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Oversight of Laboratory Biosafety and Biosecurity: Current Policies and Options for Congress

August 14, 2024

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R48155

CRS REPORT
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SUMMARY

R48155

August 14, 2024

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Oversight of Laboratory Biosafety and Biosecurity: Current Policies and Options for Congress

In the United States, oversight of the life sciences, in particular laboratory biosafety and biosecurity, is exercised pursuant to a mixture of federal law, federal guidance, and self-governance, dependent on the types of experiments and biological agents being used. There currently is no overarching federal law that provides oversight of laboratory biosafety and biosecurity with enforceable legal penalties beyond those in the Federal Select Agent Program, which covers only certain types of biological agents and toxins. Many of the biosafety and biosecurity laws, policies, and guidelines were developed in response to specific events. Privately funded research is generally not covered by federal policy or agency guidance.

Biosafety in Microbiological and Biomedical Laboratories (BMBL) is the overarching guidance document for U.S. biosafety practices for protecting workers and preventing exposures in biological laboratories. The BMBL provides guidance for addressing the safe handling and containment of infectious microorganisms and hazardous biological materials. The Federal Select Agent Program (FSAP) has oversight of the people who have access to select agents and the facilities where select agents are used and stored, both of which are required by statute to register with the program. FSAP is comanaged by the U.S. Department of Health and Human Services and U.S. Department of Agriculture, which, in part, must establish and maintain a list of biological agents that have the potential to pose a severe threat to animal or plant health and safety or to the safety of animal or plant products. The National Institutes of Health *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* prescribe certain safety practices and procedures to be in place when creating and handling recombinant and synthetic nucleic acid molecules, and organisms and viruses containing such molecules. The *Framework for Nucleic Acid Synthesis Screening*, released by the White House Office of Science and Technology Policy, outlines a process for screening purchases of synthetic nucleic acids and benchtop nucleic acid synthesis equipment.

In May 2024, the White House Office of Science and Technology Policy released its most recent policy update, the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 policy). It addresses oversight of research on biological agents and toxins that, when enhanced, have the potential to pose risks to public health, agriculture, food security, economic security, or national security. It is scheduled to go into effect on May 6, 2025. Once in effect, it would supersede the 2012 *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*, the 2014 *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, the 2017 *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight*, and the Department of Health and Human Services *Framework for Guiding Funding Decisions About Proposed Research Involving Enhanced Potential Pandemic Pathogens*. The 2024 policy, compared with prior policies, potentially expands the number of research undertakings that meet the qualifications of dual use research of concern.

In the 118th Congress, both the House and Senate are conducting ongoing investigations into U.S. oversight of life sciences research. For example, the Senate Committee on Homeland Security and Governmental Affairs held a hearing in July 2024 on S. 4667, the Risky Research Review Act, which principally would amend current law by establishing a Life Sciences Research Security Board. Other options for Congress could include

- expanding federal government oversight to privately funded research under certain circumstances along with assessing how the convergence of artificial intelligence and life sciences research may impact biosafety and biosecurity concerns;
- establishing an overarching federal biosafety and biosecurity management system or law that brings all of the current oversight mechanisms into a single common framework; and
- continuing the current oversight system for life sciences research and waiting to evaluate how the Administration and relevant federal agencies interpret and implement the 2024 policy after it goes into effect.

Contents

Figures

Tables

Contacts

Introduction

The United States has multiple, overlapping policies that provide biosafety and biosecurity oversight for life sciences research. Oversight of a particular activity or group can take different forms. It can be codified into law, which prescribes certain responsibilities along with legally enforceable penalties for noncompliance; can be set out in federal guidance or policy and then prescribed as part of the terms and conditions of a federal grant or contract; and can be achieved through self-governance via best practices or individual entities' own internal policies. Each method has pros and cons for reaching a particular oversight goal. In the United States, oversight of the life sciences, in particular laboratory biosafety and biosecurity, is a mixture of these methods—including federal law, federal guidance, and self-governance, depending on the types of experiments and biological agents used, as discussed herein. Many of these federal policies and guidelines were developed in response to specific events.

While some biosafety and biosecurity oversight measures are required by law (i.e., the Federal Select Agent Program, or FSAP), others are issued as federal policy or agency guidance. While these policies and guidance do not have the force of law, they can become de facto mandatory requirements for an institution (e.g., university, nonacademic research foundation, other organization conducting research) or individual to follow. For example, the prescribed oversight may become part of the terms and conditions of a federal grant or contract that the recipient must agree to in order to receive federal funding from an agency. Noncompliance could result in an individual agency retracting or denying funding in the future. Privately funded research is generally not covered by these federal policies or agency guidance.

There currently is no overarching federal law that provides oversight of laboratory biosafety and biosecurity with enforceable legal penalties beyond those described in the "Federal Select Agent Program (FSAP)" section below, but FSAP covers only certain types of biological agents and toxins.

This report provides an overview of U.S. policies for biosafety and biosecurity oversight, including the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 policy), which was released in May 2024 and is scheduled to go into effect on May 6, 2025.[1] This report also presents a number of policy options and considerations for Congress in weighing potential changes to oversight policies.

Table 1. Selected U.S. Policies for Biosafety and Biosecurity Oversight

Oversight Measures	Risks Addressed	Description of Oversight
Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th ed.[a]	Biosafety	Applies to: Life sciences research involving infectious microorganisms and hazardous biological materials. Description: General biosafety practices and biological containment for various classifications (risk groups) of microorganisms and etiological, disease-causing agents.

[1] White House Office of Science and Technology Policy (OSTP), *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*, May 2024, p. 1, https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf (hereinafter referred to as the "2024 policy").

Oversight Measures	Risks Addressed	Description of Oversight
National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*[b]	Biosafety	Applies to: Basic or clinical life sciences research that involves recombinant or synthetic nucleic acid molecules and is conducted at an institution receiving NIH funding for any such research. Description: Describes roles and responsibilities of institutions and investigators in safely conducting research. Requires institutional review with a focus on the concepts of risk assessment, risk group classification of agents, physical and biological containment levels, practices, personal protective equipment, and occupational health.
Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) Select Agent Program[c]	Biosecurity (physical and personnel) and biosafety	Applies to: Specified biological agents and toxins deemed by HHS or USDA to pose a severe threat to public health and safety, based on a set of criteria. Description: Regulates, pursuant to statute and implementing regulations, the possession, use, and transfer of select agents and toxins. Overseen by the Federal Select Agent Program (FSAP). Requires registration of individuals and entities, federal background investigations, federal review of restricted experiments, training, and institutional compliance, among other things.
United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential[d]	Biosafety and biosecurity, including risks that the knowledge, information, products, or technologies generated by the research could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security Biosafety and biosecurity risks associated with pathogens with pandemic potential and pathogens with enhanced pandemic potential	Applies to: Federal departments and agencies that fund or sponsor intramural or extramural research at research institutions in the United States and internationally with biological agents or toxins where the research is within "Category 1" or "Category 2." Covers research funded or sponsored by grants, contracts, cooperative agreements, and other agreements. Includes the research proposal stage and the full life cycle of the research. Description: The policy is designed to preserve the benefits of such research while minimizing the biosafety and biosecurity risks, including risks that the knowledge, information, products, or technologies generated by the research could be used in a manner that results in harm to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

