ENVISIONING AN INDEPENDENT BIORESPONSIBILITY AUTHORITY TO SAFEGUARD U.S. LEADERSHIP IN THE LIFE SCIENCES

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This white paper, written by staff at the Scowcroft Institute's Biosecurity and Pandemic Policy Center and colleagues and informed by working groups convened by the center, articulates the authors' vision for an ideal biorisk management framework. The opinions and views expressed in this document should not be construed as representing those of the Bush School of Government and Public Service, Texas A&M University, or any institution or person other than its authors.

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Envisioning an Independent Bioresponsibility Authority to Safeguard U.S. Leadership in the Life Sciences

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Executive Summary

Background

Safeguarding U.S. leadership in the life sciences will require a unified, modernized, and fully independent governance framework that can ensure the safety and security of basic and early-stage research and adapt to rapid scientific and technological advances. These advances can unlock incredible benefits, including life-saving treatments and economic vitality, but they also contribute to a swiftly evolving safety and security risk landscape.

The assortment of federal biological risk management policies is fragmented, with major gaps in some areas and overly burdensome requirements in others. A more flexible and comprehensive system of oversight is needed to enable innovation and minimize risks. Such a system would foster collaboration and information sharing to obtain higher levels of safety, security, and compliance with regulatory standards and voluntary guidelines.

Bioresponsibility **is the commitment to conducting life science research in an ethical, secure, and safe manner to reduce the risk of misuse and accidents.**

In keeping with best practices for U.S. Government (USG) oversight in other fields that face significant risks—including air travel, finance, chemical production, and nuclear power—an independent federal bioresponsibility agency is needed to support the nation's continued preeminence in global life science research and the international bioeconomy. To be fully independent, such an agency would need to be separate from any existing department or agency that funds, conducts, or promotes life sciences research. The recommendations contained in this document lay out a vision for what a bioresponsibility agency would do, and in some cases, how it might go about doing it. They reflect the professional experience of its authors, informed by conversations with experts in biosafety, biosecurity, and the life sciences.

Findings

Finding 1: Life sciences leadership offers health, economic, and security benefits
Driven by public and private investments in research and development, the bioeconomy makes up 5% of the U.S. GDP with significant growth expected by 2050. Research can save lives, as shown by the record-breaking speed of COVID-19 vaccine development. Biology can also be leveraged for security advantage by, for example, producing critical inputs for military equipment and supplies.

Finding 2: A small subset of life sciences research poses risks that could endanger public safety or national security and jeopardize public support
A wide range of experts agree that some potentially important life sciences research, especially work involving high-consequence pathogens, nevertheless poses safety and security risks. A major accident or security breach would not only endanger public health and safety but could also erode public support for the life sciences. In the nuclear industry, the Three Mile Island accident significantly increased public opposition to new power plants.

Finding 3: Rapid technological advances are raising new risks and expanding the pool of actors with access to advanced capabilities
Genetic engineering techniques once confined to the world's top laboratories are increasingly accessible and affordable, partly driven by the ability to outsource nucleic acid synthesis or even entire experiments. Artificial

intelligence promises to accelerate this trend and may also help bad actors evade common biosecurity controls, such as screening for nucleic acid synthesis orders.

Finding 4: Public trust in science has significantly declined
Surveys show a loss of public trust in science since 2020, although support for government funding of basic science remains high. While the origins of COVID-19 remain hotly debated, a majority of the public believes that the pandemic originated in a laboratory, suggesting that Americans are likely concerned about the possibility of research-induced disease outbreaks.

Finding 5: International bioresponsibility governance remains weak
High containment laboratory capacity is expanding worldwide in the absence of strong biosafety and biosecurity controls. While the World Health Organization and International Standards Organization have released guidance or standards related to biorisk management, lack of funding, weak institutions, and other challenges pose barriers to implementation.

Finding 6: The current USG biorisk management policy landscape is fragmented, imposing a high compliance burden while leaving gaps
The core bioresponsibility mission is divided between at least eight programs across four federal agencies and two departments, with no clear point of ownership or accountability. Many requirements are attached to federal funding, rather than implemented as regulations with force of law. As a result, commitment to safety and security may vary across institutions, and some high-risk work at non-federally funded laboratories receives no USG oversight. At the same time, compliance remains confusing and expensive for researchers and institutions.

Finding 7: USG policies do not uniformly provide transparent, independent oversight
Federal funding agencies and departments currently have a leading role in overseeing the research they support, raising concerns about perceived or actual conflicts of interest. Independence is widely regarded as an important feature of effective oversight. Additionally, little information is publicly available about oversight processes, laboratory accidents, or safety and security measures in place.

Finding 8: Other countries with strong life sciences sectors have stronger, more cohesive biorisk management frameworks than the United States
Switzerland, Canada, and the United Kingdom all have regulatory frameworks owned by a smaller set of agencies, resulting in more harmonized and consistent oversight than in the United States. Canada also promotes a collaborative approach to compliance. These countries have life sciences research productivity that rivals or exceeds the United States, showing that innovation can flourish under this kind of oversight.

Finding 9: Existing USG policies do not prioritize collaboration or information sharing
Existing oversight either relies on institutions to discharge their responsibilities without independent verification or uses threats of punitive action and burdensome investigations to ensure compliance. Other countries and industries use systems that aim to improve compliance and collect valuable safety information through collaborative compliance actions, non-punitive reporting systems, and technical assistance. While programs like the Federal Select Agent Program (FSAP) are moving in this direction, there remain few avenues for non-punitive engagement and no centralized government resource for answering compliance questions. Collaboration is important as regulations and other formal policy processes move slowly and lack the flexibility to adapt to rapid technological advances.

Finding 10: Little evidence exists to assess the effectiveness of many requirements
Bioresponsibility requirements have been developed based on judgment and experience rather than systematic study. There may be requirements that add little benefit compared to their cost.

Finding 11: Training on and awareness of bioresponsibility varies widely between institutions and the bioresponsibility workforce is rapidly aging
Although a strong safety culture requires widespread buy-in, surveys suggest that familiarity with key bioresponsibility topics varies widely within the research community. Every institution must create its own training materials, leading to duplicated effort. Also, there are few formal training or credential programs for bioresponsibility professionals, and the workforce is rapidly aging.

Recommendations

These recommendations form an integrated bioresponsibility policy framework overseen by an independent authority. While each recommendation can be considered separately, they are highly interconnected and meant to be implemented together.

Recommendation 1: Establish an independent bioresponsibility authority
Creating an independent federal agency to own the USG's bioresponsibility mission would improve focus and accountability, avoid perceived conflicts of interest or undue political influence, and create an opportunity to foster the culture needed to adapt to rapid advances. An independent authority should report to the President rather than an existing agency or department head.

Recommendation 2: Create a comprehensive, consolidated bioresponsibility regulatory framework
Based on a review of existing policies in the U.S. and abroad, the authority should create a unified set of regulations for the safe, secure, and ethical conduct of potentially high-risk life sciences activities. Regulations should apply to all research in the United States regardless of funding source, and equivalent processes should be developed for U.S.-funded work at international institutions.

Review of Dual Use Research of Concern (DURC) and research involving Pathogens with Enhanced Pandemic Potential (PEPP)
The authority should enact regulations to mandate a research review process based on that described in the White House DURC-PEPP Policy. Major proposed changes include:

- Non-federally funded research should undergo review;
- The definition of PEPP should be expanded to include animal and plant pathogens;
- All PEPP reviews should be conducted by a panel within the independent authority;
- DURC reviews that would be conducted by federal funding agencies should instead be conducted by the research institution or, by request, the independent authority. All results should be forwarded on an informational basis to the independent authority;
- The independent authority should be able to provide feedback on DURC reviews to research institutions but not overrule decisions except in extreme circumstances; and
- The authority should publish as much about its review process and rationale for individual decisions as is consistent with protecting privacy, proprietary information, and security.

Regulatory standards for DURC & PEPP and activities involving high-consequence agents and organisms
Based on the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*, FSAP regulations, the *NIH Design Requirements Manual*, existing practices at high-performing institutions, and empirical biosafety research findings, the authority should promulgate specific standards for laboratory engineering and design and laboratory operations for high-containment facilities. This should include filling gaps in existing standards, such as the training and experience needed to be a biosafety officer. The authority should take on the activities of FSAP, currently housed within CDC (U.S. Department of Health and Human Services) and APHIS (U.S. Department of Agriculture). It should also assume oversight responsibilities for the BMBL and *NIH Guidelines*, including coordinating future updates to align with its regulations, but NIH and CDC, the current owners of these documents, should continue to develop and update them.

Adherence to standards should be required for facilities conducting DURC & PEPP research or activities involving high-consequence agents and organisms, initially defined as a list that includes all select agents regulated by FSAP, Risk Group 3 and 4 pathogens listed in the *NIH Guidelines*, and Pathogens with Pandemic Potential (PPPs), as defined in the White House DURC-PEPP Policy with the addition of animal and plant pathogens. The authority should develop procedures to determine when novel or modified agents or organisms fall into this category. The authority should exempt low-risk strains and remove agents or organisms from the list that no longer pose significant risks. Ultimately, the authority should seek to move toward a risk-based rather than list-based approach.

The authority should create certifications or require third-party certification of compliance. On-site inspection frequency should depend on the risk of an institution's activities and its track record.

Nucleic acid synthesis screening requirement
Based on existing publications—the White House framework, U.S. Department of Health and Human Services (HHS) guidance, and other literature—the authority should establish regulatory requirements for nucleic acid synthesis providers, including vendors of benchtop synthesizers. The authority should require providers to screen orders for likely matches with high-consequence agents and organisms and assess whether customers have a legitimate reason to possess those materials and are capable of handling them. Orders with significant unresolved concerns should be forwarded to law enforcement.

Registration for laboratories and nucleic acid synthesis providers
All laboratories conducting DURC & PEPP research or using high-consequence agents and organisms, and all regulated nucleic acid synthesis providers, should be required to register with the authority and periodically provide basic information about their operations. This information should be available to the public unless classified or law enforcement sensitive, with priority access for public health authorities and emergency managers.

Human and animal pathogen import permitting
The authority should assume responsibility for CDC's Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors and the USDA APHIS Veterinary Services Organisms and Vectors (OV) Permitting Unit and harmonize these requirements with its other regulations.

Monitoring for biotechnology products indicative of regulated activities
The authority should require or conduct monitoring of transactions involving materials, services, or equipment indicative of regulated activities. This should start with creating a list of products needed for pathogen research with few other applications, such as BSL-4 containment suits. The data collected should be used to identify entities that

should be required to register or to uncover patterns of misuse. Providers should not be penalized for their customers' misconduct.

Time-limited exemptions
To accelerate the response to acute threats to human, animal, plant, or environmental health, the authority should have the ability to exempt relevant activities from regulatory requirements while the threat remains active.

Decision review process
If they can clearly articulate grounds for reversal, regulated entities should be able to appeal regulatory decisions to a dedicated review board that includes external subject matter experts.

Enforcement continuum
The authority should employ an enforcement continuum that treats most compliance issues as learning opportunities and prioritizes working with researchers and institutions to promptly address them. This approach aims to identify and solve system-level problems before a serious incident occurs. Refusals, delays, or repeat offenses should lead to incremental escalation. Intentional wrongdoing or recklessness should immediately result in administrative or legal penalties.

Recommendation 3: Establish an office for technical assistance and policy research
The authority should create an office to provide technical assistance, track technological developments, and recommend policy changes. To encourage collaboration, this office should be separate from—though in communication with—the authority's regulatory wing.

Technical assistance
The authority should offer on-demand, timely assistance on compliance and other bioresponsibility questions for the regulated community. This should include legal protections for following its advice. Assistance should also be available to local authorities responding to rare bioresponsibility issues.

Policy research and trends in emerging technologies
The authority should conduct horizon-scanning exercises and policy research to identify emerging bioresponsibility risks and opportunities from scientific and technological advances. The authority should also collect and publish lessons learned from its regulatory, technical assistance, and research activities. It should investigate how its processes, regulatory definitions, and activities may need to change in response to these findings. The authority should convene and house relevant advisory boards, including the National Science Advisory Board for Biosecurity (NSABB).

Recommendation 4: Create a semi-independent board to manage a non-punitive reporting system and conduct informal engagement across the life sciences research enterprise
An independent office, the National Bioresponsibility Incident Board (NBIB), should be created to facilitate information sharing about biosafety or biosecurity lapses or near-lapses. The Board should develop a trusted relationship with the research community and provide objective analysis.

Non-punitive reporting system
The NBIB should host or contract out a non-punitive reporting system for safety and security incidents and near-misses at regulated entities. When needed, the NBIB could refer reports for non-punitive follow-up, but reports should be prevented from serving as the basis for administrative or legal penalties or civil judgments except in

cases of recklessness, intentional misconduct, or fraud. By request, the NBIB could also conduct non-punitive fact-finding missions to determine the causes of incidents. Based on observed trends, the NBIB should recommend improvements to bioresponsibility practices and policies.

Informal education, outreach, and inquiries

The NBIB should conduct outreach within the regulated community and across the broader life sciences enterprise to strengthen bioresponsibility norms, encourage adherence to voluntary standards, collect information about best practices, and solicit feedback on the authority's activities.

Recommendation 5: Develop a bioresponsibility research program

The authority should employ program managers to fund research advancing biosafety and biosecurity. It should not fund any DURC or PEPP research or activities involving high-consequence agents and organisms. Research should include studies in empirical biosafety to determine the causes of common accidents and the effectiveness of risk mitigation measures, including identifying highly cost-effective measures for use in low-resource environments. It should also fund the development of safer materials and practices, such as self-decontaminating surfaces, and technologies to build safety and security into biotechnology products, such as controls on benchtop nucleic acid synthesizers. The authority should also support the dissemination and promotion of findings from its research program.

Recommendation 6: Support bioresponsibility education, training, and workforce development

The authority should support bioresponsibility training and education, including creating a library of drop-in training materials and creating curricula or lesson plans to be incorporated into life sciences courses. The authority should also fund the recruitment and training of bioresponsibility professionals and support the development of curricula that meet its certification requirements.

Recommendation 7: Support international engagement on bioresponsibility

In support of the U.S. Department of State, the HHS Office of Global Affairs, and other interagency partners, the authority should work to internationalize its standards, promote strong bioresponsibility norms and systems, and disseminate bioresponsibility training materials and research findings abroad.

Path forward

Recent policy developments demonstrate an interest in strengthening and harmonizing federal bioresponsibility oversight. This document represents an attempt to account for those realities and chart an ideal path forward. Based on the operational and policy experience of its authors and the input of more than thirty domain experts, the document envisions collecting the pieces of a fragmented system into a cohesive whole. Its recommendations aim to create a comprehensive, adaptable, and transparent oversight system that effectively mitigates risks while enabling innovation.

Many stakeholders agree about high-level principles like the importance of risk-based approaches; however, there is widespread disagreement about how to operationalize them. Some stakeholders, including several biosafety and biosecurity professionals, reacted enthusiastically to this document's vision. Others, including some life sciences researchers, expressed concern that changes in oversight would likely result in burdens that slow down research and hinder scientific progress. More extensive engagement across industry, academia, government, and the general public is needed to further test and refine these ideas.

Other biosafety and biosecurity scholars and practitioners have proposed creating an independent agency to own the federal government's bioresponsibility mission. Given the urgency of these issues and increasing political interest, the idea warrants serious consideration. The examples of Canada's biosafety and biosecurity regulator and the U.S. Federal Aviation Administration show that flexible, and systematic regulatory approaches can succeed.

Introduction

Biotechnology and the life sciences are advancing rapidly, and the application of artificial intelligence (AI) will further accelerate this trend. The United States leads the world in these areas and is well-positioned to reap incredible benefits such as access to life-saving treatments and strong growth in the bioeconomy. The ability to engineer both biological molecules and living organisms underpins this promise; however, some organisms and molecules can replicate or otherwise spread widely and cause damage to humans, animals, or plants.

