

Revisit NIH biosafety guidelines

To celebrate the anniversary of an arcane federal guideline is a rare event. For an agency to use that moment to invite reflection on modifying policies is even rarer. Last month, the U.S. National Institutes of Health (NIH) did just that, with a workshop that marked the 40th anniversary of its Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. The meeting was an inspiring start for charting future oversight of nonclinical applications.

The guidelines, created to address research risks associated with genome engineering, affect institutions receiving NIH support for such research. Responsibilities include setting up Institutional Biosafety Committees (IBCs) to assess risks and potential hazards through standards for containment and laboratory practices. Noncompliance on any project, whatever the funding source, can result in loss of all such NIH funding. In his address to the workshop, David Baltimore—an organizer of the 1975 Asilomar Conference that motivated the safety guidelines for recombinant DNA technology—argued that research conducted under the guidelines has been safe and adequately contained, and that natural selection “took care of the rest,” as genetic alterations did not confer fitness or reproductive advantages.

Today, however, three developments may necessitate modification of oversight. Easy-to-use gene-editing tools are diffusing from universities and companies to personal and community labs and across international borders. These new locales typically do not depend on NIH funding and lack IBC oversight. Gene drive systems can increase the odds of inheritance of an altered gene from 50 to 99.5%; natural selection may not limit propagation of non-Mendelian constructs. And conventional risk management practices that focus on listed pathogens may underestimate risks of new, unlisted organisms. The informality of voluntary guidelines has enabled prompt responses by funders and researchers

to emerging evidence on benefits and risks of technologies. But what has worked with those receiving NIH funding with IBCs may not work with the wider range of actors who now have access to these technologies.

How might the NIH address these issues? Its participation in international forums should expand, including consultations with the International Expert Group on Biosafety and Biosecurity Regulations, World Health Organization, and United Nations Biological Weapons Convention. Research funders, publishers, insurers, and the NIH should set common benchmarks on researcher conduct and link access to funding, publication, and

underwriting to adherence to common standards. The NIH should engage more directly with institutional biosafety officers, whose awareness of events on the ground should inform the guidelines and who provide a direct channel for influencing researcher behavior. Programs are needed in settings lacking IBCs, such as the Woodrow Wilson Center’s “ask a biosafety officer” program. Another example is the safety committee of the International Genetically Engineered Machine competition, which provides mechanisms to reach community laboratory teams.

The scope of the guidelines to address biosecurity concerns also should expand. For example, NIH

could require researchers to obtain synthesized DNA from firms adhering to U.S. Department of Health and Human Services’ guidance on security screening of orders. And it would be wise for the NIH to require open preregistration of experiments as a condition of funding, starting in high-risk fields such as gene drives, to foster reevaluation of safeguards, benefits, and risks.

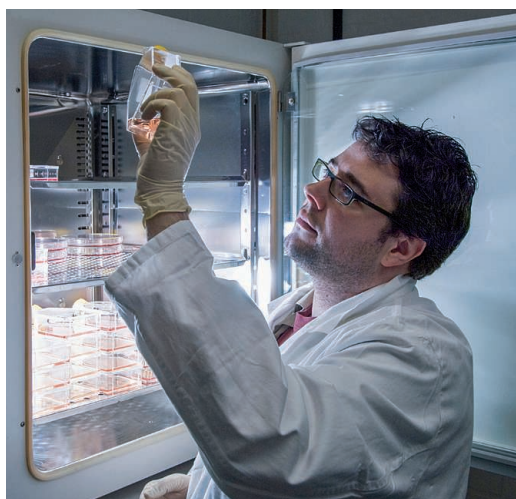
Ideally, research supported by all funding sources in all countries and research settings would be covered in the future guidelines. We call upon all stakeholders and interested parties to work creatively and expeditiously to build a system that will meet these needs.

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