Source: CRS, adapted from National Science Advisory Board for Biosecurity, *Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research*, 2016, pp. 57-58, https://osp.od.nih.gov/wp-content/uploads/2016/06/NSABB_Final_Report_Recommendations_Evaluation_Oversight_Proposed_Gain_of_Function_Research.pdf.

a. Paul J. Meechan and Jeffrey Potts, *Biosafety in Microbiological and Biomedical Laboratories*, 6th ed. (Washington, DC: Department of Health and Human Services, 2020), https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf.

b. Department of Health and Human Services, *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, April 2024, https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

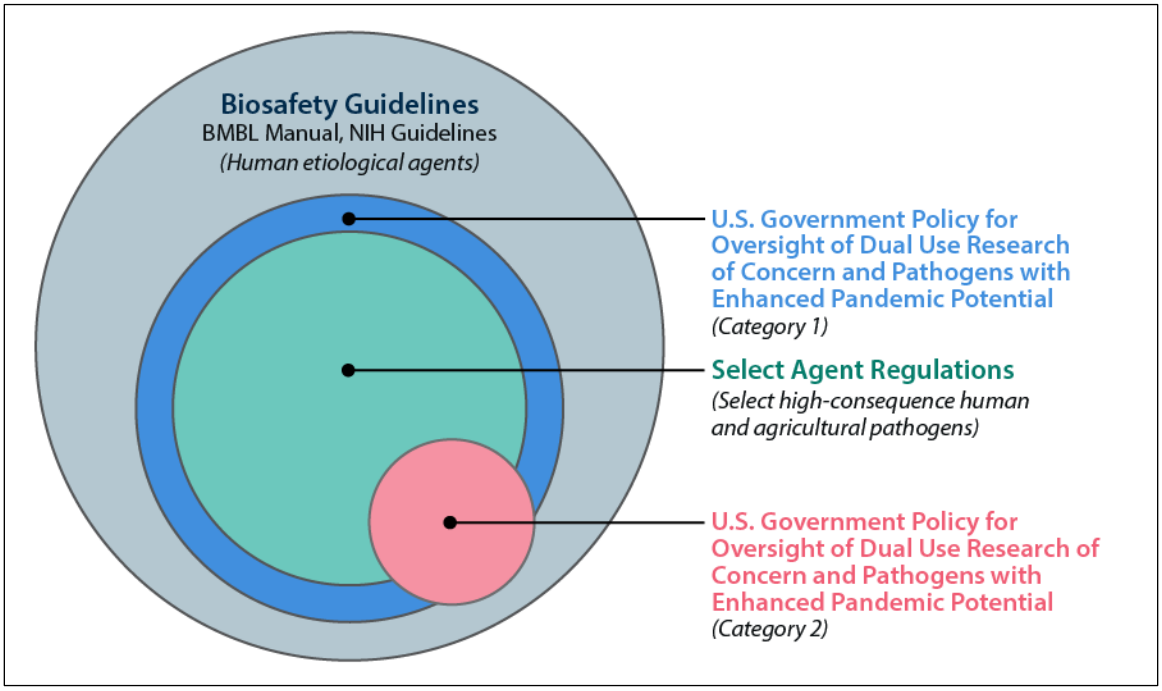
c. HHS and USDA, "Federal Select Agent Program," June 5, 2024, https://www.selectagents.gov.

d. White House Office of Science and Technology Policy, *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*, May 2024, https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf.

Figure 1 shows the overlapping U.S. polices that provide biosafety and biosecurity guidance and oversight for life sciences research, depending on the types of experiments and biological agents used.

Figure 1. Overlap of Selected U.S. Policies for Biosafety and Biosecurity Oversight

(oversight applies to specific agents, toxins, and/or types of experiments)

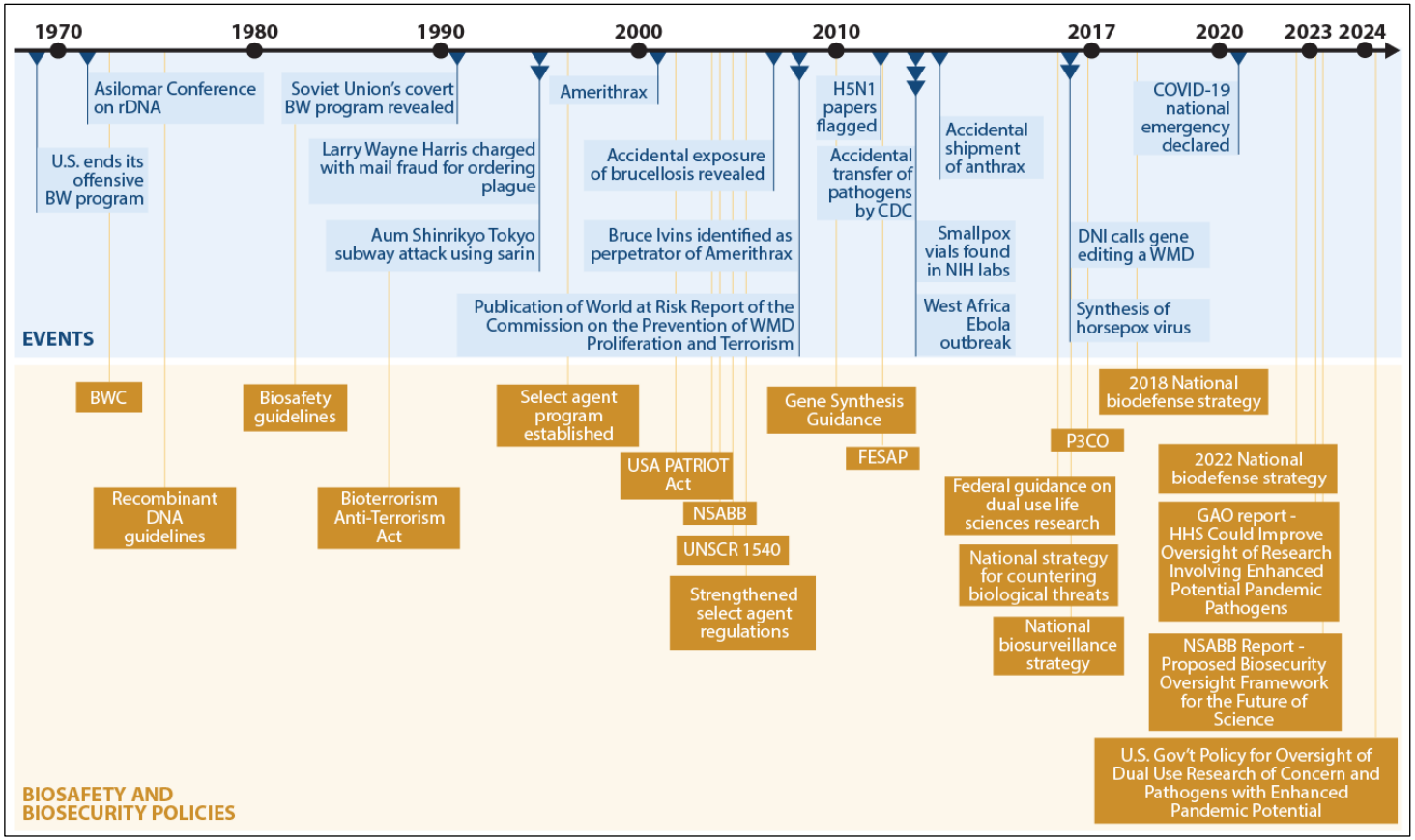


Source: CRS, adapted from National Science Advisory Board for Biosecurity, *Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research*, May 2016, p. 28, https://osp.od.nih.gov/wp-content/uploads/2016/06/NSABB_Final_Report_Recommendations_Evaluation_Oversight_Proposed_Gain_of_Function_Research.pdf.