The possibility of laboratory accidents and intentional misuse raises safety and security risks. Biological engineering tools are also becoming more accessible, increasing the pool of actors able to acquire such agents and organisms, especially outside of federally funded research institutions. At the same time, flagging public trust in science at home and a proliferation of global high-containment laboratory capacity in the absence of consistent standards abroad call for reaffirming U.S. Government (USG) leadership.

The current landscape of USG biological risk management policies is not equipped to handle these challenges. Policies are fragmented and spread across the federal government, leaving major gaps in some areas while also imposing compliance burdens on research institutions. Enforceability varies, creating a perverse incentive to skimp on biosafety and biosecurity. Transparency and independence—key features of effective oversight—are sometimes lacking.

A more flexible and consolidated system of oversight is needed to enable innovation and minimize risk. Such a system would foster engagement and collaboration to obtain higher levels of safety, security, and compliance with regulatory standards and voluntary guidelines. This approach aimed at responsibly advancing life science research in a safe, secure, and ethical manner merits a new term: bioresponsibility.

Many other fields and industries face risks from low-probability high-consequence events. In several of these cases, the USG provides safety and security oversight through an independent or semi-independent agency. This includes the Federal Aviation Administration for air travel, the Securities and Exchange Commission and the Commodity and Futures Trading Commission for finance, the Nuclear Regulatory Commission for nuclear power, and the Chemical Safety and Hazard Investigation Board for chemical production. Inspired by best practices in these other fields, this document proposes establishing an independent bioresponsibility agency to promote the nation’s continued preeminence in global life science research and the international bioeconomy. The following findings and recommendations analyze challenges faced by existing bioresponsibility policies and lay out a high-level vision for the functions and responsibilities of an independent bioresponsibility agency. They reflect the professional experience of its authors and conversations with dozens of experts in biosafety, biosecurity, and the life sciences.

Findings

The following findings identify major bioresponsibility challenges facing the United States and shortcomings in the U.S. Government (USG) bioresponsibility policy landscape. These findings are informed by published literature, conversations with subject matter experts, and the authors' experience.

Finding 1: Life sciences leadership offers health, economic, and security benefits

The term bioeconomy, as used in a 2022 Executive Order, refers to economic activity based on biomanufacturing or biotechnology, including innovative work across sectors such as pharmaceuticals, medicine, chemicals, agriculture, and energy. Based on fundamental research conducted in academia and the private sector in the United States, the U.S. bioeconomy was estimated to account for 5% of GDP in 2016, equivalent to nearly a trillion dollars annually.[1] Some estimates suggest this contribution is likely to grow to $30 trillion over the next two decades.[2]

Our nation's biotechnology industry and life sciences research enterprise continue to lead those of our nearest competitors. U.S. firms and institutions produce more life sciences patents, publications, and PhD candidates than any other country, although China appears to be catching up in some areas such as R&D investment.[3] This leadership enables the U.S. to leverage key discoveries for the public good and security advantage. For example, rapid COVID-19 vaccine development in the United States supported by Operation Warp Speed not only saved hundreds of thousands of American lives but also supported the global pandemic response.[4] Some experts have also raised the possibility of harnessing biotechnology to improve military supply chains by producing key inputs for equipment or even synthesizing products when and where they are needed in the field.[5,6]

Finding 2: A small subset of life sciences research poses risks that could endanger public safety or national security and jeopardize public support

Experts in virology, biosafety, other life sciences disciplines, and national security have noted that while research on pathogens offers many scientific and public health benefits, a subset of that work poses significant safety and security risks.

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[1] National Academies of Sciences, Engineering, and Medicine, "Frameworks for Measuring the Value of the U.S. Bioeconomy," in *Safeguarding the Bioeconomy* (Washington, DC: The National Academies Press, 2020), https://doi.org/10.17226/25525.

[2] John Cumbers, "White House Unveils Strategy To Grow Trillion Dollar U.S. Bioeconomy," *Forbes*, September 12, 2022, https://www.forbes.com/sites/johncumbers/2022/09/12/white-house-inks-strategy-to-grow-trillion-dollar-us-bioeconomy/.

[3] National Academies of Sciences et al., "AREAS OF LEADERSHIP IN THE GLOBAL ECONOMY," in *Safeguarding the Bioeconomy* (National Academies Press (US), 2020), https://www.ncbi.nlm.nih.gov/books/NBK556430/.

[4] Sumedha Gupta et al., "Vaccinations Against COVID-19 May Have Averted Up To 140,000 Deaths In The United States," *Health Affairs* 40, no. 9 (September 2021): 1465–72, https://doi.org/10.1377/hlthaff.2021.00619.

[5] Henry S. Gibbons and Anna M. Crumbley, "Accelerating Transition of Biotechnology Products for Military Supply Chains," *Joint Force Quarterly*, no. 113 (2024), https://ndupress.ndu.edu/Media/News/News-Article-View/Article/3837475/accelerating-transition-of-biotechnology-products-for-military-supply-chains/.

[6] Brandi Vincent, "'Waste to Value': Inside Cutting-Edge DARPA Efforts to Make Food out of Trash and Gasses," *DefenseScoop*, October 3, 2024, https://defensescoop.com/2024/10/03/waste-to-value-inside-cutting-edge-darpa-efforts-to-make-food-out-of-trash-and-gasses/.

In 2015, leading virologists Michael Imperiale and Arturo Cadedevall outlined the two major sources of risk: "There are individuals and groups who would like to engage in bioterrorism" and could misuse beneficial research findings, and "there is a chance that, despite our best efforts, dangerous agents might be accidentally released [from laboratories]." In response, they argue that "although risks and benefits posed by certain experiments are difficult to quantify, efforts must be made to assess the risks and benefits to ensure that they are on the table and considered carefully, employing available tools that include accepted methods of risk-benefit analysis to optimize benefit and minimize risk." They also advocate for the "creation of a national board to vet issues related to research with dangerous pathogens."[7]

In 2024, an international group of scientists and policy experts convened by the *Bulletin of Atomic Scientists* as part of the Pathogens Project reached similar conclusions about research on viruses. They point to ongoing biosafety risks given the historical occurrence of research-acquired infections and accidental releases and argue that "there is a small subset of research on known or potential pandemic pathogens for which biosafety risks go beyond the laboratory and affect the health of significantly larger groups of humans or other animals. Indeed, if a virus has true pandemic potential, the entire world can be affected by an accident." They also highlight the potential for malicious actors—including individuals, groups, or nation-states—to misuse scientific insights or laboratory samples to develop bioweapons or engage in bioterrorism.[8]

Many other experts have echoed these concerns. Over 100 prominent scientists joined a 2014 consensus statement by the Cambridge Working Group contending that laboratory research to create "highly transmissible, novel strains of dangerous viruses" poses elevated biosafety risks that need to be addressed.[9]

The most significant safety and security risks result from an exceedingly small subset of life sciences research, especially work involving organisms or agents capable of spreading wide, uncontrolled spread. Although some non-pathogenic organisms likely fall into this category, this document follows existing USG policies in that it regards research that uses or enhances Pathogens with Pandemic Potential (PPPs) as the greatest potential threat. A 2017 White House policy established a government-wide requirement that such research undergo additional review, and the U.S. Department of Health and Human Services (HHS) implemented that policy by establishing a committee to review research of this type before funding it.[10,11] Only four projects were referred to this committee between 2017 and 2024.[12]

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[7] Michael J. Imperiale and Arturo Casadevall, "A New Synthesis for Dual Use Research of Concern," *PLOS Medicine* 12, no. 4 (April 14, 2015): e1001813, https://doi.org/10.1371/journal.pmed.1001813.

[8] The Pathogens Project, "A Framework for Tomorrow's Pathogen Research" (Chicago, IL: Bulletin of Atomic Scientists, 2024), https://thebulletin.org/wp-content/uploads/2024/02/Pathogens-Project_A-Framework-for-Tomorrows-Pathogen-Research_Final-Report-2024.pdf.

[9] The Cambridge Working Group, "Cambridge Working Group Consensus Statement on the Creation of Potential Pandemic Pathogens (PPPs)," The Cambridge Working Group, July 14, 2014, https://www.cambridgeworkinggroup.org/index.html.

[10] White House Office of Science and Technology Policy, "Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO)" (Washington, DC, January 9, 2017).

[11] U.S. Department of Health and Human Services, "Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens" (Washington, DC: U.S. Department of Health and Human Services, 2017), https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf.

[12] U.S. Department of Health and Human Services, "Research Reviewed Under the HHS P3CO Framework," Administration for Strategic Preparedness and Response (ASPR), 2024, https://aspr.hhs.gov:443/S3/Pages/Research-Reviewed-Under-the-HHS-P3CO-Framework.aspx.

Evidence suggests that some indeterminate number of projects funded by HHS that meet the definition of enhanced PPP research have not been referred to the department-level committee. A survey of 520 U.S. biosafety and biosecurity professionals found that 14% (53/368) of respondents at federally funded institutions reported that their workplace conducts research that may generate enhanced Pandemic Potential Pathogens (ePPP).[13] This likely represents an overestimate due to some survey recipients being from the same institutions and possible confusion about the definition of ePPP. Even so, these results strongly imply a higher prevalence of work with PPPs than the four projects reviewed by HHS. Nonetheless, compared to the more than 58,000 research awards given out by NIH annually, if 50 institutions conduct a new PPP project each year (a highly conservative assumption), the share of this research would be no more than 0.1%. Given the risks and limited commercial applications of PPP research, it likely makes up an even smaller share of non-federally funded research.

Dual Use Research of Concern (DURC) forms another category of potentially high-risk life sciences research. Since nearly all life sciences research could be considered "dual use" to some degree, the federal government defines DURC to capture the subset of life sciences work with the highest potential for misuse.[14] There are no comprehensive studies of the prevalence of DURC, but a search of English-language publications using a machine learning classifier identified around 7,000 publications that likely involved modifying pathogens to alter their risk profile out of a total of 159,000 publications (4.4%) on pathogens between 2000 and 2022.[15] Some of these experiments decreased a pathogen's ability to cause disease, so DURC likely makes up less than the reported 4.4% of research on pathogens (which is itself a small proportion of overall life sciences research).

A slightly broader range of research poses significant—though lesser—safety and security risks, although most research with pathogens poses minimal risk to the public. The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* classify biological agents and organisms into four risk groups (Table 1). All work with pathogens poses a risk to the researchers conducting it, but research involving pathogens in Risk Groups (RG) 3 and 4 could threaten public health and national security. However, there is increasing potential for genetic engineering to create more dangerous strains of pathogens from lower-risk groups.

[13] Gillum, David R., An Tran, Jennifer Fletcher, and Kathleen M. Vogel, "Bridging Biosafety and Biosecurity Gaps: DURC and ePPP Policy Insights from U.S. Institutions," *Frontiers in Bioengineering and Biotechnology* 12 (September 25, 2024), https://doi.org/10.3389/fbioe.2024.1476527.

[14] National Academies of Sciences, Engineering, and Medicine, "1 Introduction," in *Dual Use Research of Concern in the Life Sciences: Current Issues and Controversies* (Washington, DC: The National Academies Press, 2017), https://doi.org/10.17226/24761.

[15] Caroline Schuerger et al., "Understanding the Global Gain-of-Function Research Landscape" (Washington, DC: Center for Security and Emerging Technology, August 2023), https://cset.georgetown.edu/publication/understanding-the-global-gain-of-function-research-landscape/.

Classification	Definition	Example
Risk Group 1	Agents that are not associated with disease in healthy adult humans. This group includes a list of animal viral etiologic agents in common use. These agents represent no or little risk to an individual and no or little risk to the community.	Non-pathogenic strains of *E. coli.*
Risk Group 2	Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. These agents represent a moderate risk to an individual but a low risk to the community.	*Salmonella*, pathogenic strains of *E. coli.*, Hepatitis viruses.
Risk Group 3	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. These agents represent a high risk to an individual but a low risk to the community.	*Yersinia pestis* (plague), SARS-associated coronavirus (SARS-CoV)
Risk Group 4	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. These agents represent a high risk to the individual and a high risk to the community.	Ebola virus, Lassa fever virus

Table 1. *Definitions of Risk Groups 1-4 based on the* NIH Guidelines.[16]

There are no precise estimates of the amount of ongoing work with RG3 and RG4 or equivalent agents, although such work typically occurs under Biosafety Level (BSL) 3 or 4 conditions. While no comprehensive database currently exists, estimates put the number of high-containment laboratories in the United States at 148 for BSL-3 and 11 for BSL-4.[17,18] By comparison, conversations with experts suggest there are thousands or tens of thousands of BSL-2 laboratories in the United States. In Canada, labs working with Risk Group 2 agents (typically at BSL-2) make up around 95% of the facilities licensed to work with pathogens.[19] Like RG3 and RG4 pathogens for human health, plant and animal pathogens could pose similar risks by threatening U.S. or global agriculture or environmental health.

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[16] U.S. Department of Health and Human Services, "Risk Groups," Administration for Strategic Preparedness and Response (ASPR), accessed December 12, 2024, https://aspr.hhs.gov:443/S3/Pages/Risk-Groups.aspx.

[17] Caroline Schuerger, Sara Abdulla, and Anna Puglisi, "Mapping Biosafety Level-3 Laboratories by Publications" (Center for Security and Emerging Technology, August 2022), https://doi.org/10.51593/20220019.

[18] Filippa Lentzos et al., "Global Biolabs Map," Global Biolabs, accessed December 12, 2024, https://www.globalbiolabs.org/map.

[19] Office of Audit and Evaluation, Health Canada and the Public Health Agency of Canada, "Evaluation of the Human Pathogens and Toxins Act and Regulations Framework" (Ottawa: Health Canada and the Public Health Agency of Canada, March 2022), https://publications.gc.ca/collections/collection_2024/aspc-phac/HP5-224-2022-eng.pdf.

Accidents during or misuse of life sciences research could not only threaten public health, public safety, national security, agriculture, and the environment but also jeopardize public support for life science research or the deployment of biotechnology. In turn, this could result in the United States ceding leadership of the life sciences industry to foreign competitors and losing access to its benefits. The widely publicized death of an 18-year-old participant in a gene therapy clinical trial in 1999 generated fear of the risks among regulators, the public, and investors and significantly slowed down progress in the field.[20] Similarly, accidents at Three Mile Island and Fukushima Daiichi generated public opposition to and increased regulatory scrutiny of nuclear power, contributing to the decline in new nuclear reactors built since the 1970s and accelerating decommissioning of nuclear plants since 2011.[21,22]

Finding 3: Rapid technological advances are raising new risks and expanding the pool of actors with access to advanced capabilities

Major advances, especially in synthetic biology, are contributing to a rapidly evolving security landscape. CRISPR gene editing techniques, bioinformatics with large biological datasets, and plummeting gene sequencing and gene synthesis costs are elevating the capabilities of experienced scientists while making previously cutting-edge techniques more widely accessible and affordable. These developments may unlock great benefits, but they also raise new risks and change the distribution of actors capable of accessing pathogens and other dangerous biological materials.[23] This is especially true as rapid technological changes threaten to outpace slow U.S. government policymaking processes.

Diffusion

Advances in biotechnology have greatly democratized biology, putting more and more power in the hands of actors without specialized expertise or outside of traditional research institutions. Today, cutting-edge techniques quickly proceed from use only in the most sophisticated laboratories to being taught in university lab classes. They are becoming widely available on a commercial "fee-for-service" basis at an accelerating rate, averaging around five years from discovery to wide commercial availability for major innovations since 2000.[24] The “Do-It-Yourself” (DIY) biology or “biohacker” community, which aims to empower non-scientists to experiment and build with biology, has

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[20] James M. Wilson, “A History Lesson for Stem Cells,” *Science* 324, no. 5928 (May 8, 2009): 727–28, https://doi.org/10.1126/science.1174935.

