



AUG 28 2014

National Institutes of Health
Bethesda, Maryland 20892

TO: Institutional Biosafety Committee (IBC) Chairs
Biological Safety Officers
Contacts for IBCs

FROM: Director, NIH

SUBJECT: Participation in National Biosafety Stewardship Month

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.

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 to do the same at the local level (please see the applicable notice in the [NIH Guide for Grants and Contracts](#)). In this effort, as critically important leaders at the local level, the biosafety community has a vital role. I am hoping that you can support this effort at your institution by reinforcing and optimizing activities that are already part and parcel of how you normally do your jobs.

What is National Biosafety Stewardship Month?

During the month of September, NIH laboratories will, and NIH grantee institutions 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 (regardless of whether they involve recombinant or synthetic nucleic acids) 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

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- 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.

What's my role?

You already have important responsibilities to oversee implementation of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* at your institution. Under the *NIH Guidelines*, institutions, IBCs, and Biological Safety Officers are expected to run rigorous programs of biosafety oversight that include attention to safe laboratory practices, training, appropriate policies and procedures, and more. 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 institution's investigator community and senior leadership to achieve shared biosafety goals.

What should my institution do if we uncover problems such as inadequate training or improperly stored samples?

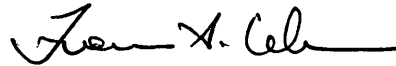
Our common aim is to correct any problems as soon as possible. So, a priority is to discern the nature of the problem, identify its root cause, and to implement immediately corrective actions. You should also be empowered to undertake the necessary follow-up activities with regulatory and oversight authorities that would be expected. For example, if violations of the *NIH Guidelines* are found, or other significant problems involving research subject to the *NIH Guidelines*, you should report those to NIH, as required by the *NIH Guidelines*. If a problem involves a Select Agent, it should be reported to the CDC or USDA Select Agent program as appropriate. Other problems may require notification of public health officials or law enforcement. In short, all existing reporting requirements should continue to be followed, and your institutional leadership should partner with you and give you the necessary support to see that this happens.

What if I have questions about our efforts to participate in National Biosafety Stewardship Month?

Please feel free to contact NIH as follows:

<p>Questions about adherence to the <i>NIH Guidelines</i> can be directed to:</p> <p>Program on Biosecurity and Biosafety Policy Office of the Director National Institutes of Health 6705 Rockledge Drive, Suite 750 Bethesda, MD 20892-7985 301-496-9838 (ph) 301-496-9839 (fax) PBBP@od.nih.gov</p>	<p>Questions about the <i>NIH Guide</i> notice, or NIH grants requirements:</p> <p>Office of Policy for Extramural Research Administration Office of Extramural Research National Institutes of Health 6705 Rockledge Drive, Suite 3500 Bethesda, MD 20892-7985 301-435-0949 (ph) 301-435-3059 (fax) GrantsInfo@nih.gov</p>
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Thank you for your attention to this important matter.



Francis S. Collins, M.D., Ph.D.