitude to the scientific community to identify which pathogens, in particular, labs and institutions should be inventoried.

- **How is this enforceable**? **What are the consequences for non-compliance**? In short, it's not enforceable and there are no consequences for non-compliance. This request is deliberately more about best practices in lab management than it is about imposing new regulations on the community. As of now, the government cannot force any individual or institution to go through this process. Instead, the government is seeking voluntary compliance in a timely manner consistent with the proper management of pathogens. In that vein, the American Society of Microbiology is calling on its members to go through a similar inventory exercise: https://www.asm.org/index.php/publicpolicy-2/statements-testimony/99-policy/policy/93059-freezer-8-14 .

Institutions should consider revisiting policies and procedures for closing out labs when investigators transfer to other institutions, retire or change research focus. Often, pathogens are left behind for the use of post-doctoral fellows and graduates to complete work in progress. With the departure of fellows and students, pathogens languish forgotten or ignored in freezers and cold rooms. The Federal government hopes that a systematic stand-down and thorough inventory will allow institutions to identify orphaned pathogens and conduct orderly

disposals of the materials. The discovery of small pox on the NIH campus was just such an event – materials used by long-departed investigators and stored for a future use that never evolved.

- **Will this result in new policy/regulations**? That is not currently the government's intent. It is good to keep in mind that opportunities for additional biosafety/biosecurity regulations are always a possibility, as we are still expecting the next iteration of the dual use research of concern (DURC) policy which will be an institutional policy as a companion to the US Government policy for agencies already in effect and the Select Agent regulations are periodically updated. For the moment, however, this stand-down remains the sum total of government actions.

When the official memo is released, or if we or AAU receive any additional information, we will keep the membership informed.

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