[21] Nathan Hultman and Jonathan Koomey, “Three Mile Island: The Driver of US Nuclear Power’s Decline?,” *Bulletin of the Atomic Scientists* 69, no. 3 (May 1, 2013): 63–70, https://doi.org/10.1177/0096340213485949.

[22] Barbara D. Melber, “The Impact of TMI upon the Public Acceptance of Nuclear Power,” *Progress in Nuclear Energy*, Impact of the Three Mile Island Accident on the Nuclear Power Industry, 10, no. 3 (January 1, 1982): 387–98, https://doi.org/10.1016/0149-1970(82)90015-4.

[23] As an example of a new risk, a group of scientists recently published an article, “Confronting risks of mirror life,” in *Science* warning that biotechnology is likely to eventually make possible the creation of so-called “mirror organisms,” or organisms consisting entirely of molecules that are mirror images of the molecules that constitute existing organisms. They warned that such organisms could pose unparalleled dangers to terrestrial life. Although there might be commercial and scientific benefits from creating mirror organisms, the scientists argue that those benefits are all available in ways that do not require the construction of mirror organisms and do not justify the risks of doing so. They therefore urged that research with the objective of producing mirror life be halted. If that recommendation is adopted globally, no such research would be conducted in legitimate laboratories, and protecting against the harms any covert programs might cause would become a law enforcement, intelligence, and national security problem that is beyond the scope of this paper.

[24] Shawn S. Jackson et al., “The Accelerating Pace of Biotech Democratization,” *Nature Biotechnology* 37, no. 12 (December 2019): 1403–8, https://doi.org/10.1038/s41587-019-0339-0.

grown rapidly since its beginning around 2008. As of 2019, researchers documented more than 50 DIY biology labs available to amateur biologists.[25] Very little, if any, DIY biology work poses significant safety or security risks, but the movement's growth reflects increasingly widespread access to life sciences tools.

Outsourcing

Outsourcing in biotechnology is quickly growing, providing access to the tools and expertise needed to manipulate biology on a large scale for anyone able to pay for these services; however, biosecurity in the outsourcing industry is not robust. These services include scaling up protein, bacteria, and virus production; modification of bacteria and viruses; and even complete design of modified strains. Although mail-order providers of synthetic nucleic acids typically screen orders for regulated agents and organisms, procedures are not standardized and biosecurity gaps remain.[26] Other companies, known as contract research organizations, conduct experiments and research procedures on behalf of their clients. Recently, highly automated and remotely accessible "cloud laboratories" have also begun providing these services over the web. Security experts have highlighted that these cloud laboratories lack consistent biosecurity standards and practices.[27]

Artificial Intelligence

Artificial intelligence (AI) systems could enable users to circumvent current biosecurity safeguards and facilitate misuse. Some experts additionally suggest they may destabilize current security paradigms by producing leaps in capabilities faster than security measures can adapt or by making relevant capabilities widely available. These systems can help users obtain key dual-use items by providing guidance on how to exploit longstanding gaps in biosecurity, increasing the importance of closing these gaps.[28] For example, current AI biological design (biodesign) tools may allow users to design functional equivalents to regulated toxins, potentially allowing them to evade gene synthesis screening controls and carry out bioterrorism attacks.[29] Large language models may also increase access to these capabilities by providing high-level guidance and step-by-step instructions to users without the field-specific expertise currently required to, for example, perform the reverse genetics and viral rescue procedures needed to create synthetic viruses.[30] In the future, such systems—or a combination of different AI systems—may also enable malicious users to develop more dangerous biological agents.[31] If we act now, we can capitalize on the unique opportunity to ensure biosecurity is baked into nascent AI frameworks.

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[25] Morgan Meyer and Frédéric Vergnaud, "The Rise of Biohacking: Tracing the Emergence and Evolution of DIY Biology through Online Discussions," *Technological Forecasting and Social Change* 160 (November 1, 2020): 120206, https://doi.org/10.1016/j.techfore.2020.120206.

[26] Arianne Kane and Michael T. Parker, "Screening State of Play: The Biosecurity Practices of Synthetic DNA Providers," *Applied Biosafety* 29, no. 2 (June 2024): 85–95, https://doi.org/10.1089/apb.2023.0027.

[27] Jeffrey Lee and Barbara Del Castello, "Robust Biosecurity Measures Should Be Standardized at Scientific Cloud Labs," *RAND Research & Commentary* (blog), November 8, 2024, https://www.rand.org/pubs/commentary/2024/11/robust-biosecurity-measures-should-be-standardized.html.

[28] Griffin, Riley, "AI-Made Bioweapons Are Washington's Latest Security Obsession," *Bloomberg*, August 2, 2024, https://www.bloomberg.com/news/features/2024-08-02/national-security-threat-from-ai-made-bioweapons-grips-us-government.

[29] Philip Hunter, "Security Challenges by AI-Assisted Protein Design," *EMBO Reports* 25, no. 5 (March 26, 2024): 2168–71, https://doi.org/10.1038/s44319-024-00124-7.

[30] Sarah R. Carter et al., "The Convergence of Artificial Intelligence and the Life Sciences" (Washington, DC: Nuclear Threat Initiative, October 30, 2023), https://www.nti.org/analysis/articles/the-convergence-of-artificial-intelligence-and-the-life-sciences/.

[31] Jonas B. Sandbrink, "Artificial Intelligence and Biological Misuse: Differentiating Risks of Language Models and Biological Design Tools" (arXiv, December 23, 2023), https://doi.org/10.48550/arXiv.2306.13952.

Finding 4: Public trust in science has significantly declined

Public trust in science is at a historical low point, and significant measures are needed to revive this trust to ensure that the United States remains at the forefront of the life sciences field. Recent surveys in the United States suggest significant declines in trust in scientists since the COVID-19 pandemic, although the public support for government funding of basic science remains strong.[32,33] Whether the COVID-19 pandemic originated from a natural zoonotic spillover event or a research-related incident remains hotly contested. The U.S. intelligence community remains divided over the question and assesses that both hypotheses are plausible.[34] Regardless, recent surveys of public opinion suggest that more than 60% of Americans believe that COVID-19 came from a laboratory.[35,36] This indicates that laboratory safety and the risk of research-induced disease outbreaks are likely a matter of significant public concern. Other surveys found a majority of respondents were skeptical of dual use research of concern and had significant concerns about the threat of lab accidents with engineered pathogens.[37] Better and more transparent oversight would build public trust in the responsible conduct of research, especially that paid for by U.S. tax dollars.

Finding 5: International bioresponsibility governance remains weak

Access to advanced biological capabilities is expanding around the world, coupled with increasing high-containment laboratory capacity. The number of planned or operating high containment laboratories capable of working with highly dangerous pathogens—BSL-4 and enhanced BSL-3 laboratories—has nearly doubled since 2010.[38] Global biosafety and biosecurity oversight for these facilities is inconsistent, and some countries lack policies and strong institutions needed to hold laboratories accountable for following rigorous safety and security requirements.

International bodies including the World Health Organization (WHO) and the International Standards Organization (ISO) have produced standards and guidelines. The WHO maintains a *Laboratory Biosafety Manual* and recently published *Laboratory Biosecurity Guidance* and ISO has created standard ISO 35001:2019 for laboratory biorisk management and ISO/TS 5441:2024 for biorisk management advisors. However, adherence to these standards and guidelines is rarely independently certified. Experts suggest there is a need for education, training, and incentives for adopting and complying with international standards.[39] The high costs of compliance, especially for operations

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[32] Lupia, Arthur, David B. Allison, Kathleen Hall Jamieson, Jennifer Heimberg, Magdalena Skipper, and Susan M. Wolf, "Trends in US Public Confidence in Science and Opportunities for Progress," *Proceedings of the National Academy of Sciences* 121, no. 11 (March 12, 2024): e2319488121, https://doi.org/10.1073/pnas.2319488121.

[33] National Science Board, National Science Foundation, "Science and Technology: Public Perceptions, Awareness, and Information Sources," *Science and Engineering Indicators 2024*, Alexandria, VA, 2024.

[34] National Intelligence Council, "Updated Assessment on COVID-19 Origins" (Office of the Director of National Intelligence, 2023), https://www.dni.gov/files/ODNI/documents/assessments/Declassified-Assessment-on-COVID-19-Origins.pdf.

[35] Linley Sanders and Kathy Frankovic, "Two-Thirds of Americans Believe That the COVID-19 Virus Originated from a Lab in China," *YouGov* (blog), March 10, 2023, https://today.yougov.com/politics/articles/45389-americans-believe-covid-origin-lab.

[36] Gitanjali Poonia, "7 out of 10 American Voters Think COVID-19 Came from a Lab," *Deseret News*, April 17, 2024, sec. Politics, https://www.deseret.com/politics/2024/04/17/what-are-the-origins-of-covid-19/.

[37] Chandini Raina MacIntyre et al., "Public Awareness, Acceptability and Risk Perception about Infectious Diseases Dual-Use Research of Concern: A Cross-Sectional Survey," *BMJ Open* 10, no. 1 (January 1, 2020): e029134, https://doi.org/10.1136/bmjopen-2019-029134.

[38] Jocelyn Kaiser, "Growing Number of High-Security Pathogen Labs around World Raises Concerns," *ScienceInsider*, March 17, 2023, https://www.science.org/content/article/growing-number-high-security-pathogen-labs-around-world-raises-concerns.

[39] *Biosafety and Risky Research: Examining if Science is Outpacing Policy and Safety: Testimony Before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives,* 118th Cong. (2023) (statement of Gregory Koblentz, Director of the Biodefense Graduate Program at George Mason University).

and maintenance, and the presence of laboratories in resource-constrained environments are significant barriers to widespread implementation. The United States can help support and lead international bioresponsibility efforts, especially if the nation gets its own house in order and uses its domestic biorisk management policies to lead by example.

Finding 6: The current U.S. government biorisk management policy landscape is fragmented, imposing a high compliance burden while leaving gaps

Current bioresponsibility frameworks are fragmented across agencies, authorities, and funding sources. More than a dozen agencies and components across several federal departments own part of the federal government's bioresponsibility mission. Different binding legal bioresponsibility requirements are attached to receiving federal funding, exporting dual-use materials or technology, and working with pathogens on a specific list. Other elements of the current bioresponsibility framework are based on voluntary guidance that is not specific enough to dictate practices in a laboratory or to permit enforcement.

Even core bioresponsibility policies governing the safety and security of life sciences research laboratories are divided between nearly a dozen programs across at least four agencies. Given the overlapping, complex requirements, researchers often struggle to understand their obligations across guidelines and policies, including the Federal Select Agent Program (FSAP), the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), the *NIH Design Requirements Manual*, the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (DURC-PEPP Policy), and the White House's Framework for Nucleic Acid Synthesis Screening, among others. USG bioresponsibility functions are outlined in Table 2. The first five rows, highlighted in green, represent core bioresponsibility requirements housed in agencies with a significant focus on life sciences activities.

Agency/Component	Department	Selected Bioresponsibility Functions
Centers for Disease Control and Prevention (CDC)	Health and Human Services (HHS)	Federal Select Agent Program (with USDA APHIS), Import Permit Program, updating the BMBL (with NIH)
National Institutes of Health (NIH)	Health and Human Services (HHS)	Updating and administering the *NIH Guidelines*, the *NIH Design Requirements Manual*, implementing the DURC-PEPP Policy, implementing nucleic acid synthesis screening requirements
Administration for Strategic Preparedness and Response (ASPR)	Health and Human Services (HHS)	HHS department-level review committee for research on enhanced Potential Pandemic Pathogens (ePPP), updating and publishing gene synthesis screening guidance
Animal and Plant Health Inspection Service (APHIS)	Agriculture	Federal Select Agent Program (with CDC), animal and plant pathogen import, and interstate transport permitting

Office of Science and Technology Policy	White House	Updating the DURC-PEPP Policy
Bureau of Industry and Security (BIS)	Commerce	Export Administration Regulations
National Institute for Standards and Technology (NIST)	Commerce	The AI Safety Institute (science on reducing chemical and biological risks from AI models)
Bureau of Political-Military Affairs	State	International Traffic in Arms Regulations (export controls)
Bureau of International Security and Nonproliferation	State	Cooperative Threat Reduction, engagement with the Biological Weapons Convention
Environmental Protection Agency (EPA)	N/A	EPA Biotechnology Regulations
Occupational Safety and Hazards Administration (OSHA)	Labor	Bloodborne Pathogens Standard
Federal Bureau of Investigations	Justice	Weapons of Mass Destruction (WMD) statute investigations and enforcement
Pipeline and Hazardous Materials Safety Administration	Transportation	Biological Transport Regulations

Table 2. *Federal departments, agencies, and components with a role in bioresponsibility U.S. government bioresponsibility functions. Rows highlighted in green correspond to agencies with a significant focus on life sciences research activities.*

The lack of clear ownership of the bioresponsibility mission reduces accountability to Congress and the general public and contributes to neglect of bioresponsibility issues.

Current governance policies rely heavily on guidelines and bottom-up responsibility to ensure compliance, both of which are essential components of an effective risk management framework. Only export control regulations and FSAP provide direct regulatory oversight of research activities. However, the degree of oversight and enforceability varies between different policies and is not always correlated with the risks involved. For example, the USG's nucleic acid synthesis screening policy currently requires providers to attest to their own compliance without a mechanism for verification despite the increasing importance of this step in light of AI advances.[40] Furthermore, documents like the BMBL are often insufficiently specific to outfit, staff, or prescribe practices within a laboratory. Standards and

[40] The policy does announce the White House's intention to explore ways of verifying compliance.

guidelines provide few specifics—like hours, methods, or example materials—on how to train researchers and bioresponsibility professionals, leading to duplication of effort and inconsistencies across institutions. There is also a lack of guidance for determining whether the risk that remains after all mitigation measures have been taken is acceptable or if the research should be abandoned, which may be the most critical decision a laboratory must make.

While many institutions strive to uphold the highest standards in bioresponsibility, these policies leave room for different interpretations and create the option for institutions to save money by dedicating fewer resources to bioresponsibility. At the same time, compliance with the existing patchwork of requirements is expensive and burdensome. Private conversations with one high-containment research institution revealed that compliance costs over one million dollars and a thousand person-hours annually. Several different government entities conduct inspections, sometimes repeating the same procedures without coordination. Inspections require lengthy and costly pauses in laboratory activities.
To the extent possible, consolidating compatible bioresponsibility functions and harmonizing them under a single administrative authority would simplify the regulatory burden on practitioners. However, it may not be possible or desirable to transfer all existing functions from the agencies currently responsible for them.

Limited oversight of non-federally funded research
Non-federally funded research makes up a significant and likely growing share of potentially high-risk life sciences research, and some of this work receives no federal oversight. Estimates suggest that 25% of human pathogen research occurs in the private sector, of which one quarter (~6% overall) receives no oversight from the USG.[41] Unless working with a Select Agent, institutions that do not receive federal funding are not subject to federal oversight, safety, or security requirements, except for providing basic worker protections. For example, under current policies, no federal authority could prevent a well-intentioned but reckless privately funded researcher from conducting experiments aimed at discovering more transmissible forms of Middle East respiratory syndrome coronavirus (MERS-CoV) or enforce any safety or security standards on this activity. MERS-CoV has a globally reported fatality rate of 35%.[42] Expanding USG oversight of non-federally funded research likely cannot be accomplished under current authorities and would require Congressional action.