Notes: Circles depicting policies with oversight are meant to be estimates and are subject to interpretation and change. BMBL = *Biosafety in Microbiological and Biomedical Laboratories*; NIH = National Institutes of Health.

Figure 2 provides a historical perspective of various events related to biosafety and biosecurity, and subsequent policy-related developments.

Figure 2. Selected Biosafety and Biosecurity Events and Associated U.S. Policy Implementation 1960-2024



Source: CRS, adapted from Diane DiEuliis et al., "Biodefense Policy Analysis—A Systems-Based Approach," *Health Security*, vol. 17, no. 2 (2019), pp. 83–99, https://doi.org/10.1089/hs.2018.0082.

Notes: Figure represents a selection of major events and should not be interpreted as comprehensive. BW = bioweapons; BWC = UN Bioweapons Convention; CDC = Centers for Disease Control and Prevention; DNI = Director of National Intelligence; FESAP = Federal Experts Security Advisory Panel; GAO = Government Accountability Office; HHS = Department of Health and Human Services; H5N1 = a strain of a highly pathogenic avian influenza virus; NIH = National Institutes of Health; NSABB = National Science Advisory Board for Biosecurity; P3CO = *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight*; rDNA = recombinant DNA; UNSCR = UN Security Council Resolution; WMD = weapon of mass destruction.

U.S. Policies for Biosafety and Biosecurity Oversight

Biosafety in Microbiological and Biomedical Laboratories Guidelines

The Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) together publish *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), which is the overarching guidance document for U.S. biosafety practices for protecting workers and preventing exposures in biological laboratories (**Figure 1**). The BMBL provides guidance for addressing the safe handling and containment of infectious microorganisms and hazardous biological materials.[2] Some federal agencies include adherence to the BMBL as a condition for receiving certain federal grants. In addition, some federal laws (see "Federal Select Agent Program (FSAP)") recommend the BMBL as guidance[3] to assist entities in the development of biosafety and biocontainment plans.

The BMBL describes biosafety levels (BSLs)—a minimum set of safety practices and procedures, required safety equipment, and administrative and engineering controls—which are four designations applied to projects or activities conducted in laboratories. Each BSL is described in ascending order of containment based on the degree of the health-related risk associated with the work being conducted.[4] Each BSL (BSLs 1-4) builds on the previous level (see **Table 2** for descriptions of the BSLs).

Table 2. Laboratory Biosafety Levels (BSLs)

BSL	Description
BSL 1	Biosafety Level 1 (BSL-1) is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans and that present minimal potential hazards to laboratory personnel and the environment. Work is typically conducted on open benchtops using standard microbiological practices. Special containment equipment or facility design is not generally required but may be used as determined by appropriate risk assessment. Laboratory personnel receive specific training in the procedures conducted in the laboratory and are supervised by a scientist with training in microbiology or a related science.
BSL 2	Biosafety Level 2 (BSL-2) is suitable for work with agents associated with human disease and [that] pose moderate hazards to personnel and the environment. BSL-2 differs from BSL-1 primarily because 1) laboratory personnel receive specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in [biosafety cabinets] or other physical containment equipment.
BSL 3	Biosafety Level 3 (BSL-3) is suitable for work with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel receive specific training in handling pathogenic and potentially lethal agents, and they are supervised by scientists competent in handling infectious agents and associated procedures. A BSL-3 laboratory has special engineering and design features.

[2] Paul J. Meechan and Jeffrey Potts, *Biosafety in Microbiological and Biomedical Laboratories*, 6th ed. (Washington, DC: Department of Health and Human Services, 2020), https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf.

[3] 42 U.S.C. §73.12.

[4] Department of Health and Human Services (HHS), "Science Safety Security: Biosafety Levels," November 13, 2015, https://www.phe.gov/s3/BioriskManagement/biosafety/Pages/Biosafety-Levels.aspx.

BSL	Description
BSL 4	Biosafety Level 4 (BSL-4) is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening diseases that are frequently fatal, agents for which there are no vaccines or treatments, or work with a related agent with unknown risk of transmission. Laboratory staff receive specific and thorough training in handling extremely hazardous infectious agents. ... The laboratory supervisor controls access to the laboratory in accordance with institutional policies.

Source: Paul J. Meechan and Jeffrey Potts, *Biosafety in Microbiological and Biomedical Laboratories*, 6th ed. (Washington, DC: U.S. Department of Health and Human Services, 2020), https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf.

Notes: Each BSL describes standard practices, safety equipment, and facility specifications that are generally appropriate for the organism(s) being worked on.

The appropriate BSL for a research project is determined by the institution in which the work is being conducted. The determination is made in consultation with the principal investigator, based on a risk assessment of the specific organism (see **Table 3** for a description of risk groups) and the types of experiments to be performed. In 2022, 187 entities with BSL-3 laboratories and 8 entities with BSL-4 laboratories were registered in FSAP in the United States (see **Figure 3**); they were operated by a variety of actors (i.e., federal, commercial, academic, and private).[5] Not all of these laboratories are research labs; for example, they also include clinical laboratories in public health settings that deal with select agents.[6]

Table 3. Classification of Biohazardous Agents by Risk Group

Risk Group	Description
Risk Group 1	Agents that are not associated with disease in healthy adult humans
Risk Group 2	Agents that are associated with human disease that is rarely serious and for which preventive or therapeutic interventions are often available
Risk Group 3	Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk)
Risk Group 4	Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)

Source: Department of Health and Human Services, National Institutes of Health (NIH), *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, April 2024, https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

Notes: NIH guidelines require that a risk assessment be conducted on the proposed agents to be used based on the potential effect of a biological agent on a healthy human adult. The risk assessment does not account for instances in which an individual may have increased susceptibility to such agents. The risk group determination informs the biosafety level in which research on those agents is to be conducted.

While the BMBL serves as an "advisory document recommending best practices for the safe conduct of work in biomedical and clinical laboratories,"[7] the Government Accountability Office

[5] Federal Select Agent Program, *2022 Annual Report of the Federal Select Agent Program*, 2022, p. 13, https://www.selectagents.gov/resources/publications/annualreport/2022.htm.

[6] These laboratories are a subset of the total number of BSL-3/4 laboratories in operation. Laboratories that do not work with select agents do not need to register under the Select Agent Program. Therefore, the total number of BSL-3/4 laboratories may be higher. See "Federal Select Agent Program (FSAP)" for more detail on select agents.

[7] Paul J. Meechan and Jeffrey Potts, *Biosafety in Microbiological and Biomedical Laboratories*, 6th ed. (Washington, DC: Department of Health and Human Services, 2020), p. iii, https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf.

