NIH National Biosafety Stewardship Month

Recent lapses in biosafety practices involving Federal laboratories remind us of the importance of constant vigilance over the implementation of biosafety standards. These events potentially put individuals at risk, undermine public confidence in the research enterprise, and must be addressed to prevent their reoccurrence. Therefore, the National Institutes of Health (NIH) announced that September 2014 would be declared “National Biosafety Stewardship Month” with the primary goal to strengthen biosafety oversight and practices.

UCSF is actively working under the guidance of UCOP to establish a formal response to the requests made by the NIH, other funding agencies, and the White House Office of Science and Technology Policy (OSTP). In conjunction with these efforts, all laboratories should continue to evaluate their individual biosafety status and maintain a high level of safety and security. Your participation in this biosafety review is critical.

To ensure that UCSF complies with the attached NIH announcement, the UCSF Institutional Biosafety Committee (IBC) requires all laboratories perform the following:

- Conduct an inventory for all infectious agent(s) and toxin(s) present in all PI laboratories (including all refrigerators, freezers, liquid N\textsubscript{2} storage units, and cold rooms)
  - Ensure that all biological materials (both in use and in storage) are listed on your Biological Use Authorization (BUA)
  - Dispose of infectious agent(s) and toxin(s) that will no longer be used
  - Notify the UCSF Biosafety Officer if sample cannot be identified and/or ownership cannot be determined
- Review validation and training for infectious agent and toxin inactivation procedures
- Verify that all lab members are listed on the BUA and are current with required UCSF safety trainings

The full text of the NIH announcement is attached.

For questions or to request assistance, please contact the Biosafety Officer at 514-2824 or peili.zhu@ucsf.edu.

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Notice of National Biosafety Stewardship Month and Health and Safety Requirements for NIH Grantees

Issued by
National Institutes of Health (NIH)

Purpose
Recent reports of lapses in biosafety practices involving Federal laboratories have served to remind us of the importance of constant vigilance over our implementation of biosafety standards. These events potentially put individuals at risk, undermine public confidence in the research enterprise, and must be addressed to prevent their reoccurrence. Efforts to strengthen biosafety oversight and practice must be supported and carried out by organizational leadership, biosafety programs, and individual laboratories.

The purpose of this notice is to announce a new biosafety stewardship initiative and to remind institutions of the NIH requirement to meet all applicable Federal, State, and local health and safety standards, as well as the specific terms and conditions of award outlined below.

National Biosafety Stewardship Month
As a measure toward preventing future lapses as well as promoting stewardship of the life sciences and biosafety awareness across Federal entities, Federal laboratories will reinforce their attention to safe practices in biomedical research. In that regard, the NIH and other HHS agencies will be instituting National Biosafety Stewardship Month, and we urge all NIH grantee institutions and/or contractors to do the same at the local level.

In the month of September, NIH laboratories will, and grantee institutions and/or contractors are encouraged to, do the following:

- Reexamine current policies and procedures for biosafety practices and oversight to ascertain whether they require modification to optimize their effectiveness;
- Conduct inventories of infectious agents and toxins in all laboratories to ensure that the institution has a record of which infectious agents and toxins are being utilized, has documentation that those materials are properly stored under the appropriate containment conditions, and has documentation that cites the party responsible for appropriate stewardship of the materials; and
- Reinforce biosafety training of investigators, laboratory staff, and members of IBCs to include reexamining training materials and practices being utilized by the institution;
- Updating materials as appropriate; and
- Ascertaining the appropriate frequency of training and conduct training when the interval between training or other considerations warrant it.

NIH grantee institutions and/or contractors are expected to run rigorous programs of biosafety oversight that include attention to safe laboratory practices, training, appropriate policies and procedures. National Biosafety Stewardship Month is an opportunity for you to reinforce what you do in that regard, to optimize further biosafety oversight, and to strengthen your partnership with your investigator community to achieve shared biosafety goals. Your Institutional Biosafety Committees (IBCs) and Biological Safety Officers (BSOs) will have an important role to play in the success of this effort, and NIH will be sending them a letter to encourage their participation. Institutional leadership should do what it can to support IBCs and BSOs in this effort and in the conduct of their duties generally.
General Health and Safety Requirements

NIH continues to require its grantees and/or contractors to meet applicable Federal, State, and local health and safety standards and for establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, terms and conditions of all NIH grant awards require that grantees and/or contractors adhere to the following when developing and implementing health and safety operating procedures and practices for both personnel and facilities:

- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. The NIH Guidelines articulate biosafety practices, containment measures, and oversight requirements that must be employed by institutions receiving NIH funding for research involving recombinant or synthetic nucleic acid molecules, and apply to all such research regardless of source of funding. The NIH Guidelines may be found at: [http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines)

- 29 CFR 1910.1030, Blood borne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety and Health Administration (OSHA) and included in 29 CFR 1910. Moreover, compliance with the regulations will reflect a culture of safety consciousness, accountability, organization, and education. A sound safety organization that is respected by all requires the participation and support of laboratory administrators, workers, and students. A successful health and safety program requires a daily commitment from everyone in the organization. To be most effective, safety and health must be balanced with, and incorporated into, laboratory processes. These regulations are available at [http://www.osha.gov/pls/oshaweb/owastand/display_standard_group?p_toc_level=1&p_part_number=1910](http://www.osha.gov/pls/oshaweb/owastand/display_standard_group?p_toc_level=1&p_part_number=1910).


The following guidelines are among other resources available for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:


The signature of the Authorized Organization Representative on the application certifies that the organization will comply with all applicable assurances and certifications referenced in the application. By drawing funds from the HHS payment system, the NIH grantee further agrees to the terms and condition of grant/contract award. Although grantee organizations and are not required to submit documented assurance of their compliance with or implementation of these regulations and guidelines, if requested by NIH, grantees should be able to provide evidence that applicable Federal, State, and local health and safety standards have been considered and have been put into practice.