Additionally, many products that are used only or primarily for work on high-consequence pathogens can be sold to any buyer without scrutiny. For example, while some manufacturers of the protective suits needed for work in high-containment laboratories do screen their customers, no federal policy dictates how and when to do so. Legally binding requirements have been applied to customers or providers of other dual-use goods with far less potential for misuse. For example, the Department of Homeland Security regulates the sale and transfer of ammonium nitrate fertilizer to prevent its misuse as an explosive.[43]

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[41] Greene, Daniel, Audrey Cerles, and Rocco Casagrande, "Characterizing the Private Sector in US Human Pathogen Research," *Health Security* 22, no. 5 (October 2024): 402–7, https://doi.org/10.1089/hs.2024.0003.
[42] Pormohammad, Ali, Saied Ghorbani, Alireza Khatami, Rana Farzi, Behzad Baradaran, Diana L. Turner, Raymond J. Turner, Nathan C. Bahr, and Juan-Pablo Idrovo, "Comparison of Confirmed COVID-19 with SARS and MERS Cases - Clinical Characteristics, Laboratory Findings, Radiographic Signs and Outcomes: A Systematic Review and Meta-analysis," *Reviews in Medical Virology* 30, no. 4 (July 2020): e2112, https://doi.org/10.1002/rmv.2112.
[43] Cybersecurity and Infrastructure Security Agency, "Ammonium Nitrate Security Statutes and Regulations," America's Cyber Defense Agency, accessed December 13, 2024, https://www.cisa.gov/resources-tools/programs/ammonium-nitrate-security-program/statutes-and-regulations.

The federal response to an illegal laboratory in Reedley, California highlights these issues

In December 2022, a city code enforcement officer in Reedley, California responded to a complaint about cars in the parking lot of a supposedly empty warehouse. [44] To her surprise, the warehouse was illegally occupied by a facility containing nearly a thousand mice along with samples of human blood, hazardous chemicals, and twenty infectious agents including HIV, hepatitis, and what appeared to be clinical samples of SARS-CoV-2 and tuberculosis. In addition to these pathogen samples, officials found many vials and other containers missing labels or with labels that could not be read and whose contents were never determined. Officials assessed that the building posed a fire hazard due to improper wiring and that infectious materials were stored in unsafe conditions.[45]

The primary purpose of the building appeared to be the packaging and shipping of fraudulent test kits, including COVID-19 and pregnancy tests. While the facility contained little laboratory equipment, making it unlikely that research was actively occurring, the presence of pathogen samples are indicative of research efforts at some point in the company's history. The facility was operated by two Chinese citizens now charged with several federal crimes, including fraud and conspiracy, by the U.S. Department of Justice.[46]

The federal response to this incident underscored the gaps and limitations of fragmented biorisk management policies. The investigation involved fourteen different agencies at the local, state, and federal levels, and officials reported significant confusion about who was responsible for what part of the response. The FBI conducted an initial investigation, and upon finding no evidence of terrorism and deeming the facility safe to enter, handed the case back to local officials. State and local officials then reached out to CDC, but investigators on the House Select Committee on the Chinese Communist Party allege a team from the Federal Select Agent Program (FSAP) was sent to investigate only after Reedley officials contacted their Representative to help. The team did not test any materials but concluded that no select agents were present based on the labels of samples.[47]

After concluding that no select agents were involved, the CDC determined that it did not have the authority to assist state and local officials with laboratory testing or site remediation. As a result, the samples were destroyed without a thorough investigation and state and local authorities were left to assess public health risks and lead complex cleanup efforts with limited access to federal expertise. Additionally, despite circumstantial evidence of illegal importation of pathogen samples, the CDC declined to investigate this likely violation due to the absence of company importation records.[48]

The Reedley laboratory illustrated the lack of federal requirements for non-federally funded laboratories. Even if the facility had been conducting research on dangerous pathogens, its only federal violation — assuming no select agents were involved — would have been importing pathogen samples without a permit. There are no laws dictating proper safety and security practices for this kind of facility. It also highlights the lack of federal awareness

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[44] Sheehan, Tim, "How a Secret Chinese-Run Lab in Reedley Illegally Stored Vials of COVID-19, Infectious Diseases," *Fresno Bee*, August 3, 2023, https://www.fresnobee.com/news/local/article277836263.html.

[45] Fresno County Department of Public Health's Application for Abatement Warrant, 23CECG00912, Superior Court of California, County of Fresno, June 15, 2023.

[46] United States Attorney's Office Eastern District of California, "Conspiracy and Fraud Charges Added Against Operator of Central California Bio-Lab and His Partner in Connection with Sale of Millions of Dollars in COVID-19 Test Kits," U.S. Department of Justice, August 15, 2024, https://www.justice.gov/usao-edca/pr/conspiracy-and-fraud-charges-added-against-operator-central-california-bio-lab-and-his.

[47] Bickerton, James, "CDC Responds to Claims about Chinese Biolab in California," *Newsweek*, November 17, 2023, sec. U.S, https://www.newsweek.com/cdc-responds-claims-about-chinese-biolab-california-1844760.

[48] Id.

for unusual purchases of pathogen samples and pathogen handling equipment. The story also reveals the lack of resources available to state and local governments, and even companies and research institutions, for technical assistance on complex biosafety and biosecurity issues. Finally, the tepid response of federal agencies shows the lack of ownership of (and accountability for) the overall bioresponsibility mission within the U.S. government. Creating a dedicated home for this work would likely improve coordination and ensure that potential public health hazards resulting from laboratory activities would be prioritized.

Finding 7: USG policies do not uniformly provide transparent, independent oversight

Current USG policies often make researchers, research institutions, and federal funding agencies and departments responsible for critical oversight decisions, creating perceived or actual conflicts of interest. Although programs such as FSAP have taken significant steps to avoid potential conflicts of interest in its oversight of CDC and USDA Animal and Plant Health Inspection Service (APHIS) laboratories (FSAP is run jointly by CDC and APHIS), best practices in other industries include fully independent oversight. Similarly, while the DURC-PEPP policy includes measures to insulate department-level review from conflicts of interest, agencies play a large role in overseeing the research that they themselves fund. As noted, compliance with nucleic acid synthesis screening requirements is assessed based on self-reporting.

USG bioresponsibility policies often lack mechanisms to provide public transparency about their processes and outcomes. The current process for PPP research review under the HHS P3CO Framework provides little public transparency.[49] The new DURC-PEPP Policy will provide additional transparency to the White House and make aggregate information about projects reviewed publicly available. However, this stops short of the National Science Advisory Board for Biosecurity's (NSABB's) 2023 recommendation to publish a "summary of key determinants" that informed funding decisions.[50] Additionally, no comprehensive database of U.S. BSL-3 laboratories exists.[51] As a result, neither the USG nor the public knows where all high-containment laboratory work is occurring and local communities may have no easy way to determine what facilities are located in their area.

Laboratory accident and incident reporting follows a similar pattern. Laboratory incidents reported to FSAP are published in aggregate form in the program's annual reports, but no public information is released about incidents reported under the *NIH Guidelines*. No system exists to provide public transparency about the occurrence of laboratory incidents, the safety and security measures in place that mitigated the effects of the incident, or the actions taken in response. Some existing U.S. high containment research institutions, notably Galveston National Laboratory, maintain a public database of laboratory incidents.[52] Anecdotally, this commitment to transparency seems to have helped sustain high levels of public trust within the local community.

Efforts to increase public transparency must protect potentially sensitive personal and proprietary information and avoid disclosing details that would jeopardize national security. There are also some limited circumstances under which research with pathogens should be classified. Public transparency requirements should preserve this option.

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[49] Gregory D. Koblentz and Rocco Casagrande, "Beyond Gain of Function: Strengthening Oversight of Research with Potential Pandemic Pathogens," *Pathogens and Global Health* 118, no. 3 (n.d.): 197–208, https://doi.org/10.1080/20477724.2023.2265627.

[50] National Science Advisory Board for Biosecurity, "Proposed Biosecurity Oversight Framework for the Future of Science" (National Institutes of Health, March 2023), https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf.

[51] Schuerger, Abdulla, and Puglisi, "Mapping Biosafety Level-3 Laboratories by Publications."

[52] "Laboratory Safety at UTMB," Galveston National Laboratory, accessed December 13, 2024, https://www.utmb.edu/gnl/about/lab-safety.

The U.S. Government Accountability Office has identified independence and transparency as two of five essential elements for effective oversight in environments where low-probability, high-consequence events must be avoided.[53]

Finding 8: Other countries with strong life sciences sectors have stronger, more cohesive biorisk management frameworks than the United States

Other countries—notably Canada, Switzerland, and the United Kingdom—boast more comprehensive and harmonized regulatory frameworks for bioresponsibility. In each of these countries, bioresponsibility functions are concentrated in a handful of agencies that oversee consolidated regulations. They have also experimented with innovative provisions such as flexible and cooperative enforcement in Canada and liability insurance requirements in Switzerland.

Not only do these systems show that such regulatory approaches are possible, but they demonstrate that researchers have not fled these countries due to overreach. Canada, Switzerland, and the United Kingdom are generally considered to possess strong life sciences research enterprises. Moreover, their research productivity per capita and per government research dollar rivals or exceeds that of the United States (Table 3). More detail about the bioresponsibility oversight systems in each of these countries is provided below.

[53] *Concerns over Federal Select Agent Program Oversight of Dangerous Pathogens: Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives,* 115th Cong. (2017) (Statement of Mary Denigan-Macauley, GAO Acting Director of Healthcare).

Country	Biological and biomedical sciences and health science publications (2020)[54]	Population (millions)[55]	Government life sciences research funder & budget (2020, USD)	Publications per capita (million people)	Publications per million government life sciences research dollars
United States	298,929	341.96	NIH: $41.69B[56]	874	7.17
Canada	48,988	38.79	CIHR: $1.07B[57]	1,263	45.78
Switzerland	23,237	8.86	SNSF: $364M[58]	2,623	63.84
United Kingdom	84,479	68.46	Various: $3.47B[59]	1,234	24.35

***Table 3**. Biological, biomedical, and health sciences publication productivity of the United States, United Kingdom, Canada, and Switzerland.*

The Canadian bioresponsibility framework relies on three statutes: the Human Pathogens and Toxins Act, the Health of Animals Act, and the Plant Protection Act. A single consolidated set of regulatory standards known as the Canadian Biosafety Standard covers all work with human pathogens and most work with animal pathogens. Aquatic animal pathogens and plant pests and pathogens are governed by separate sets of requirements. Human pathogens work is overseen by the Public Health Agency of Canada while animal and plant pathogens are overseen by the Canadian Food Inspection Agency.[60] Like the U.S. Federal Aviation Administration, Canadian bioresponsibility regulators employ a compliance and enforcement continuum that aims to address most compliance problems cooperatively. The continuum ranges from maintaining an active dialogue with regulated entities and requesting corrective actions to revoking licenses and pursuing criminal prosecutions.[61] According to the Centre for Biosecurity, the Public Health Agency of Canada's biosafety regulator:

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[54] National Science Board, National Science Foundation., "Science and Technology: Public Perceptions, Awareness, and Information Sources.," *Science and Engineering Indicators 2024* (Alexandria, VA, 2024), https://ncses.nsf.gov/pubs/nsb20244/public-perceptions-of-science-and-technology.

[55] U.S. Central Intelligence Agency, "Country Comparisons - Population," *The World Factbook*, accessed December 18, 2024, https://www.cia.gov/the-world-factbook/field/population/country-comparison/.

[56] Kavya Sekar, "National Institutes of Health (NIH) Funding: FY1995-FY2021" (Washington, DC: Congressional Research Service, May 12, 2020), https://crsreports.congress.gov/product/pdf/R/R43341/39.

[57] Canadian Association for Neuroscience, "Science Funding in Canada – Statistics," Canadian Association for Neuroscience, October 2023, https://can-acn.org/science-funding-in-canada-statistics/.

[58] Swiss National Science Foundation, "SNSF Key Figures: Disciplines," Swiss National Science Foundation Data Portal, 2024, https://data.snf.ch/key-figures/disciplines?s2=1.

[59] Office of Life Sciences, "Life Science Competitiveness Indicators 2022" (London: U.K. Department of Health and Social Care and U.K. Department for Science, Innovation and Technology, July 21, 2022), https://www.gov.uk/government/publications/life-science-sector-data-2022/life-science-competitiveness-indicators-2022.

[60] Public Health Agency of Canada and Canadian Food Inspection Agency, "Canadian Biosafety Standard, Third Edition," regulations (Ottawa, ON: Government of Canada, November 24, 2022), https://www.canada.ca/en/public-health/services/canadian-biosafety-standards-guidelines/third-edition.html.

[61] Public Health Agency of Canada, "Compliance Activities and Enforcement Continuum," regulations, Government of Canada, July 17, 2014, https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/compliance-enforcement/compliance-activities-enforcement-continuum.html.

> "The Centre starts from the premise that the majority of the regulated community will comply with legislative and regulatory requirements if they understand the requirements and have the proper tools to comply with them. The Centre actively works with its regulated parties to encourage and promote the knowledge and understanding of the [relevant laws and regulations].
>
> Compliance is normally achieved through a co-operative approach between the regulated party and the Centre. Correcting non-compliance can often be achieved through the development of appropriate corrective measures or other methods. However, when this co-operative approach does not lead to compliance, or when the regulated party is incapable of correcting non-compliance, enforcement actions may be used. In some cases, enforcement actions may be the appropriate initial tool to correct or prevent non-compliance."[62]

In Switzerland, a single set of regulations known as the Ordinance on Handling Organisms in Contained Systems covers most bioresponsibility requirements. A handful of other policies such as the Ordinance on Protection of Employees from Dangerous Microorganisms, the Epidemics Act, and the Animal Diseases Act also apply. The Ordinance on Handling Organisms in Contained Systems is overseen by the Federal Office of Public Health (FOPH) together with the Federal Office for the Environment (FOEN).[63] This ordinance requires laboratories conducting work with "moderate" or "high" risk to obtain 20 million francs of insurance against damage to human health and property and 2 million francs of insurance against damage to the environment.[64]

In the United Kingdom, four regulations govern most pathogen research. The Control of Substances Hazardous to Health Regulations provides the overarching framework for managing the risk of biological agents and organisms in workplaces. Genetically modified pathogens are further controlled under the Genetically Modified Organisms (Contained Use) Regulations with additional risk assessment and mitigation measures required. Animal pathogens that could impact livestock are regulated under the Specified Animal Pathogens Order. These regulations are all overseen by a single regulatory body, the Health and Safety Executive.[65] The United Kingdom also possesses an analog to FSAP under the Anti-terrorism, Crime and Security Act (ATCSA) that regulates specific pathogens and toxins that could be used in acts of terrorism and adds requirements such as personnel background checks. These regulations are overseen by the National Counter Terrorism Security Office.[66]

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[62] Public Health Agency of Canada, "Centre for Biosecurity Compliance and Enforcement Policy," Government of Canada, December 1, 2015.
[63] Federal Office of Public Health, "Biosafety Legislation," Federal Office of Public Health FOPH, August 29, 2018, https://www.bag.admin.ch/bag/en/home/gesetze-und-bewilligungen/gesetzgebung/gesetzgebung-mensch-gesundheit/gesetzgebung-biosafety.html.
[64] Ordinance of 9 May 2012 on Handling Organisms in Contained Systems, SR 814.912 (Switzerland), https://www.fedlex.admin.ch/eli/cc/2012/329/en.
[65] University College London, "Regulation of Biological Agents," UCL Safety Services, January 17, 2023, https://www.ucl.ac.uk/safety-services/policies/2023/jan/regulation-biological-agents.
[66]Virology Research Services, "A Guide to UK Biosecurity and Biosafety Regulations," *Virology Research Services Blog* (blog), May 21, 2023, https://virologyresearchservices.com/2023/05/21/a-guide-to-uk-biosecurity-and-biosafety-regulations/.