(GAO) reported in 2013 that there were no national standards for how to design, construct, commission, operate, or maintain a high-containment laboratory.[8] Subsequent GAO studies have reviewed individual agency policies and made recommendations on how to improve laboratory safety and oversight.[9]

Federal Select Agent Program (FSAP)

FSAP is one federal regulatory program addressing biosecurity. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188, as amended; 42 U.S.C. §362a) requires HHS to establish and regulate a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. The Agricultural Bioterrorism Protection Act of 2002 (Title II, Subtitle B, of P.L. 107-188) requires the U.S. Department of Agriculture (USDA) to establish and maintain a list of biological agents that have the potential to pose a severe threat to animal or plant health and safety or to the safety of animal or plant products. FSAP is managed jointly by the Division of Select Agents and Toxins at CDC and the Division of Agricultural Select Agents and Toxins at USDA. CDC and USDA share responsibility for some agents because they potentially threaten both humans and animals. By statute (42 U.S.C. §262a and 7 U.S.C. §8401), CDC and USDA are required to review and republish the lists of select agents and toxins on at least a biennial basis.[10]

FSAP has oversight of the people who have access to select agents and the facilities where select agents are used and stored, both of which must be registered with the program. According to the 2022 FSAP annual report, 8,516 individuals[11] and 234 entities[12] were registered with FSAP.[13] Entities possessing select agents are required by law (42 U.S.C. §262a and 7 U.S.C. §8401) to develop explicit biosecurity and biosafety plans, as well as an incident response plan, all of which are reviewed and certified by the FSAP agency that has jurisdiction over the particular select

[8] U.S. Government Accountability Office (GAO), *High-Containment Laboratories: Assessment of the Nation's Need Is Missing*, February 25, 2013, https://www.gao.gov/products/gao-13-466r. According to GAO, in May 2013, OSTP reported that it had been examining the need for national standards relating to designing, constructing, commissioning, maintaining, and operating high-containment laboratories through its Interagency Biorisk Management Working Group chartered in May 2012. According to GAO, an OSTP official stated that the group was chartered to coordinate and collaborate on mechanisms for strengthening research laboratory biorisk management that includes biosafety, biocontainment, and biosecurity.

[9] U.S. GAO, *High-Containment Laboratories: Comprehensive and Up-to-Date Policies and Stronger Oversight Mechanisms Needed to Improve Safety*, GAO-16-305, March 21, 2016, https://www.gao.gov/products/gao-16-305; U.S. GAO, *High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens*, GAO-18-145, October 19, 2017, https://www.gao.gov/products/gao-18-145; U.S. GAO, *Laboratory Safety: FDA Should Strengthen Efforts to Provide Effective Oversight*, GAO-20-594, September 8, 2020, https://www.gao.gov/products/gao-20-594; and U.S. GAO, *HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens*, GAO-23-105455, January 18, 2023, https://www.gao.gov/products/gao-23-105455.

[10] Federal Select Agent Program, "Select Agents and Toxins," May 6, 2024, https://www.selectagents.gov/sat/index.htm.

[11] 42 C.F.R. §73.7(a) states that "an individual or entity shall not possess, use, or transfer any HHS select agent or toxin without a certificate of registration issued by the HHS Secretary," and 7 C.F.R. §331.7(a) states that "an individual or entity shall not possess, use, or transfer any select agent or toxin without a certificate of registration issued by the Administrator."

[12] An *entity* is defined in 7 C.F.R. §331.1 and 42 C.F.R. §73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal [organization]." An entity is thus not limited to a single facility or to a single laboratory. An entity may possess one or multiple facilities, each facility containing one or multiple laboratories.

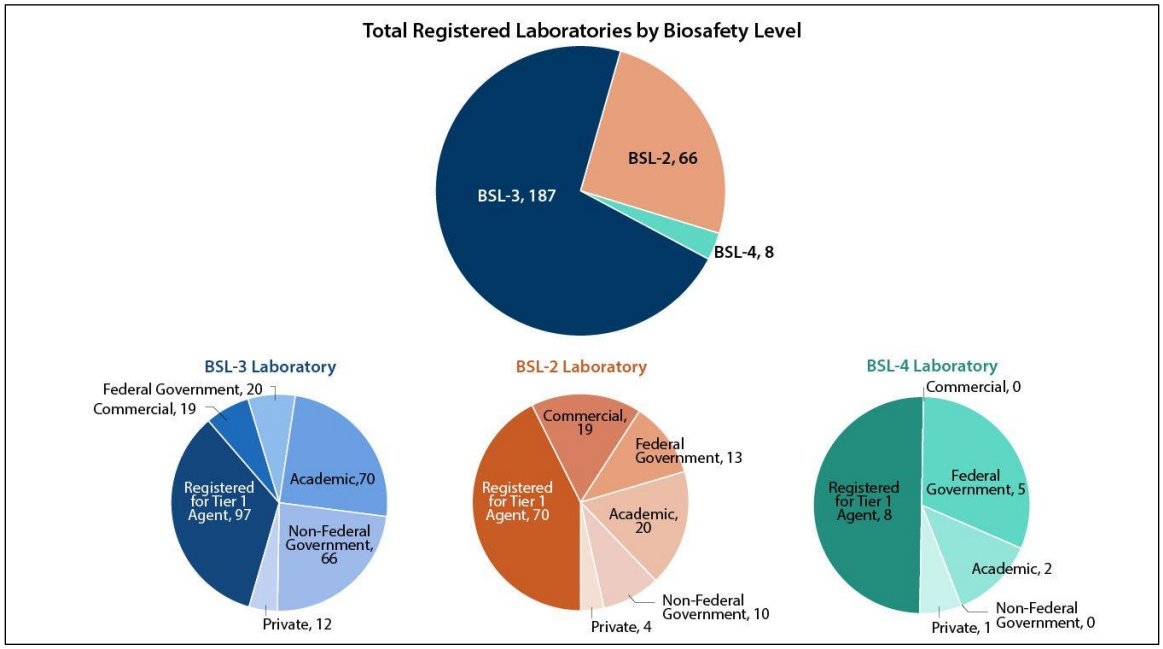
[13] Federal Select Agent Program, *2022 Annual Report of the Federal Select Agent Program*, 2022, p. 25, https://www.selectagents.gov/resources/publications/annualreport/2022.htm.

agent. FSAP provides guidance documents that describe attributes that each plan must have.[14] The Inspector General of the Department of Health and Human Services (HHS) is delegated authority to conduct investigations and to impose civil monetary penalties against any individual or entity for violations of the regulations.[15]

Figure 3 shows the number of laboratories registered with the program.

Figure 3. Laboratories Registered with FSAP by Biosafety Level

(based on the 2022 FSAP Annual Report)



Source: Federal Select Agent Program (FSAP), *2022 Annual Report of the Federal Select Agent Program*, 2022, https://www.selectagents.gov/resources/publications/annualreport/2022.htm.

Note: Biosafety guidelines would require a minimum of Biosafety Level 2 (BSL-2) to work with select agents; therefore BSL-1 laboratories are not shown.