Finding 9: Existing USG policies do not prioritize collaboration or information sharing

Government bioresponsibility policies are outdated and issued on an ad-hoc basis that struggles to keep pace with the rapid advance of underlying technologies. Regulations and other formal policy processes often move slowly. For example, it took HHS over a decade to update its nucleic acid synthesis screening guidance (the first version was published in 2009). List-based approaches face particularly significant challenges as synthetic biology increasingly enables the creation of modified or novel organisms that defy simple categorization. Iterative, adaptable, and proactive policy solutions are needed. This will require prioritizing collaboration and information sharing.

As discussed above, some USG bioresponsibility policies provide minimal external or independent verification and may not be fully enforceable. On the other hand, regulatory policies such as FSAP tend to rely on the threat of administrative and legal penalties. Even when an investigation finds no fault, it creates significant burdens for researchers and institutions under investigation and can result in reputational harm. Many in the life sciences community recall the prosecution of Thomas Butler after a failure to account for 30 vials of *Yersinia pestis* (plague) in 2003 in the early years of FSAP. This case was viewed by many as grossly unfair and generated a significant backlash in the research community.[67]

In other countries, like Canada (see Finding 8), and in other industries, such as aviation, oversight bodies have taken an approach that instead prioritizes collaboration and information sharing while targeting intentional misconduct and reckless behavior with strict, punitive enforcement actions. For example, the U.S. Federal Aviation Administration has a compliance program under which some compliance issues can be addressed without recourse to punitive measures. Aspects of this system include an enforcement continuum as discussed above, non-punitive accident and incident reporting, technical assistance, and education and informal engagement efforts.

Non-punitive accident and incident reporting

Comprehensive non-punitive reporting systems that collect information about accidents, near accidents, compliance issues, and potential safety problems are credited with reducing errors in the healthcare and airline industries and could do the same in the life sciences.[68] Such a reporting system could also provide evidence of the effectiveness of risk mitigation measures, identify gaps, and build a collaborative relationship with the research community. No comprehensive incident reporting system exists for the life sciences enterprise. Many policy experts and researchers have called for such a system, including the Federal Experts Security Advisory Panel (FESAP), which made recommendations to improve the Federal Select Agent Program.[69,70]

Technical assistance and voluntary collaboration

No central government forum exists to provide technical assistance on the wide range of compliance, biosafety, and biosecurity questions that may arise during life sciences research. Customer service varies widely between the government owners of different policies. According to discussions with scientists, the Federal Select Agent Program

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[67] Barbara E. Murray et al., "Destroying the Life and Career of a Valued Physician-Scientist Who Tried to Protect Us from Plague: Was It Really Necessary?," *Clinical Infectious Diseases* 40, no. 11 (June 1, 2005): 1644–48, https://doi.org/10.1086/431348.

[68] Robert L Helmreich, "On Error Management: Lessons from Aviation," *British Medical Journal* 320, no. 7237 (March 18, 2000): 781–85, https://doi.org/10.1136/bmj.320.7237.781.

[69] Federal Experts Security Advisory Panel, "Report of the Federal Experts Security Advisory Panel" (Washington, DC: U.S. Administration for Strategic Preparedness and Response, December 2014), 28–29, https://www.phe.gov/s3/Documents/fesap.pdf.

[70] David R. Gillum et al., "Seven Opportunities for Effective Biosafety and Biosecurity Governance," *Health Security* 22, no. 4 (August 1, 2024): 324–29, https://doi.org/10.1089/hs.2023.0189.

(FSAP) has recently moved toward a more collaborative model and could serve as an example. This is reflected in a 2024 update to its website that describes providing guidance to regulated entities, education and outreach efforts, and "corrective actions" short of administrative or legal penalties.[71] However, FSAP's scope is limited to research with select agents. Some countries have bioresponsibility agencies that work collaboratively with researchers to jointly devise the best risk management approaches. This reflects overarching trends in the field of biological risk management toward collaborative oversight that treats biosafety officers as partners rather than enforcers.

Technological advances will inevitably move faster than formal policymaking processes, and researchers and bioresponsibility practitioners will likely face novel situations that they will not know how to address. Creating a dedicated home for technical assistance with access to in-house or external expertise in biosafety, biosecurity, other life sciences disciplines, and national security can allow the government to quickly respond to address emerging issues.

Additionally, there is a gap between the bioresponsibility missions of the Centers for Disease Control and Prevention (CDC)—mitigating active public health hazards—and the Federal Bureau of Investigations (FBI)—investigating possible bioterrorism. The FBI will investigate potential bioterrorism and weapons of mass destruction threats in the biotechnology industry, but neither the FBI nor CDC can provide advice on how a biotechnology company should handle suspicious activity that does not rise to the level of facilitating terrorism. An authority is needed that can quickly provide collaborative advice and technical assistance on handling these potential threats.

Finding 10: Little evidence exists to assess the effectiveness of many requirements

Current bioresponsibility requirements are based on experience, not data, and the power of new biotechnologies is rapidly outstripping the value of experiential frameworks.[72] There is little or no experience to draw on for work with novel, modified, or resurrected pathogens, and work involving these kinds of agents is becoming more frequent.

Bioresponsibility policies, with the possible exception of the *NIH Guidelines*, have tended to evolve in a single direction—toward more requirements. Since there is no evidence regarding exactly which measures mitigate risk, each new risk requires adding new systems, equipment, or training, increasing the cost of research and decreasing its efficiency. Fundamental research in bioresponsibility could increase the efficiency of the entire life sciences enterprise, enabling more research dollars to go to science instead of being wasted on unnecessary risk management measures. This could also address concerns about the cost of sustaining safe laboratory operations and facilities, especially in environments where funding is scarce.

Understanding of how laboratory accidents occur is also limited. As a result, investigations of laboratory-acquired infections (LAIs) and other accidents often struggle to identify their underlying causes. An analysis in 1979 of more than 4,000 Laboratory-Acquired Infections (LAIs) found that immediate causes could not be determined in 80% of cases.[73] A more recent review of 309 LAIs in the published literature between 2000 and 2021 found that 9% had

[71] Division of Regulatory Science and Compliance, U.S. Centers for Disease Control and Prevention, "About Us," Federal Select Agent Program, November 8, 2024, https://www.selectagents.gov/overview/index.htm.
[72] Ritterson, Ryan, and Rocco Casagrande, "Basic Scholarship in Biosafety Is Critically Needed To Reduce Risk of Laboratory Accidents," *mSphere* 2, no. 2 (March 29, 2017), https://doi.org/10.1128/msphere.00010-17.
[73] Pike, Robert M, "Laboratory-Associated Infections: Incidence, Fatalities, Causes, and Prevention," *Annual Review of Microbiology* 33, (October 1, 1979): 41–66, https://doi.org/10.1146/annurev.mi.33.100179.000353.

unknown causes.[74] This is likely an undercount because the LAIs described in published articles are more likely to be the ones whose origins are understood, but 9% is still a significant proportion.

Finding 11: Training on and awareness of bioresponsibility varies widely between institutions and the bioresponsibility workforce is rapidly aging

A safety culture is an essential part of risk management and requires awareness of safety problems and the solutions needed to address them. However, surveys suggest that training methods and frequency vary across institutions and there are few assessments of the effectiveness of training programs or approaches.[75,76] Another survey found that just 41% of responding life sciences researchers knew the definition of dual use in the context of the life sciences.[77] Life sciences degrees and other formal education programs rarely include education on bioresponsibility. Although organizations like ABSA International produce training resources employed by some institutions, most institutions create their own training programs, leading to duplicated efforts. The USG could promote effective and consistent bioresponsibility training for researchers and laboratory workers.

The bioresponsibility workforce is rapidly aging while demand for bioresponsibility professionals continues to rise.[78] There are few training or education programs focused on developing future bioresponsibility professionals, and requirements have not been based on a systematic analysis of what experience, skills, and training are most important for doing the job well. Training and recruitment are needed to ensure U.S. laboratories remain safe.

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[74] Blacksell, Stuart D., Sandhya Dhawan, Marina Kusumoto, Khanh K. Le, Kathrin Summermatter, Joseph O'Keefe, Joseph P. Kozlovac, et al., "Laboratory-Acquired Infections and Pathogen Escapes Worldwide between 2000 and 2021: A Scoping Review," *The Lancet Microbe* 5, no. 2 (February 1, 2024): e194–202, https://doi.org/10.1016/S2666-5247(23)00319-1.

[75] Stephanie L. Richards, Victoria C. Pompei, and Alice Anderson, "BSL-3 Laboratory Practices in the United States: Comparison of Select Agent and Non–Select Agent Facilities," *Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science* 12, no. 1 (February 1, 2014): 1–7, https://doi.org/10.1089/bsp.2013.0060.

[76] Dana Perkins et al., "The Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences: A Comprehensive Literature Review," *Applied Biosafety*, March 1, 2019, https://www.liebertpub.com/doi/10.1177/1535676018778538.

[77] Svenja Vinke, Irina Rais, and Piers Millett, "The Dual-Use Education Gap: Awareness and Education of Life Science Researchers on Nonpathogen-Related Dual-Use Research," *Health Security*, February 15, 2022, https://doi.org/10.1089/hs.2021.0177.

[78] David Gillum, "The Making of a Biosafety Officer," *Issues in Science and Technology* 39, no. 3 (April 19, 2023): 67–71, https://issues.org/making-biosafety-officer-gillum/.

Recommendations for a Modernized USG Bioresponsibility Framework

Adoption of the following seven recommendations would create an integrated bioresponsibility policy framework centered on an independent bioresponsibility authority, as proposed in Recommendation 1. Recommendations 2-7 lay out the functions and responsibilities envisioned for such an entity. Although each recommendation can be considered separately, they are highly interconnected and would function best if implemented together. The final part of this section summarizes the proposed functions of an independent bioresponsibility authority and briefly discusses how it could be structured.

Recommendation 1: Establish an independent bioresponsibility authority

Establishing an independent bioresponsibility authority would mean creating an independent agency reporting directly to the President, rather than an existing agency or department head, and having a director removable only for cause. The authority should be tasked with ensuring the safety and security of the U.S. life sciences research enterprise while minimizing the burden on scientific and industrial progress.

Such an authority would concentrate diffuse responsibility for the bioresponsibility mission in a single location, creating a clear point of contact for researchers and policymakers and improving accountability. The authority would have the opportunity to unify and harmonize the nation's fragmented bioresponsibility framework, reducing uncertainty and compliance burdens while filling key gaps, such as uneven oversight for non-federally funded life sciences activities. Establishing a new organization would also create an opportunity to foster the flexible, iterative, and collaborative culture needed to adapt to rapid technological advances. Finally, creating a fully independent agency would avoid the perceived conflicts of interest associated with existing governance structures, reduce the risk of undue political influence, and promote consistent oversight across federal departments and agencies.

The authority would need the expertise, capacity, and authority to issue, oversee, administer, and enforce regulations—including conducting inspections and investigating violations—and manage programs as described in this document. The authority should have access to expertise in the life sciences, biotechnology, biosafety, national security, ethics, and relevant social sciences, such as management science.

Recommendation 2: Create a comprehensive, consolidated bioresponsibility regulatory framework

Based on a review of existing bioresponsibility policies in the United States and around the world, the independent authority should create a single framework for the safe, secure, and ethical conduct of potentially high-risk life sciences activities.

This should involve assuming responsibility for and taking on the existing activities of the Federal Select Agents Program (FSAP); the Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors; and the USDA APHIS Veterinary Services Organisms and Vectors (OV) Permitting Unit. The authority would write regulations that incorporate and supersede the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential (DURC-PEPP Policy). The regulatory framework should also incorporate elements of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), published by the CDC and NIH, the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH*

Guidelines), and the *NIH Design Requirements Manual*. The authority should assume primary oversight responsibilities for these biosafety and biosecurity guidelines and coordinate future updates to ensure harmonization with the authority's regulatory framework. However, the development and updating of the *NIH Guidelines, NIH Design Requirements Manual* and BMBL should remain the responsibility of the organizations that now produce them.

The authority's regulations should apply to all activities within the United States, regardless of funding source. Where applicable, activities funded by the United States government (USG) at foreign institutions should be governed by processes equivalent to those required for domestic research in the United States.

One-time review of bioresponsibility frameworks

Before issuing regulations, the authority should lead a one-time top-to-bottom review of all existing guidelines, regulations, and laws related to bioresponsibility in the United States and their counterparts in peer nations. This should involve:

- Identifying gaps and proposing solutions and opportunities for harmonization;
- Identifying opportunities to streamline oversight procedures, improve customer service for the regulated community, and/or relax requirements on lower-risk activities, including those under the Federal Select Agent Program;
- Identifying lessons learned from the experience of peer nations in regulating and overseeing high-risk life science activities, including how they engaged with their research communities and what the impact was; and
- Consulting with stakeholders across the life sciences research, biotechnology, biosafety, biodefense, and national security communities to consider the impact of new regulations on safety, security, and innovation.

Review of Dual Use Research of Concern (DURC) and research involving Pathogens with Enhanced Pandemic Potential (PEPP)

The authority should enact regulations requiring all DURC and PEPP research to undergo review. Reviews should be required regardless of funding source and conducted before work begins or as soon as it meets the definition of DURC or PEPP research.

Definition of DURC and PEPP

DURC and PEPP should be defined as in the DURC-PEPP Policy except that the definition of a Pathogen with Pandemic Potential (PPP) should be expanded to include pathogens likely capable of wide and uncontrolled spread in animal and plant populations and that would likely cause moderate or severe disease in those populations. This would also expand the definition of PEPP to cover animal and plant pathogens that pose global threats.

The authority should add or remove agents, organisms, and research activities from the lists covered by DURC based on periodic assessments of the risks involved, or as needed.

Review process

The definitions, decision criteria, and review process should be based on those laid out in the DURC-PEPP Policy. Researchers or Principal Investigators (PIs) should inform the authority and their institutions about proposed or ongoing research that may constitute DURC or PEPP research. Research institutions should be required to have an Institutional Review Entity (IRE), which would share responsibility for flagging these projects to the authority. The authority should specify criteria and processes for flagging research with a focus on making the process user-friendly (e.g., by receiving notification through a secure online portal). The authority should provide resources, such

as case studies, to facilitate this process. PIs and institutions should share responsibility and accountability for identifying DURC and PEPP research, and the authority should be obligated to assist them by answering questions about compliance or related safety and security issues in a timely manner.

For PEPP research, the authority should make a prompt determination about whether flagged research falls within the scope of its definition. If so, the research would not be permitted to begin or resume until the authority finishes its review and makes a go/no-go decision. Based on a risk-benefit analysis and risk mitigation plan submitted by the PI and institution, the authority would assess whether the benefits of the work justify its risks and whether it satisfies the other criteria specified in the 2024 DURC-PEPP Policy, including whether it can be conducted safely and securely. In addition to a go/no-go decision, the authority should be able to specify modifications to the risk mitigation plan, including adherence to additional standards and/or additional oversight measures (like inspections).

For DURC, the institution should have the option either to forward the project for review by the authority or to conduct an internal review. Review by the authority would follow the same process as that for PEPP, although the authority would apply a lower degree of scrutiny commensurate with the lower degree of risk from DURC. That said, the authority should be especially cautious of work that would provide experimental confirmation of potential high-consequence threats. For internal reviews, the results should be forwarded to the authority. The authority could opt to provide feedback to the institution about how a given review was conducted and the conclusions it reached. Implementation of any recommendations made should be voluntary. However, the authority should be able to overrule an institution's review decision if an egregious error of judgment were identified. This power should be exercised sparingly with the expectation that researchers and research institutions can begin conducting DURC as soon as the internal review is completed.

Unlike the process described in the DURC-PEPP policy, the authority's review process should be entirely separate from the research funding process and would apply to both federally and non-federally funded research. Funding agencies would likely want to coordinate funding processes and decisions with the authority to minimize the chances that projects could be approved for funding but not permitted by the authority to proceed, and the authority should be obligated to respond to their requests for information about research under review.