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules

The *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines) require certain safety practices and procedures to be in place when creating and handling recombinant and synthetic nucleic acid molecules, and organisms and viruses containing such molecules.[16] Compliance with NIH Guidelines is a condition of grant awards for recipients of funding from NIH and certain other federal agencies. The guidelines are structured in a manner

[14] Federal Select Agent Program, *Select Agents and Toxins Biosafety/Biocontainment Plan Guidance*, 2018, https://www.selectagents.gov/compliance/guidance/biosafety/index.htm, and Federal Select Agent Program, *Incident Response Plan Guidance*, 2021, https://www.selectagents.gov/compliance/guidance/incident-response/index.htm.

[15] 42 U.S.C. §73.21.

[16] HHS, *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, April 2024, https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

that can apply to an entire research institution, even if a particular research project/experiment is not funded by NIH.

The NIH Guidelines describe and designate the responsibilities of institutions, investigators, and Institutional Biosafety Committees (IBCs). IBCs provide local review and oversight of research utilizing recombinant or synthetic nucleic acid molecules. Many institutions have chosen to assign their IBCs the responsibility of reviewing a variety of experiments that involve biological materials and other potentially hazardous agents. This additional responsibility is assigned entirely at the discretion of the institution.[17] The guidelines classify organisms into the four risk groups based on their pathogenicity toward humans, as shown in **Table 3**.

U.S. Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential

In May 2024, the White House Office of Science and Technology Policy (OSTP) released its most recent policy update on this issue. The *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 policy) is "a unified federal oversight framework for conducting and managing certain types of federally funded life sciences research on biological agents and toxins."[18] It addresses oversight of research on biological agents and toxins that, when enhanced, have the potential to pose risks to public health, agriculture, food security, economic security, or national security. The 2024 policy supersedes the 2012 *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*,[19] the 2014 *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*,[20] and the 2017 *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (P3CO Framework).[21] Once in effect, it will also replace the HHS *Framework for Guiding Funding Decisions About Proposed Research Involving Enhanced Potential Pandemic Pathogens*.[22]

The 2024 policy combines what had been two separate policies, the dual use research of concern (DURC) and P3CO Framework. It creates two categories of research ("Category 1" and "Category 2") that require certain oversight based on the biological agent or toxin used and the type of research being conducted.

[17] National Institutes of Health, *FAQs on Institutional Biosafety Committee (IBC) Administration—May 2019*, February 2023, https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy/faqs-on-institutional-biosafety-committee-ibc-administration-may-2019/.

[18] 2024 policy.

[19] White House, *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*, 2012, https://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf.

[20] White House, *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, September 24, 2014, https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf.

[21] OSTP, *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight*, 2017, https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf.

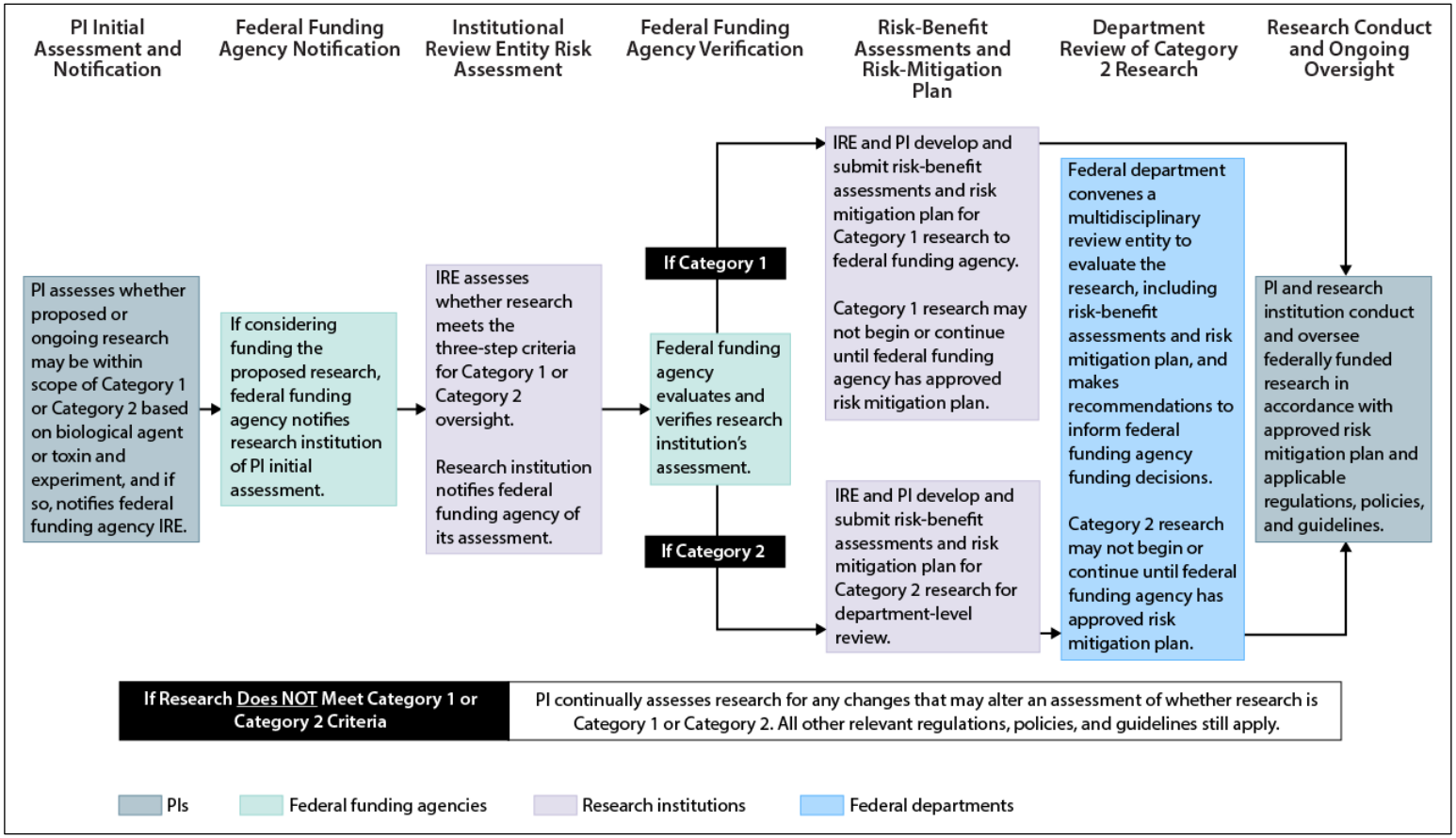
[22] HHS, *Framework for Guiding Funding Decisions About Proposed Research Involving Enhanced Potential Pandemic Pathogens*, 2017, https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf.

Figure 4 provides an overview of the entire review process for the two categories of research, which are discussed in more detail in the "Category 1 Research" and "Category 2 Research" sections below.

The 2024 policy states that at least every two years, OSTP, in consultation with relevant federal departments and agencies, may review the implementation guidance to this policy, including the associated lists of biological agents and toxins, and update it as needed.[23]

[23] 2024 policy, p. 29.

Figure 4. Overview of Review Process for Category 1 or Category 2 Research



Source: White House Office of Science and Technology Policy, *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*, May 2024, https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-DURC-PEPP-Implementation-Guidance.pdf.

Notes: IRE = Institutional Review Entity; PI = principal investigator.

Category 1 Research

Under the 2024 policy, Category 1 research, or dual use research of concern, is subject to oversight by research institutions and federal funding agencies. *Dual use research* is defined in the 2024 policy as "research conducted for legitimate purposes that generates knowledge, information, technologies, and/or products that can be utilized for benevolent or harmful purposes." *Dual use research of concern* (DURC) is defined in the 2024 policy as

> life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be misapplied to do 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.

Category 1 pertains to research that is considered DURC, the meaning of which has been expanded compared with the previous DURC policies.[24] Under the 2024 policy, Category 1 research must meet three criteria:

- it must involve "one or more of the biological agents and toxins" listed in the "Biological Agents and Toxins Within Scope of Category 1 Research" text box below;
- it must be "reasonably anticipated to result, or does result, in one of the experimental outcomes" listed in the "Category 1 Research Experimental Outcomes" text box below; and
- "based on current understanding, the research institution and/or federal funding agency assesses that the research constitutes DURC" as defined in the policy.[25]

One major change in the 2024 policy is that all individual agents and toxins listed under FSAP now constitute a criterion to be considered as Category 1. This potentially expands the number of research proposals/projects that meet the qualifications of DURC compared with previous policies. As of August 2024, FSAP has 68 listed agents and toxins. The 2014 DURC policy used a list of 15 agents and toxins. Institutions may need to meet the requirements under both the 2024 policy and FSAP. While FSAP is codified in law and specified in regulations,[26] the 2024 policy is not; adherence to its requirements will be set via the terms and conditions of each grant.

Biological Agents and Toxins Within Scope of Category 1 Research

- All select agents and toxins listed under the Federal Select Agent Program.
- All Risk Group 4 pathogens listed in the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines), Appendix B: Classification of Human Etiologic Agents on the Basis of Hazard.
- A subset of Risk Group 3 pathogens listed in the NIH Guidelines, Appendix B: Classification of Human Etiologic Agents on the Basis of Hazard.

[24] White House, *United States Government Policy for Oversight of Life Sciences Dual Use Research of Concern*, 2012, https://www.phe.gov/s3/dualuse/Documents/us-policy-durc-032812.pdf, and White House, *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, September 24, 2014, https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf.

[25] 2024 policy, pp. 10-12.

[26] 7 U.S.C. §8401, 7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73.

- For biological agents affecting humans that have not been assigned a risk group in the NIH Guidelines, refer to the current edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). In such cases, agents affecting humans that are recommended to be handled at Biosafety Level 3 (BSL-3) or Biosafety Level (BSL-4) per the BMBL guidance are subject to this policy.
- Biological agents added during future updates to the implementation guidance.

Source: White House Office of Science and Technology Policy, *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*, May 2024, https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-DURC-PEPP-Implementation-Guidance.pdf.

Category 1 Research Experimental Outcomes

- Increases transmissibility of a pathogen within or between host species
- Increases the virulence of a pathogen or conveys virulence to a non-pathogen
- Increases the toxicity of a known toxin or produces a novel toxin
- Increases the stability of a pathogen or toxin in the environment or increases the ability to disseminate a pathogen or toxin
- Alters the host range or tropism of a pathogen or toxin
- Decreases the ability for a human or veterinary pathogen or toxin to be detected using standard diagnostic or analytical methods
- Increases resistance of a pathogen or toxin to clinical and/or veterinary prophylactic or therapeutic interventions
- Alters a human or veterinary pathogen or toxin to disrupt the effectiveness of preexisting immunity, via immunization or natural infection, against the pathogen or toxin
- Enhances the susceptibility of a host population to a pathogen or toxin

Source: White House Office of Science and Technology Policy, *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*, May 2024, https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-DURC-PEPP-Implementation-Guidance.pdf.

Category 2 Research

Under the 2024 policy, Category 2 research, or research with pathogens with enhanced pandemic potential (PEPP), sometimes referred to as gain of function (GOF) research,[27] is subject to oversight by research institutions, federal funding agencies, and their federal department, if applicable, due to heightened potential for biosafety and biosecurity risks.[28] In addition to instituting new oversight and review procedures, the 2024 policy developed the following terms to address certain aspects of GOF research:

- Pathogen with pandemic potential (PPP): "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."
- PEPP: "A type of [PPP] resulting from experiments that enhance a pathogen's transmissibility or virulence, or disrupt the effectiveness of pre-existing immunity, regardless of its progenitor agent, such that it may pose a significant

[27] For additional information on gain of function research, see CRS Report R47114, *Oversight of Gain of Function Research with Pathogens: Issues for Congress*, by Todd Kuiken.

[28] 2024 policy, p. 10.

threat to public health, the capacity of health systems to function, or national security."[29]

The 2024 policy clarifies that "wild-type pathogens that are circulating in or have been recovered from nature are not PEPPs but may be considered PPPs because of their pandemic potential."

GOF is a research term that covers a broad area of scientific inquiry. GOF refers to any genetic mutation in an organism that confers a new or enhanced ability.[30] Such changes often occur naturally. Additionally, scientists can induce some changes to organisms through experimentation. Some of this research involves changing the genetic code of an organism or virus to observe how such changes affect its key properties. Through such experiments, scientists hope to improve their understanding of human-pathogen interactions, increase their knowledge of how viruses evolve and mutate, and further public health preparedness by making better vaccines and treatments.

The term *gain of function* entered public policy debates and became more common in 2011 when it was used to describe two controversial research projects on H5N1 avian influenza virus funded by NIH.[31] Subsequent U.S. policy has narrowly defined GOF research and how proposals are reviewed and approved by federal funding agencies.[32]

Under the 2024 policy, Category 2 research must meet three criteria:

- it must involve, or be "reasonably anticipated to result in, a PPP";
- it must be "reasonably anticipated to result in, or does result in, one or more of the experimental outcomes or actions" listed in the "Category 2 Research Experimental Outcomes or Actions" text box; and
- "based on current understanding, the research institution and/or federal funding agency assesses that the research is reasonably anticipated to result in the development, use, or transfer of a PEPP or an eradicated or extinct PPP that may pose a significant threat to public health, the capacity of health systems to function, or national security."[33]

[29] 2024 policy.

[30] Amber Dance, "The Shifting Sands of 'Gain-of-Function' Research," *Nature*, vol. 598, no. 7882 (October 27, 2021), pp. 554-557, https://doi.org/10.1038/d41586-021-02903-x. For additional discussion of gain of function research, see CRS Report R47114, *Oversight of Gain of Function Research with Pathogens: Issues for Congress*, by Todd Kuiken.

[31] Kelsey Lane Warmbrod, Michael G. Montague, and Gigi Kwik Gronvall, "COVID-19 and the Gain of Function Debates: Improving Biosafety Measures Requires a More Precise Definition of Which Experiments Would Raise Safety Concerns," *EMBO Reports*, vol. 22, no. 10 (October 5, 2021), Article e53739, https://doi.org/10.15252%2Fembr.202153739.

[32] OSTP, *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight*, 2017, https://www.phe.gov/s3/dualuse/Documents/P3CO-FinalGuidanceStatement.pdf.

[33] 2024 policy, pp. 12-13.