The authority could periodically conduct scans of selected academic publications and other research outputs, such as pre-prints circulated online, to identify DURC or PEPP research that PIs or institutions failed to flag. In such cases, the authority could audit the institution's processes and identify areas for improvement, or in case of serious lapses, take enforcement actions.

The authority should publish information about the review process, including how it conducts risk-benefit analyses and makes decisions. As in the DURC-PEPP policy, aggregate information about PEPP research reviewed, anticipated risks, anticipated benefits, and risk mitigation measures should be made public, without releasing information that would compromise national security, safety of research activities, confidential business information, or sensitive information about individuals. The authority should study whether it would be appropriate to make additional information public, balancing these concerns with the public's right to know what high-risk work is taking place and how those risks are justified and mitigated. Information that is withheld from public release due to these sensitivities should be exempt from release under FOIA.

Regulatory standards for DURC & PEPP and activities involving high-consequence agents and organisms

The authority should endorse existing standards or develop specific laboratory safety and security standards required for facilities conducting DURC or PEPP research or engaged in activities involving high-consequence biological agents or organisms (defined below). For work outside these categories, the standards would be considered voluntary guidance, although compliance could be made a condition of federal funding.

Standards should be tied to containment levels, setting out requirements for minimum engineering and design features, laboratory practices, safety equipment, staffing, training, and internal risk assessments and oversight. They should integrate requirements from the BMBL, *NIH Guidelines*, *NIH Design Requirements Manual,* and FSAP. While the BMBL and the *NIH Guidelines* should continue to be maintained by organizations other than the authority, the core, enforceable requirements should be incorporated into the authority's standards, and the authority should take a lead role in drafting future editions to ensure that they do not create overlapping or duplicate requirements. As in existing policies, containment levels should be assigned based on research institutions' risk assessments. The highest containment levels and most stringent controls should be required for work that could pose a severe threat at the national or global scale, such as research involving PPPs.

In most cases, standards should mirror the practices already in place at high-performing institutions. This will avoid penalizing leaders in safety and security while incentivizing consistently strong practices across institutions. To the extent possible, standards should be cost-effective based on evidence from empirical studies and research conducted using reports of accidents and near-misses. These sources of information would be supplemented by expert judgment and studies of existing best practices in the life sciences and analogous fields. Standards should be frequently updated to account for new evidence, experiential learning, and new risks, including removing requirements that show little benefit compared to their cost.

Definition of high-consequence agents and organisms

High-consequence biological agents and organisms are those that pose a significant threat to public health or safety, national security, agriculture, or the environment, initially defined as a list that includes all select agents regulated by FSAP, Risk Group 3 and 4 pathogens listed in the *NIH Guidelines*, and Pathogens with Pandemic Potential (PPPs), as defined in the White House DURC-PEPP policy with the addition of animal and plant pathogens.

The authority would develop procedures to determine when modified or novel agents or organisms fall into this category, including Risk Group 2 agents modified to be more deadly, more transmissible, or countermeasure-resistant such that they pose the same level of risk. The authority would remove pathogens from the list or exempt specific strains based on periodic risk assessments, reducing burdens on the life sciences enterprise for agents and organisms that no longer pose a significant threat.

The authority should move toward a risk-based rather than list-based approach to define and identify high-risk biological agents and organisms to flexibly account for risks from modified and novel agents and organisms and focus oversight on the activities that pose the greatest threat. Developing such a system will itself require research and a deliberative study based on existing proposals and other related literature.

Laboratory engineering and design

The authority should provide detailed design and construction requirements for high-containment laboratories and could provide technical assistance in helping institutions develop and build them. This would be closely modeled on

the *NIH Guidelines*, BMBL, FSAP regulations, and the *NIH Design Requirements Manual* requirements for high-containment laboratories.

Laboratory operations

Standards should include specific requirements for operating a high-containment laboratory, including how to assess the risk of proposed lab work and assign it to an appropriate containment level. Operating standards should be informed by the BMBL, *NIH Guidelines*, and FSAP regulations and should create a single, unified, enforceable set of laboratory biosecurity and biosafety standards. While enforceable, standards need to be applied flexibly enough to preserve scientists' ability to innovate and deal with novel situations. This document does not contain a comprehensive list of what standards would cover, but key features, especially those not included in current guidelines or regulations, are summarized below:

- A requirement to have an Institutional Biosafety Committee and standards for its composition, transparency, and risk-assessment process, including the evaluation of residual risk;
- Similar standards for having an Institutional Review Entity, which is required to conduct research reviews, including its composition, public communications, risk-benefit analyses, and risk mitigation plans;
- Biosafety and biosecurity training requirements for each level of containment, including topics covered, shadowing and live work requirements, and hours needed;
- Appropriate staffing levels for bioresponsibility professionals, including the number of FTEs needed at different scales and containment levels;
- Biosafety and biosecurity facility management and operations;
- Timely and consistent reporting of accidents and other safety incidents internally, to local public health officials, and to federal authorities;
    - Other government agencies requiring biosafety or biosecurity incident reporting would need to coordinate with the authority.
- Standards for public communications about breaches of containment, security incidents, and laboratory-acquired infections;
    - This would include communication of accidents and near-misses to the public and how they were prevented from becoming major incidents. If a security incident results from the exploitation of a vulnerability, information should not be made public about the incident until the vulnerability has been ameliorated. A deliberative study is needed to determine what should be communicated about a laboratory's activities and what should not be. Such a study should analyze best practices at existing labs and other facilities that handle hazardous materials, such as chemical plants.
- Standards for public transparency about research activities;
    - The authority would seek to maximize transparency to the extent permitted by relevant laws and regulations and the imperatives to protect national security, personal safety, and proprietary information.
- Standards for field biosafety;
- Standards for laboratory emergency management planning and exercises;
- Personnel reliability standards focused on the highest-risk activities, including PEPP research;
- Cybersecurity standards; and
- Standards for bioresponsibility professionals, including training and experience required.

Certification and compliance

The authority should create certifications or require third-party certifications to commission high-containment laboratories, operate at a given containment level, and be considered a bioresponsibility professional. This should involve intermittent on-site inspections, according to the criteria established by the authority, of laboratories

conducting DURC or PEPP research or work involving high-consequence biological agents or organisms. Inspection frequency should depend on the risk level of the activities involved. To reduce duplicate inspections, other state, local, and federal agencies with a remit to oversee the biosafety and biosecurity at regulated entities should review the authority's inspection results before conducting their own. Additional inspections should occur only if the authority's inspection fails to meet an important need, and they should be targeted to that need. Moreover, to the greatest extent possible, any inspections by other agencies should be coordinated with inspections by the authority to minimize disruption to the facility.

Research institutions with a strong demonstrated record of compliance should be subject to fewer periodic on-site inspections.

Nucleic acid synthesis screening requirement

The authority should mandate "Know-Your-Customer" (KYC) and "Know-Your-Product" (KYP) screening for DNA and RNA synthesis providers, including providers of benchtop synthesis devices. Screening requirements should be informed by the existing U.S. Department of Health and Human Services (HHS) guidance, the White House framework, and other scientific and policy literature on the topic.

"Know-Your-Customer" (KYC) and "Know-Your-Product" (KYP) requirements

"Know-Your-Customer" (KYC) and "Know-Your-Product" (KYP) requirements refer to a regulatory framework aimed at preventing the misuse of nucleic acid synthesis services and equipment. These technologies significantly lower the barriers for irresponsible or malicious actors to evade the authority's regulations, potentially enabling unsafe research or even bioterrorism.

As described in existing guidance and policy documents, KYC requirements would mandate that providers collect identifying information about their customers and check their legitimacy, such as verifying that names and addresses match publicly available records. KYP screening would involve checking synthesis requests for sequences associated with high-consequence biological agents or organisms. Screening of sequences produced by benchtop synthesizers would likely need to be phased in over time given the immature state of that capability. The existing White House framework will apply to screening on benchtop synthesizers beginning in October 2026, and the authority should establish a similar timeline.

Orders flagged during initial KYP or KYC screening would receive follow-up screening that should confirm the validity of the initial concern and, if applicable, verify that the customer will handle the requested sequence safely and securely. This could involve, for example, confirming that the customer has a valid registration with the authority and that the customer's biosafety committee has approved the activity. If concerns cannot be resolved by follow-up screening, then the order should be denied and reported to law enforcement and any other relevant bodies (e.g., to share information with other providers). The stringency of the follow-up investigation should be calibrated according to the potential risk of the activity. Orders suggesting work with PPPs or other activities with national- or global-scale risks should receive the greatest scrutiny.

The authority would be the appropriate home for any future USG role in nucleic acid synthesis screening activities, possibly including analyzing orders across providers to identify suspicious patterns or maintaining lists of sequences of concern. The authority should provide guidance and technical advice to assist providers in making decisions about whether or not to fill potentially concerning orders. This would not supersede other USG responsibilities, including relevant law enforcement and export control authorities.

Registration for laboratories and nucleic acid synthesis providers

All laboratories conducting DURC & PEPP research or using high-consequence agents and organisms and all nucleic acid synthesis providers should be required to register with the authority. Registration should include providing basic information, such as what kind of institution the entity is, where it is located, what activities require it to register, what facilities are used for those activities, and what high-risk agents and organisms the entity possesses.

Scope

All entities based in the United States, receiving research grants from the USG, or selling to the U.S. market should be subject to registration requirements if they engage in any activities described above.

Registration process

Registered authorities should periodically update the information provided about their operations. It is expected that the vast majority of BSL-3 and BSL-4 laboratories in the United States would be covered by registration requirements.

Registration could be revoked, suspended, or denied if the laboratories were judged not to be operating safely or were unable to project sources of support sufficient to ensure safe and secure operations and maintenance. Registration information would be available to public health authorities and emergency managers, and it would be available to the public by default unless classified or law enforcement sensitive.

Human and animal pathogen import permitting

The authority should regulate the import and interstate transport of human and animal pathogens, including infected vectors, based on existing statutes and regulations. The authority should assume responsibility for and take on the existing activities of the CDC Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors and the USDA APHIS Veterinary Services Organisms and Vectors (OV) Permitting Unit. The authority should maintain the original intent of these policies to protect public health and safety, animal health, and the agricultural industry while finding ways to harmonize these regulations with each other and with the import and transport requirements of the Federal Select Agent Program and any other regulations the authority creates. This would include reducing unnecessary overlap and finding opportunities to improve customer service for the regulated community. The authority could also take on permitting for the import and interstate transport of infected plants and plant pathogens. However, plant pathogens are currently integrated into the overall USDA APHIS Plant Protection and Quarantine import and interstate transport permitting schemes for plants, plant products, and plant pests. It would likely create additional confusion to split up these programs. Instead, the authority should coordinate with USDA to harmonize requirements.

Monitoring for biotechnology products indicative of regulated activities

The authority should require or provide monitoring of transactions involving biotechnology services, materials, or equipment that are indicative of the activities it regulates. Certain services, materials, and equipment are closely associated with work involving high-consequence agents and pathogens, DURC & PEPP research, and the interstate transport or importation of pathogens. For example, a request to purchase BSL-4 containment suits would provide evidence that a customer should be registered or otherwise regulated by the authority.

The authority should create a list of such services, materials, and equipment and establish a requirement to collect information on transactions with listed products to assist in identifying improper, illegal, and dangerous activities. Unlike existing export controls, the list should focus on products required for regulated activities but not used

widely in other life sciences activities (e.g., the list should not include ordinary benchtop centrifuges). The purpose of this monitoring would be to provide the data needed to identify patterns of misuse, and the authority should not hold providers accountable for misuse by their customers. Providers should only be responsible for making data available according to the authority's requirements.

Time-limited exemptions and outbreak response

The authority should be able to issue time-limited regulatory exemptions for certain activities. Exemptions should require a showing of good cause—such as accelerating the nation's response to an acute public health threat—so long as such exemptions are consistent with protecting public health and safety, national security, agriculture, and the environment from significant biological threats. When an agent or organism begins to circulate widely, the authority should act rapidly to update its risk assessment and likely reduce or eliminate requirements.

Decision review process

Impacted members of the regulated community should have recourse to a review process for some decisions made by the independent authority if they can clearly articulate grounds for reversal. Actions subject to review should include suspension, revocation, or denial of registration; adding or removing biological agents, organisms, or sequences of concern from the scope of regulation; import permitting decisions; and research review decisions. Reviews should be conducted by a dedicated review board appointed by the authority's leadership that includes subject matter experts from outside of the authority without conflict of interest. A decision to change a regulatory requirement in a particular circumstance could trigger a process to investigate whether the overall requirement should be revised.

Access to the authority's review process should be constrained to avoid resource-intensive, bad-faith appeals through means such as limited review windows and initial screening to dismiss cases that lack merit.

Enforcement continuum

As argued elsewhere by the authors, "oversight policies should include an enforcement continuum with options ranging from cooperative engagement (e.g., support for root cause analysis of an identified issue) to legal penalties (e.g., fines). This enforcement continuum should treat most compliance problems as learning opportunities rather than evidence of wrongdoing. It should also address potential problems earlier and more quickly by leveraging the option to take actions with a lower cost than administrative or legal proceedings."[79]

Inspired by the practices of the Canadian biosecurity and biosafety regulator and the Federal Aviation Administration's compliance philosophy, the authority should prioritize collaboration with well-intentioned individuals and institutions to rapidly address compliance issues.[80,81] Typically, in case of delays or repeated issues, enforcement should escalate incrementally toward administrative and legal penalties. However, obstruction, recklessness, and intentional wrongdoing should not be tolerated and should immediately result in strict penalties.

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[79] Snyder, Ben C., Joshua M. Wentzel, Gerald L. Epstein, Robert P. Kadlec, and Gerald W. Parker, "Trust, but Verify: A 'Just Culture' Model for Oversight of Potentially High-Risk Life Sciences Research," *Applied Biosafety*, December 20, 2024, https://doi.org/10.1089/apb.2024.0053.

[80] U.S. Federal Aviation Administration, "Compliance Program," 2024, https://www.faa.gov/about/initiatives/cp.

[81] Public Health Agency of Canada, "Centre for Biosecurity Compliance and Enforcement Policy," Organizational descriptions, December 1, 2015, https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/compliance-enforcement/centre-biosecurity-compliance-enforcement-policy.html.

Recommendation 3: Establish an office for technical assistance and policy research

The authority should create an office to provide technical assistance to regulated entities, track the bioresponsibility implications of technological advances, and identify needed policy changes. To encourage collaboration with the regulated community, this office should be separate from the authority's regulatory enforcement wing. Although each office should have a separate reporting line, they should remain in close communication about providing technical assistance and identifying policy needs.

Technical assistance with legal safe harbor

The authority should provide on-request, timely technical assistance on bioresponsibility questions within the scope of its expertise. Technical assistance would reduce uncertainty and help the regulated community arrive at the best biorisk management approaches.

The authority should provide legal safe harbor for individuals, institutions, and companies that receive and follow its guidance on regulatory compliance. Requests for technical assistance that reveal past criminal violations should not immunize entities for those violations, but they could be seen as a mitigating factor in any enforcement action.

Technical assistance should go beyond answering basic compliance questions. It should help the regulated community address complex edge cases and novel challenges that are not yet covered by formal policies. The authority should maintain a strong network of contacts within the national security and life sciences fields and make use of these connections to answer questions for which it lacks the requisite expertise. The authority should also encourage funders and research institutions to explore the use of safer, non-regulated surrogates for high-consequence agents and organisms and to develop high-fidelity model systems in surrogates (see Recommendation 5 below).

The authority may judge that the technical assistance provided in a particular case would be of general interest. If so, the authority should make its guidance public, so long as it can do so in a way that does not jeopardize proprietary information, privacy, or national security.

The authority's collaborative advice and technical assistance should also be accessible to local law enforcement, public health, and emergency response authorities dealing with rare bioresponsibility issues. The issues may involve an entity that is or should be regulated by the authority, but proving this should not be a requirement for receiving assistance. This would provide support to state and local officials in a future case like that of the laboratory discovered operating illegally in Reedley, California.