Category 2 Research Experimental Outcomes or Actions

- Enhance transmissibility of the pathogen in humans
- Enhance the virulence of the pathogen in humans
- Enhance the immune evasion of the pathogen in humans such as by modifying the pathogen to disrupt the effectiveness of pre-existing immunity via immunization or natural infection
- Generate, use, reconstitute, or transfer an eradicated or extinct PPP, or a previously identified PEPP

Source: White House Office of Science and Technology Policy, *Implementation Guidance for the United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential*, May 2024, https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-DURC-PEPP-Implementation-Guidance.pdf.

Federal Funding Agency's Department-Level Review Entity

Under the 2024 policy, federal agencies that fund Category 2 research must form a department-level review entity to review research and associated risk-benefit assessments and risk mitigation plans. It requires these entities to be composed of officials who do not have a direct reporting line to the head of the agency component that may fund the proposed research and have effective procedures in place to address potential conflicts of interest. Members of the review entity are required to have expertise in "scientific research, biosafety, biosecurity, medical countermeasure (MCM) development and availability, law enforcement and national security, ethics, public health preparedness and response, biodefense, Select Agent Regulations, public health policy, as well as other relevant areas, as determined by the department."

The 2024 policy does not appear to have made significant changes to what the federal funding agency's department-level review entity looks for in a research proposal or the recommendations it can provide to the federal funding agency in regard to the research proposal, compared with the review process prescribed in the P3CO Framework.

Privately Funded Research

Similarly to previously policies, the 2024 policy applies only to federally funded research and becomes a requirement via the terms and conditions of grants funded by the U.S. government, which does not have oversight of privately funded research.[34] However, Section 6.3 of the 2024 policy states that "research institutions that do not receive any federal funds for life sciences research, but that nevertheless conduct life sciences research with identifiable biosafety or biosecurity risks, are strongly encouraged to implement oversight procedures consistent with the culture of shared responsibility underpinning this Policy."[35]

There are limited data about the scope of research that would fall under Categories 1 and 2 being conducted at institutions or private companies that do not receive federal research funding. According to one study in 2023 by Gryphon Scientific, roughly one-quarter of human pathogen research conducted in the United States may occur in the private sector;[36] however, it is unclear how much of this private sector research, if federally funded, would be considered Category 1 or Category 2 under the 2024 policy.

[34] Private sector research, if it involves select agents, would be covered by the Federal Select Agent Program.

[35] 2024 policy.

[36] Gryphon Scientific, *Characterizing Private-Sector Research on Human Pathogens in the United States*, 2023.

White House Guidance Related to Nucleic Acid Synthesis Screening

In October 2023, President Biden issued Executive Order 14110, "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence." Section 4.4(b) directs the federal government to reduce the risks of misuse of synthetic nucleic acids and improve associated biosecurity measures. It required OSTP to develop a framework to encourage providers of synthetic nucleic acid sequences to implement comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms.[37] In April 2024, OSTP released *Framework for Nucleic Acid Synthesis Screening*, which outlines a process for screening purchases of synthetic nucleic acids and benchtop nucleic acid synthesis equipment. It provides guidance to providers of synthetic nucleic acids and manufacturers of benchtop nucleic acid synthesis equipment on how to screen purchase orders to identify sequences of concern (SOCs) and assess customer legitimacy.[38] The framework is anticipated to be incorporated into requirements for recipients of federal research funding, including through domestic and international funding documents.

The following six criteria are prescribed in the guidance for providers and manufacturers of synthetic nucleic acids and manufacturers of benchtop nucleic acid synthesis equipment:

1. "Attest to implementing this screening framework through a statement that either is posted on a public website or [is] provided to both the federally funded customer and federal funding agency."
2. "Screen purchase orders for synthetic nucleic acids to identify SOCs."
3. "Screen customers submitting purchase orders of synthetic nucleic acids with SOCs, and ... of benchtop nucleic acid synthesis equipment, to verify legitimacy."
4. "Report potentially illegitimate purchase orders of synthetic nucleic acids involving SOCs or of benchtop nucleic acid synthesis equipment."
5. "Retain records relating to purchase orders for synthetic nucleic acids and benchtop nucleic acid synthesis equipment."
6. "Take steps to ensure cybersecurity and information security."

Policy Considerations

Status Quo

Supporters of the status quo have argued that existing policies provide adequate oversight at a reasonable cost. In response to proposed additional biosecurity and biosafety requirements, supporters of the status quo have also argued that such changes could increase costs, either for research institutions, research funders (as part of research overhead costs), and/or the private sector. Some argue that such costs could be anticompetitive or inhibit innovation and might lead to research being performed in more permissive oversight environments, such as overseas.

[37] Executive Order 14110, "Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence," 88 *Federal Register* 75191-75226, November 1, 2023, https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence.

[38] OSTP, *Framework for Nucleic Acid Synthesis Screening,* April 2024, https://www.whitehouse.gov/wp-content/uploads/2024/04/Nucleic-Acid_Synthesis_Screening_Framework.pdf.

Conversely, some critics of the status quo argue either that those additional requirements are needed to ensure safety and security or that the number and overlap of current policies already create a burden on affected institutions, potentially impacting their ability to conduct scientific research effectively. Thus, those existing requirements, they argue, should be reduced or streamlined.[39] Others have also argued that a list-based approach (i.e., FSAP) "assumes that we already know what to worry about" and is not able to keep pace with emerging threats that may not yet appear on such a list.[40]

Policymakers may choose to continue the current oversight system for life sciences research and wait to evaluate how the Administration and relevant federal agencies interpret and implement the 2024 policy after it goes into effect. Congressional committees with jurisdiction could also choose to investigate how agencies implement the 2024 policy, its impact on scientific research and risk management generally, and its impacts on industry and U.S. scientific competitiveness.

In the 118th Congress, both the House and Senate are conducting ongoing investigations into the origins of COVID-19, which include examining U.S. oversight of life sciences research. For example, the Senate Committee on Homeland Security and Governmental Affairs held a hearing in July 2024, "Risky Research: Oversight of U.S. Taxpayer Funded High-Risk Virus Research," which included a discussion on S. 4667, the Risky Research Review Act, which principally would amend current law (Subtitle V of Title 31, *U.S. Code*) by establishing a Life Sciences Research Security Board (Board). The Board would evaluate high-risk proposals by life sciences researchers seeking federal funding, or intramural research conducted at agencies, and issue binding decisions on whether those federal agencies may fund such projects. Also of potential congressional interest could be the relationship between S. 4667 and the 2024 policy, and whether the proposed Board's authority to review life sciences research and development is adequately scoped to address intended policy goals and potential implementation challenges. Per S. 4667, Section 7904(a), "the mission of the Board shall be to issue an independent determination as to whether an agency may award Federal funding for proposed life sciences research."

Oversight of Privately Funded Research

GAO and the National Science Advisory Board for Biosecurity have recommended expanding U.S. oversight to privately funded research under certain circumstances.[41] Congress may choose to examine agencies' ability to conduct oversight of research performed at private institutions, companies, and international institutions. Alternately, Congress may consider whether additional legislation would be needed to provide authority and resources for federal agencies to have oversight of privately funded research.