Policy research

The authority should conduct policy research on the bioresponsibility implications of technological trends, scientific findings, and information generated by its activities. The authority should collect and publish lessons learned from its regulatory, research, and technical assistance functions.

The authority should also investigate several important issues with implications for its regulatory mission and provide reports to Congress and the White House on its findings.

- The authority should study how its definitions of DURC and PEPP research might be expanded or changed to accommodate other types of pathogen and non-pathogen research that could cause significant damage to public health or safety, agriculture, or the environment. This could include certain applications of AI to the

life sciences, some work on gene drives, or areas of research that could facilitate the creation of mirror organisms.
- The authority should study how its definition of high-consequence agents and organisms might be expanded or changed to accommodate other types of pathogens or non-pathogenic biological agents and organisms that could cause significant damage to public health or safety, agriculture, or the environment.
- The authority should study how to identify and regulate biotechnology services, materials, and equipment other than nucleic acid synthesis that might similarly enable malicious or irresponsible actors to evade the authority's requirements. This could include cloud laboratories, which are highly automated laboratories that can remotely perform scientific procedures according to user instructions.

Trends in emerging technology, including artificial intelligence

The authority should perform horizon-scanning to identify emerging bioresponsibility risks and opportunities from scientific and technological advancements that would affect its regulatory mission, in collaboration with science-, security-, and bioeconomy-related government and non-government organizations.

In consultation with the Department of Homeland Security, the Department of Energy, the White House Office of Science and Technology Policy, and the Department of Commerce, including the AI Safety Institute, the authority should monitor and assess the potential for artificial intelligence (AI) to be misused to develop or produce biological threats, as well as the potential for AI to enhance bioresponsibility. In this rapidly changing environment, the authority should focus on how these developments intersect with its functions and how to best adapt or update its regulations, technical assistance, research activities, and other functions.

Advisory boards

The authority should house relevant advisory boards, including the NSABB, and seek non-governmental expert guidance from these boards and other stakeholders on its regulations, policies, standards, and operations. The authority should review and update the charters of these advisory boards on an ongoing basis.

Policy development and periodic review of regulatory functions

The authority should periodically review its regulatory functions and definitions to ensure their currency and applicability. These reviews should integrate all information available to the authority, including its analysis of trends in emerging technologies, input from advisory boards, reports and findings received from the National Bioresponsibility Incident Board (see Recommendation 4), and results from its biosafety and biosecurity research program (see Recommendation 5). Reviews should re-assess the risk of regulated activities and recommend relaxing or removing requirements where risks have decreased.

In addition to periodic reviews, the authority should adjust its policies on an ad-hoc basis in response to developments that significantly impact its regulatory mission, such as the identification of a major gap in its requirements or a significant technological breakthrough.

Updating guidelines

The authority should convene the relevant parties to review and update existing biosafety and biosecurity guidelines, including the BMBL and *NIH Guidelines*. The authority would also assume primary oversight of the BMBL and *NIH Guidelines*, coordinate the development and publication of future editions with NIH and CDC, and ensure harmonization of these biosafety and biosecurity guidelines and the authority's own standards.

Recommendation 4: Create a semi-independent board to manage a non-punitive reporting system and conduct informal engagement across the life sciences research enterprise

Modeled after aspects of the Federal Aviation Administration (FAA) and the National Transportation Safety Board (NTSB) appropriate for the life sciences, an independent board should be created within the entity. This body, the National Bioresponsibility Incident Board (NBIB), should be charged with facilitating the voluntary exchange of information about compliance, biosafety, and biosecurity incidents.[82] The NBIB would build trust with the regulated community, cooperatively identify bioresponsibility issues, and issue recommendations aimed at preventing future occurrences. It would not conduct law enforcement or regulatory investigations and would be insulated from the authority's regulatory office. This should include using separate office spaces, having separate reporting lines, and relying on limited, formal lines of communication.

Non-punitive reporting system

The NBIB should create a comprehensive reporting system based on a bottom-up analysis of how this system should be developed and employed. This should combine mandatory accident and incident reporting required by the regulatory office (see Recommendation 2) with a confidential, possibly anonymous, non-punitive reporting system for individuals involved in potentially high-risk life sciences activities, allowing them to report accidents, near-accidents, or other safety incidents occurring or potentially occurring.

The NBIB should perform a requirements study and create data standards and ontologies as the basis for its reporting system. Consistent with its objectives, the NBIB should seek to create comprehensive, combined databases and minimize the number of separate reporting systems. For example, the NBIB might determine that separate reporting systems for safety incidents and self-disclosure of regulatory violations are needed.

Like the FAA, the NBIB should refer reports that indicate ongoing violations of bioresponsibility regulations—or imminent or ongoing threats to human, animal, plant, or environmental health—to the appropriate authority for rapid follow-up. However, the information provided to the Board should be used exclusively as the basis for non-punitive compliance actions aimed at correcting the underlying causes of incidents and re-establishing compliance—except in cases of reckless behavior, criminal negligence, or intentional misconduct or fraud. Otherwise, this information could not be used to justify administrative or legal penalties or civil judgments. Note also that these protections on the provision of information would only apply to information provided to the NBIB; they would not affect any information collected through any other investigative or law enforcement procedure.

Inspired by the FAA's voluntary and no-fault reporting systems, this would foster an environment of continuous safety improvement and help to identify system-wide risks by encouraging people who might otherwise be deterred by punitive consequences to bring problems to the Board's attention. The goal should be to identify the probable cause of incidents or near incidents to serve as the basis for judgments about the effectiveness of risk mitigation measures and recommendations for policies set by laboratories and the authority itself. As part of this mission, the NBIB could assist institutions with investigations of incidents or near incidents on a voluntary basis.

[82] The authors have written about this concept in more depth elsewhere. See Snyder, Ben C., Joshua M. Wentzel, Gerald L. Epstein, Robert P. Kadlec, and Gerald W. Parker, "Trust, but Verify: A 'Just Culture' Model for Oversight of Potentially High-Risk Life Sciences Research," *Applied Biosafety*, December 20, 2024, https://doi.org/10.1089/apb.2024.0053.

Informal education, outreach, and inquiries

The NBIB should conduct education, outreach, and inquiries with regulated entities, other laboratories, and users and providers of dual-use biotechnology services, materials, and equipment to enhance knowledge about bioresponsibility and awareness of patterns of misuse and potential risks. The NBIB should promote awareness of and adherence to voluntary guidelines like the BMBL and *NIH Guidelines* among non-regulated entities. The NBIB should also leverage these activities to collect feedback from the life sciences community, identify best practices in the field, and learn about scientific and technological developments with bioresponsibility implications. Findings should be shared with the authority's policy research office.

Recommendation 5: Develop a bioresponsibility research program

The authority should employ program managers to fund and oversee research in advancing biosafety and biosecurity. The authority should not perform or fund any of the potentially high-risk life sciences activities that it regulates. If there is a need for biosafety and biosecurity research to use high-consequence agents or organisms or involve DURC and PEPP research, the authority should seek lower-risk alternatives. Other agencies could also fund this work. Priority research areas are described below.

Empirical biosafety

Empirical research in biosafety, which includes investigations in the life sciences, physical sciences, social sciences, and human factors, would provide empirical evidence to strengthen understanding of what biosafety accidents are most likely, their impact, their causes, and what works to guard against them.

Accidents and failure modes

The authority should fund research to identify and characterize the accidents most likely to occur in laboratories working with pathogens or other high-consequence agents and organisms, including a heavy focus on how likely these accidents are to lead to laboratory-acquired infections (LAIs) or accidental pathogen escape from a laboratory (APEL). The goal would be to discover what kinds of accidents are most likely to lead to the spread of a laboratory agent or organism among laboratory workers, in local communities, and beyond and to accurately understand the risk of various laboratory procedures. Possible research questions include how infectious material travels when a spill occurs and how mitigations like engineering controls can change the outcome of accidents. As an example of this kind of work, see the 2024 study by Kim et al. assessing the rate of spills during routine biological manipulations.[83]

The authority should also fund research to determine the causes of common laboratory accidents. Laboratory accidents usually begin with a human error that leads to a cascade of failures (rather than resulting from pure equipment failures), but the initial point of error often cannot be determined. Simulations or observations of accidents in laboratory environments might help address this problem.

Effectiveness of risk mitigation measures

The authority should fund research to assess the costs and benefits of different risk mitigation measures with the goal of identifying what measures effectively prevent biosafety failures and are critical for safe operations—and what measures provide no more than a false sense of security and should likely be modified or eliminated. It should also seek to test assumptions about how biosafety equipment performs as employed by end users.

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[83] Kim, Kelly N., Henry L. Wyneken, Joan M. Ryan, Sylvia Costa, Jessie Harrell, Lily Yandow, Adam E. J. Fleming, et al., "Rate of Errors During Routine Biological Manipulations," *Applied Biosafety*, August 23, 2024, https://doi.org/10.1089/apb.2024.0009.

Low-resource biosafety

The authority should fund studies with overseas partners in bioresponsibility to support sustainable laboratories, operations, maintenance, and safe practices in low-resource settings. The goal would be to determine which measures and practices most reduce risk to create a minimal-safe laboratory that would boost the sustainability of laboratories in low-resource settings.

Safer materials and practices

The authority should fund research and development aimed at creating safer and easier-to-use equipment, consumables, and laboratory practices. It should also promote the adoption of these technologies. This could include research into self-decontaminating laboratory surfaces, cost-effective decontamination substances and practices, and establishing surrogates for high-consequence agents and organisms that would allow researchers to answer research questions without needing to work with the agents and organisms themselves (e.g., by using pseudo viruses which cannot replicate)—including scientific guidelines for surrogate use.

Safety and security by design

The authority should fund research into methods to build safety and security into biotechnology products by design and work to improve the safety and security of existing products. Initial focus areas should include benchtop nucleic acid synthesizers and assemblers. This could also involve funding—in consultation with other government partners like the Department of Homeland Security, HHS ASPR, and the National Institute of Standards and Technology—research, development, and adoption of safeguards for AI models with potentially high-risk life sciences applications, such as biological design tools which could allow users to redesign toxins and pathogens to evade controls on nucleic acid synthesis.

Recommendation 6: Support bioresponsibility education, training, and workforce development

The authority should support training and education in bioresponsibility across the life sciences enterprise and the biotechnology industry, provide funding for bioresponsibility, and help develop the next generation of bioresponsibility professionals.

Bioresponsibility training and education

The authority should develop and share a variety of bioresponsibility training and educational materials. This would not only help regulated entities understand and successfully manage their responsibilities but also foster a culture of responsibility in the broader life sciences and biotechnology communities.

The authority should create drop-in bioresponsibility training materials to support researchers and staff across all life sciences facilities and biotechnology firms. Drop-in materials would prevent duplication of effort and help support the promulgation of standards throughout the community, as many research institutions and biotechnology service providers create their own trainings. This should include both materials for researchers on safe and secure practices—including what is needed for compliance with regulations, as appropriate—and materials for students on the fundamentals of bioresponsibility. Training on dual-use and bioresponsibility for undergraduate and graduate researchers could be a requirement to receive NIH training grants at an institution.

The entity should also create other educational materials, such as curricula or lesson plans, to expose all life sciences students to concepts of bioresponsibility throughout their education. Bioresponsibility should be included in nearly every life sciences course as it is relevant to a wide range of fields, from medicine to ecology.

Support for bioresponsibility professionals

In addition to creating materials for the individuals involved in the broader bioeconomy, the authority should develop a bioresponsibility curriculum that could be used to educate budding bioresponsibility professionals in accordance with the standards and certifications required by the authority. This could include scenario-based training materials based on anonymized reports of actual accidents and compliance questions received by the authority.

The authority should provide funds for the recruitment of new highly qualified bioresponsibility professionals and support their education and training. This could involve a mixture of short-term training opportunities, formal credential-based programs, and apprenticeships. Funded training and recruitment are essential for drawing scientists into the field, as skilled individuals often have other career opportunities in academia or industry.

Additional funding for bioresponsibility

The authority will make funding available for bioresponsibility research, training and education, workforce development, and technical assistance. However, further changes in the funding ecosystem outside of the authority are needed to support biosafety and biosecurity. In particular, bioresponsibility staff and activities should be included as a direct charge on government grants. Currently, these staff and activities are typically paid from institutional overhead, which creates an incentive to skimp, rewarding institutions that do less while penalizing responsible actors. Allowing direct charges would help establish standards for how much labor and effort should be spent on bioresponsibility for different types of research. Research funders would be able to directly dictate how much bioresponsibility funding is needed for each project, commensurate with its risk.

Recommendation 7: Support international engagement on bioresponsibility

The authority should bolster U.S. international engagement to promote a strong, harmonized international bioresponsibility framework.

International standards and resources

In addition to creating standards for researchers across the United States on bioresponsibility, the authority should support efforts to internationalize these standards. The authority should make bioresponsibility training, education, and workforce development materials and research findings widely available to promote their diffusion and use abroad. This could involve prioritizing bioresponsibility training for international researchers and students temporarily in the United States. Such investments would not just be altruistic, they would also support U.S. health security. The consequences of biosafety or biosecurity lapses anywhere in the world could impact the United States.

Supporting diplomacy

The authority should assist the U.S. Department of State in enhancing diplomacy related to bioresponsibility. This could involve requiring biosecurity and biosafety investments as integral components across U.S. global health and health security policies and programs, compiling lessons learned from implementing partners for global health and health security programs abroad, investing in multilateral institutions, and engaging systematically with other countries on biosafety and biosecurity norms, including through international fora.

Implementing recommendations with an independent bioresponsibility authority

As discussed, the above recommendations are intended as a cohesive, modernized biorisk management policy framework governed by an independent bioresponsibility authority. The following table summarizes each of the proposed functions for such an authority, along with selected pre-existing programs related to those functions.

Type	Function	Scope	Pre-existing policy or function
Regulatory	Research review	DURC & PEPP research	DURC-PEPP Policy
	Safety & security standards	DURC & PEPP research; work involving high-consequence agents and organisms (select agents, and pathogens equivalent to RG3 or RG4)	BMBL; *NIH Guidelines*; *NIH Design Requirements Manual*; Federal Select Agent Program
	Customer & order screening	Nucleic acid synthesis providers, including benchtop machines	The White House's Framework for Nucleic Acid Synthesis Screening
	Registration	DURC & PEPP research; work involving high consequence agents and organisms; nucleic acid synthesis providers	Federal Select Agent Program
	Import & transport permitting	Animal and human pathogen samples, infected materials, and vectors	CDC Import Permit Program; USDA Organisms and Vectors Permitting
	Transaction monitoring	Services, materials, and equipment likely indicative of regulated activities (i.e., research with pathogens)	No formal programs identified
Information sharing	Non-punitive reporting	Safety and security incidents and near misses at regulated entities	Limited pilot underway at HHS
	Informal education, outreach, and inquiries	Regulated entities, other laboratories, and users and providers of dual-use biotechnology products on a voluntary basis	Some education conducted by the Federal Select Agent Program, NIH Office of Science Policy, and other programs and groups
	Recommended improvements	Trends in reports, findings from voluntary investigations of probable cause, feedback from	No formal programs identified

		outreach	
Support for regulations	Time-limited exemptions	Activities required for response to an acute public health threat	Federal Select Agent Program can issue exemptions
	Decision review process	Regulatory decisions with grounds for reversal articulated	Federal Select Agent Program administrative review process
	Investigations and enforcement	Non-compliance with regulations; consider non-punitive measures except for intentional misconduct or recklessness	Federal Select Agent Program, HHS and USDA OIG
Technical assistance and lessons learned	Technical assistance	Bioresponsibility and compliance questions, by request of entities subject to the authority's regulations	Some technical assistance offered by the Federal Select Agent Program
	Technological trends and lessons learned	Scientific findings and trends in emerging technologies relevant to bioresponsibility; information generated and lessons learned from its activities	No formal programs identified
	Advisory boards	Bioresponsibility technical and policy questions	National Science Advisory Board for Biosecurity
Policy	Policy development and review	The authority's regulations, policies, and processes.	Components of existing policy shops, such as NIH Office of Science Policy
	Voluntary safety & security guidelines	Coordinate updates to guidelines including the *NIH Guidelines* and BMBL to align with regulatory standards	*NIH Guidelines*, BMBL
Empirical Research	Fund research and development	Bioresponsibility, including causes of accidents, effectiveness of mitigations, low-resource biosafety, safer materials and practices, and safety and security by design	No formal programs identified
Education, training, & workforce	Create and share bioresponsibility training materials	Drop-in training materials for regulated entities, curricula for life sciences courses	No formal programs identified

	Fund recruitment and training	Bioresponsibility professionals	NIH has training grants, like National Research Service Award (NRSA) Institutional Research Training Grants (T32) or National Biosafety and Biocontainment Training Program (NBBTP)/Intramural Research Training Award (IRTA), although these are not targeted at bioresponsibility professionals
Global efforts	Make resources available	Standards, training materials, research findings	No formal programs identified
	Support engagement by USG partners	Diplomacy led by the U.S. Department of State	Existing U.S. Department of State engagement on biosafety and biosecurity

Table 4. *Proposed functions of an independent bioresponsibility authority and relevant pre-existing functions and policies, grouped by type of function.*

These functions could be arranged in a wide variety of configurations. Figure 1 presents one such arrangement that would preserve important structural features, such as insulating the National Bioresponsibility Incident Board (NBIB) from the authority's regulatory and enforcement arm.

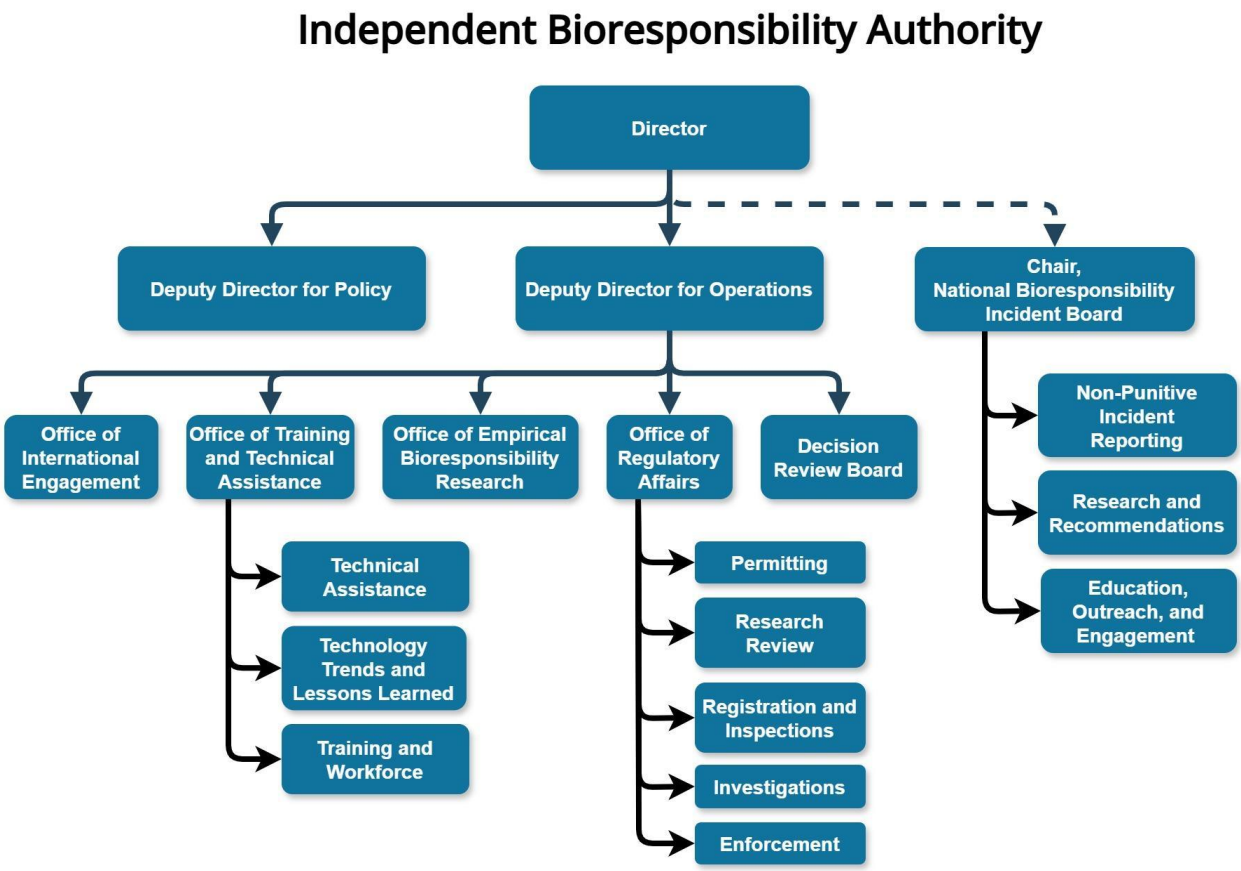

Figure 1. *Possible organizational chart for an independent bioresponsibility authority with the functions from Table 4.*

The Office of Training and Technical Assistance is also separated from the Office of Regulatory Affairs, but it is not as insulated as the NBIB, underscoring the importance of collaboration when providing technical assistance, developing training materials, and generating lessons learned over time. Although separate from the operational wing, the office of the Deputy Director for Policy would need to collaborate closely with all components of the authority and interagency partners to write and update regulations and other policies. Figure 1 is not comprehensive and leaves out components that are not unique to the independent bioresponsibility authority, such as the Office of the Inspector General and Office of Legislative Affairs.

Other proposals to reform U.S. government biorisk management policies have recommended placing a bioresponsibility authority within an existing federal agency or department. While this document makes the case for creating a new, fully independent agency, its placement and committees of jurisdiction will need to be decided by Congress and other policymakers in consultation with impacted stakeholders. Even if the bioresponsibility authority reports to another agency or department head, steps should be taken to secure operational independence. Agencies like the U.S. Food and Drug Administration (FDA) and Federal Aviation Administration (FAA) possess significant operational independence and are regarded as effective safety regulators despite their position within federal departments.

Conclusion

Recent developments demonstrate an interest in strengthening and harmonizing federal bioresponsibility oversight policies. The publication of the NSABB's 2023 recommendations and its new charge in November 2024, the release of the DURC-PEPP Policy, the creation of a USG framework for nucleic acid synthesis screening, bipartisan Congressional interest in biosafety and biosecurity legislation, and examples of life sciences governance innovation in peer countries show that the status quo is changing and that peer governance models offer something of value.

This document represents an effort to account for these realities and propose a path forward. Drawing on the authors' operational and policy experience and the input of more than thirty domain experts, its recommendations envision collecting the pieces of a fragmented landscape into a more cohesive whole. These recommendations aim to create a comprehensive, adaptable, and transparent oversight system that effectively mitigates risks while enabling innovation.

Conversations with stakeholders revealed broad agreement about the high-level principles of closing oversight gaps, emphasizing flexible and risk-based approaches, and consolidating oversight functions. However, many stakeholders disagree about which principles are most important and how to operationalize them. Some, including several biosafety and biosecurity professionals, reacted enthusiastically to this proposal. Others, including some life sciences researchers, believe that the current oversight system is sufficient or that any changes—even efforts aimed at simplification—will prove disruptive, resulting in burdens that slow down research and hinder scientific progress.

Regardless, more extensive stakeholder engagement across industry, academia, government, and the general public is needed to test and refine these ideas. Successful implementation will require broad buy-in from the life sciences community, concrete measures to build public trust, and widespread commitment to realizing the spirit of this proposal among stakeholders and policymakers.

This document joins a growing chorus of voices in support of creating an independent agency to own the federal government's bioresponsibility mission. Though this is an admittedly wide-ranging proposal, rapid technological advances have created unprecedented challenges. Given the urgency of these issues and increasing political interest, the idea warrants serious consideration. The examples of Canada's biosafety and biosecurity regulator and the U.S. Federal Aviation Administration show that flexible regulatory approaches can succeed.

About the Authors

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Robert P. Kadlec, MD served as Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services from 2017 to 2021. In this capacity, he played a central role in creating and executing Operation Warp Speed which developed COVID-19 vaccines and therapeutics in record time. His other key national leadership roles in the public sector have included Special Assistant to the President & Senior Director for Biodefense Policy in the Homeland Security Council; Special Advisor and Senior Assistant roles to the Secretary and Assistant Secretary of Defense for International Security Policy; Deputy Staff Director for the U.S. Senate Select Intelligence Committee; Staff Director for the U.S. Senate Subcommittee on Bioterrorism & Public Health Preparedness; and most recently Senior Pandemic Policy Minority Advisor to the U.S. Senate Health, Education & Labor Committee. In the private sector, he has undertaken ongoing advisory roles to the Secretary of Defense as well as the National Academy of Sciences and the Intelligence Community. As a 26-year military veteran, Kadlec also served in operational roles with the 1st Special Operations Wing, Hurlburt Field, the 24th Special Tactics Squadron at Fort Bragg, and as a U.S. Special Operations Command detailee to the U.S. Intelligence Community. He has had combat deployments in support of counterproliferation operations during DESERT STORM and IRAQI FREEDOM. Kadlec was a Distinguished Graduate from the U.S. Air Force Academy. He earned his M.D. and a masters in tropical medicine & hygiene at the Uniformed Services University of the Health Sciences. He received his masters in national security studies from Georgetown University and received an honorary Doctor of Science degree from the University of Nebraska. He is a member of the Council on Foreign Relations.

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Appendix A: Glossary of Terms

Artificial intelligence (AI)	A machine-based system that can perform complex tasks, such as generating text or analyzing images, usually done by humans. Recent AI advances have been driven by deep learning, a technique whereby AI systems are composed of multiple layers of artificial neural networks and trained on very large datasets.
BMBL	*Biosafety in Microbiological and Biomedical Laboratories* (BMBL) is a handbook for laboratory safety and security when working with infectious agents and organisms. It is produced by the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. National Institutes of Health (NIH) and published by the CDC.
Bioeconomy	Economic activity based on biomanufacturing or biotechnology, which can include work in sectors such as pharmaceuticals, medicine, chemicals, agriculture, and energy.
Biological agent	Bacteria, viruses, fungi, other microorganisms, their associated toxins, and any products of a living organism capable of continuous self-replication in nature (e.g., prions).
Biological risk (biorisk)	The danger posed by biological materials, especially infectious agents. Biorisk depends on both the probability of a harm occurring and its expected severity.
Bioresponsibility	The commitment to conducting life science research in an ethical, secure, and safe manner to reduce the risk of misuse and accidents, including implementing bioethical standards and biorisk management practices to responsibly advance life sciences research.
Bioresponsibility professional	Individuals whose job responsibilities are primarily dedicated to biosafety, biosecurity, or other aspects of biorisk management.
Biorisk management	Activities directed at minimizing the risks associated with the handling, storage, and disposal of biological agents and organisms.
Biosafety	The use of specific practices, equipment, and facilities to protect workers, communities, and the environment from accidental exposure to infectious agents and organisms.
Biosecurity	The use of measures to prevent the misuse of biological agents and organisms and prevent the intentional release of harmful biological materials. This may include securing physical samples, equipment, information, or expertise.
BSL	Biosafety Level. A Biosafety Level is a specific set of practices, equipment, and facilities used to reduce the probability of accidents or misuse at a particular level of risk. The United States Government uses a classification system with four biosafety levels. BSL-4 is the highest containment level.
DURC	Dual Use Research of Concern. As defined by the DURC-PEPP Policy, DURC is life sciences research that, based on current understanding, can be reasonably anticipated

	to provide knowledge, information, products, or technologies that could be misapplied to cause harm with no, or only minor, modification to pose a significant threat with potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.
DURC-PEPP Policy	United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential. A policy issued by the White House in May 2024 describing how the U.S. Government will oversee research it funds that might qualify as DURC or PEPP. It requires DURC and PEPP projects to undergo a review that analyzes the risks and benefits and decides whether the research may proceed and under what safety and security controls.
FSAP	The Federal Select Agent Program (FSAP) regulates a list of 63 select agents that could pose a severe threat to animal health and safety, plant health and safety, or to the safety of animal or plant products. Tier 1 agents are identified as posing the greatest risk. FSAP specifies both safety and security measures, including background checks.
NIH Guidelines	The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* are a set of guidelines specifying laboratory safety practices for working with genetically engineered organisms or nucleic acid molecules, including engineered pathogens. They also classify human pathogens into four risk groups.
Pathogen	A bacterium, virus, or other microorganism capable of causing disease.
PPP or PEPP	Pathogen with Pandemic Potential (PPP) or Pathogen with Enhanced Pandemic Potential (PEPP). As defined by the DURC-PEPP policy, a PPP is a pathogen that is likely capable of wide and uncontrollable spread in a human population and would likely cause moderate to severe disease and/or mortality in humans. A PEPP is a PPP, regardless of the starting point, that has been made more transmissible or virulent by experimentation.

Appendix B: Adjacent Bioresponsibility Functions Remaining Outside of the Authority

Many other government entities have regulatory functions adjacent to the authority's mission or relevant to bioresponsibility that will remain outside of the authority. Navigating the boundary between these activities and avoiding unnecessary overlap will require coordination between the authority and these entities. Relevant functions that will remain outside of the authority include:

- The U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) Plant Protection and Quarantine permits for the importation, interstate movement, possession, and/or environmental release of plant pests and pathogens;
- The U.S. Department of Homeland Security (DHS) National Biodefense Analysis and Countermeasures Center (NBACC);
- The Federal Bureau of Investigation's (FBI) role in investigating and prosecuting criminal weapons of mass destruction activity and biological terrorism;
- The U.S. Department of Commerce (DOC) Bureau of Industry and Security (BIS) Export Administration Regulations on biological agents and organisms and dual-use laboratory materials, supplies, and equipment;
- The U.S. Department of State (DOS) International Traffic in Arms Regulations on certain weaponizable biological agents and organisms;
- Cooperative threat reduction activities carried out by the U.S. Department of Defense (DOD) Defense Threat Reduction Agency (DTRA) and DOS Cooperative Threat Reduction program;
- Environmental Protection Agency (EPA) regulations on the environmental release of genetically modified organisms;
- Food and Drug Administration (FDA) regulations on genetically modified animals and foods; medicines and medical devices, including their production; and release of genetically modified organisms intended to improve human health;
- USDA Biotechnology Regulatory Services regulation of genetically modified agricultural plants;
- U.S. Department of Labor Occupational Safety and Health Administration (OSHA) regulations on occupational health and safety related to bloodborne pathogens;
- U.S. Centers for Medicaid and Medicare (CMS) Clinical Laboratory Improvement Amendments (CLIA) regulations for clinical laboratories;
- USDA's Animal Welfare Regulations, including requirements for animal welfare in laboratories;
- The U.S. Department of Health and Human Services's (HHS) regulation of human subjects research;
- State and local public health department preparedness and response functions;
- Office of the Director of National Intelligence (ODNI) assessments of biological threats;
- The National Center for Medical Intelligence's role in identifying and monitoring health threats.

This white paper, written by staff at the Scowcroft Institute's Biosecurity and Pandemic Policy Center and colleagues and informed by working groups convened by the center, articulates the authors' vision for an ideal biorisk management framework. The opinions and views expressed in this document should not be construed as representing those of the Bush School of Government and Public Service, Texas A&M University, or any institution or person other than its authors.

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