Expanding U.S. oversight could provide a better understanding of the scope of research being conducted in privately funded laboratories while also aligning biosafety and biosecurity practices

[39] W. Paul Duprex et al., "Gain-of-Function Experiments: Time for a Real Debate," *Nature Reviews Microbiology*, vol. 13, no. 1 (2015), pp. 58-64, https://doi.org/10.1038/nrmicro3405; Ryan Ritterson et al., "A Call for a National Agency for Biorisk Management," *Health Security*, vol. 20, no. 2 (2022) , pp. 187-191, https://doi.org/10.1089/hs.2021.0163; and Marc Lipsitch and Alison P. Galvani, "Ethical Alternatives to Experiments with Novel Potential Pandemic Pathogens" *PLOS Medicine*, vol. 11, no. 5 (2014), Article e1001646, https://doi.org/10.1371/journal.pmed.1001646.

[40] Sam Weiss Evans et al., "Embrace Experimentation in Biosecurity Governance," *Science*, vol. 368, no. 6487 (2020), pp. 138-140, https://doi.org/10.1126/science.aba2932.

[41] U.S. GAO, *Public Health Preparedness: HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens*, GAO-23-105455, 2023, https://www.gao.gov/products/gao-23-105455, and National Science Advisory Board for Biosecurity, *Proposed Biosecurity Oversight Framework for the Future of Science*, 2023, https://osp.od.nih.gov/wp-content/uploads/2023/03/NSABB-Final-Report-Proposed-Biosecurity-Oversight-Framework-for-the-Future-of-Science.pdf.

across the entire U.S. life sciences enterprise, potentially reducing risks. However, it could potentially increase costs for federal agencies and toward privately funded research, and present challenges for international partnerships.

Convergence of In Silico, Artificial Intelligence (AI), and Life Sciences Research

The 2024 policy does not cover, or have oversight of, in silico models or computational biology.[42] However, it does encourage "institutional oversight of in silico research, regardless of funding source, that could result in the development of potential dual-use computational models directly enabling the design of a PEPP or a novel biological agent or toxin."[43]

Some have argued that AI can be repurposed or misused when employed for biological design, raising certain biosafety and biosecurity concerns.[44] AI's potential ability to produce molecules that have similar properties but different chemical structures or DNA sequences has raised concerns. Specifically, current detection methods, and screening guidelines that use certain DNA sequences or other features as identifiers, may not be able to identify these new toxins of concern. For additional information on the convergence of AI and the life sciences, see CRS Report R47849, *Artificial Intelligence in the Biological Sciences: Uses, Safety, Security, and Oversight*, by Todd Kuiken.

Congress may consider whether to apply current laws and other federal funding research oversight policies to data that certain AI models are trained on, which could represent biosafety and biosecurity risks if applied in certain ways, or whether additional oversight focused on AI's use in biology and the broader scientific enterprise is justified to avoid such risks. Congress may also wish to examine whether federal agencies have the expertise, capacity, and resources to implement such oversight programs or whether current oversight systems are sufficient.

Integrated Oversight and Standardized Guidance

Oversight of life sciences research is governed by multiple regulations, policies, and guidance, many of which are implemented at the institutional level and compulsory only when the research is supported by federal funding or conducted under federal contracts. To ensure compliance, many research institutions use a biorisk management approach. Biorisk management is a system designed to minimize biosafety and biosecurity risks associated with research involving biological agents and toxins.[45] The approach can include at least three different review mechanisms for determining which regulations and federal guidance may apply to proposed research:

1. the knowledge and expertise of the researcher and laboratory personnel,
2. a formal review of the proposed research by a trained biosafety professional, and

[42] *In silico* refers to computer models of biological design, functions, and processes.

[43] 2024 policy, p. 28.

[44] Sean Ekins et al., "Generative Artificial Intelligence-Assisted Protein Design Must Consider Repurposing Potential," *GEN Biotechnology*, vol. 2, no. 4 (2023), pp. 296-300, https://doi.org/10.1089/genbio.2023.0025.

[45] Sabrina Brizee et al., "Development of a Biosecurity Checklist for Laboratory Assessment and Monitoring," *Applied Biosafety*, vol. 24, no. 2 (2019), pp. 83-89, https://doi.org/10.1177%2F1535676019838077, and Jennifer Gaudioso, Reynolds M. Salerno, and Natalie Barnett, "Developing a Risk Assessment and Management Approach to Laboratory Biosecurity," *Applied Biosafety*, vol. 11, no. 1 (2006), pp. 24-31, https://doi.org/10.1177/153567600601100105.

3. a committee review by fellow researchers evaluating the research on behalf of the institution.[46]

These review processes are designed to meet the obligations of the institution under federal regulations and guidance and to determine whether experiments can be performed at an acceptable level of safety and security by utilizing risk-mitigation measures.[47] Programs of this type vary widely among institutions based on each institution's expertise, resources, and biosafety/biosecurity cultural norms. Before the 2024 policy goes into effect, Congress may seek to hear from affected institutions regarding whether they have the proper resources and training to implement the policy effectively and its potential impact on their research programs.

Executive Order 14081 put forth a number of priorities and policies related to reducing risk by advancing biosafety and biosecurity. One such priority was to "elevate biological risk management as a cornerstone of the life cycle of biotechnology and biomanufacturing [research and development], including by providing for research and investment in applied biosafety and biosecurity innovation."[48]

If Congress determined that further action were needed, one option could be to establish an overarching federal biorisk management policy that brings the recommendations, guidance, and policies shown in **Table 1** into a single common framework. Such a framework could include guidance on how to implement policies, such as the BMBL and the 2024 policy, in order to address variation in institutional expertise. Such an approach could better align oversight of life sciences research across federal agencies and provide a consistent review process for research institutions, potentially including private laboratories and other research that is not federally funded.

If Congress were to pursue legislation providing authority for or otherwise requiring the development of an overarching federal biorisk management policy, factors for consideration could include

- which body should develop the policy—a single agency, such as HHS, or an interagency body, such as the National Science and Technology Council;[49]
- how to design the policy to anticipate emerging science and novel public health threats so that it does not need to be reactively revised when science advances or an event occurs; and/or
- whether a new regulatory oversight body, independent from agencies funding research, is necessary to coordinate and enforce the statute or policy, as suggested by some experts.[50]

[46] Rebecca L. Moritz and David R. Gillum, "Adaptation of Research Infrastructure to Meet the Priorities of Global Public Health," *Frontiers in Bioengineering and Biotechnology*, vol. 8 (2020), Article 613253, https://doi.org/10.3389%2Ffbioe.2020.613253.

[47] David Gillum and Rebecca Moritz, "Why Gain-of-Function Research Matters," *The Conversation: Science + Technology*, June 21, 2021, https://theconversation.com/why-gain-of-function-research-matters-162493.

[48] Executive Order 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," 87 *Federal Register* 56849-56860, September 15, 2022, https://www.federalregister.gov/documents/2022/09/15/2022-20167/advancing-biotechnology-and-biomanufacturing-innovation-for-a-sustainable-safe-and-secure-american. For additional information on Executive Order 14081, see CRS Report R47274, *White House Initiative to Advance the Bioeconomy, E.O. 14081: In Brief*, by Marcy E. Gallo and Todd Kuiken.

[49] White House, "National Science and Technology Council," https://www.whitehouse.gov/ostp/nstc/.

[50] Ryan Ritterson et al., "A Call for a National Agency for Biorisk Management," *Health Security*, vol. 20, no. 2 (2022), pp. 187-191, https://doi.org/10.1089/hs.2021.0163.

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