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U.S. Oversight of Laboratory Biosafety and Biosecurity: Current Policies, Recommended Reforms, and Options for Congress

September 15, 2023

Congressional Research Service
https://crsreports.congress.gov
R47695

CRS REPORT
Prepared for Members and
Committees of Congress

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Introduction

The United States has multiple, overlapping policies that provide biosafety and biosecurity guidance and oversight for life sciences research, depending on the types of experiments and biological agents used (see **Table 1** and **Figure 1**). Many of these U.S. policies and guidelines were developed in response to specific events (see **Figure 2**).

While some biosafety and biosecurity oversight mechanisms are required by law, others are guidance issued by federal science agencies and are mandatory only if the research is funded by the U.S. government. Privately funded research, or research conducted outside the United States, may therefore not be covered by certain U.S. oversight mechanisms. Recent evaluations of U.S. biosafety and biosecurity policies have highlighted these potential oversight gaps. For example, in 2023, the National Science Advisory Board for Biosecurity (NSABB)[1] and the U.S. Government Accountability Office (GAO) evaluated current U.S. polices related to research with enhanced potential pandemic pathogens (ePPPs), Dual-Use Research of Concern (DURC), the Federal Select Agent Program (FSAP), and broader biosafety and biosecurity issues related to life-sciences research.[2] Based on their findings, both organizations issued a number of recommendations, which included the need to expand U.S. oversight to privately funded life sciences research under certain circumstances. It's difficult to know for certain how much privately funded research there actually is that would be captured, if the guidance covering federally funded research is expanded to privately funded research.

This report provides an overview of five current U.S. policies for biosafety and biosecurity oversight, summarizes recent recommendations from the NSABB and GAO, and presents a number of policy options and considerations for Congress in weighing potential changes to oversight policies.

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

Oversight Measures	Risks Addressed	Description of Oversight
Biosafety in Microbiological and Biomedical Laboratories (BMBL), 6th Edition	Biosafety risks	Applies to: Life sciences research involving infectious microorganisms or hazardous biological materials.
https://www.cdc.gov/labs/pdf/SF__19_308133-A_BMBL6_00-BOOK-WEB-final-3.pdf		Description: General biosafety practices and biological containment for various classifications (risk groups) of microorganisms and etiological, disease-causing agents.

[1] The NSABB is a federal advisory committee that addresses issues related to biosecurity and dual-use research at the request of the United States government.

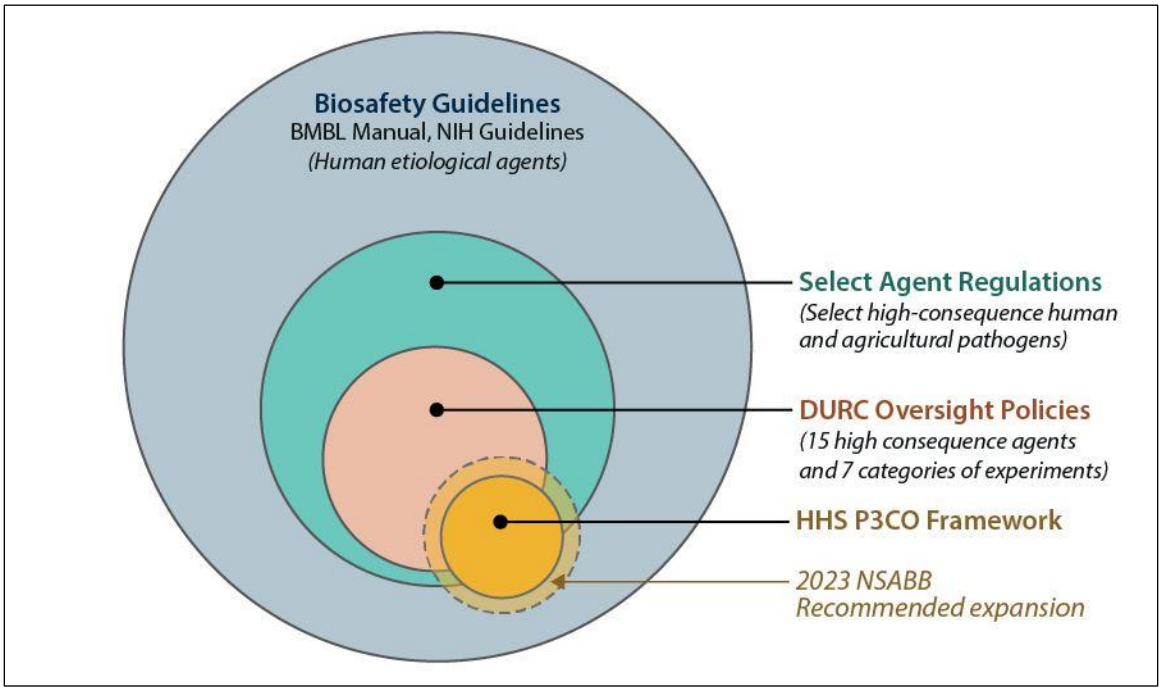
[2] U.S. Government Accountability Office, *Public Health Preparedness: HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens*, GAO-23-105455, 2023, https://www.gao.gov/products/gao-23-105455; and National Science Advisory Board for Biosecurity, *Proposed Biosecurity 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.

Oversight Measures	Risks Addressed	Description of Oversight
National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules https://osp.od.nih.gov/policies/biosafety-and-biosecurity-policy#tab2/	Biosafety risks	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 http://www.selectagents.gov/	Biosecurity (physical and personnel) and biosafety risks	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 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.
U.S. Government Policy for Federal Oversight of Dual-Use Research of Concern (DURC) and U.S. Government Policy for Institutional Oversight of DURC http://www.phe.gov/s3/dualuse/Pages/USGOversightPolicy.aspx http://www.phe.gov/s3/dualuse/Pages/InstitutionalOversight.aspx	Biosecurity risks and knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security	Applies to: Life sciences research conducted at an institution receiving U.S. government funding that involves any of the specified 15 pathogens and toxins deemed to pose the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy. Description: The policy is designed to preserve the benefits of life sciences research while minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.
HHS Framework for Guiding Funding Decisions About Proposed Research Involving Potential Pandemic Pathogens https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf	Biosafety and biosecurity risks associated with experiments that are reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens	Applies to: Gain-of-function studies that are reasonably anticipated to develop enhanced potential pandemic pathogens resulting from the enhancement of the transmissibility and/or virulence of a pathogen. Description: Describes an HHS department-level review and approval process for certain gain-of-function studies, which can result in funding, not funding, or funding with certain conditions and ongoing oversight.

Source: Adapted from National Science Advisory Board for Biosecurity, *Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research*, 2016, pp. 57-58.

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

Oversight Applies to Specific Agents and/or Types of Experiments

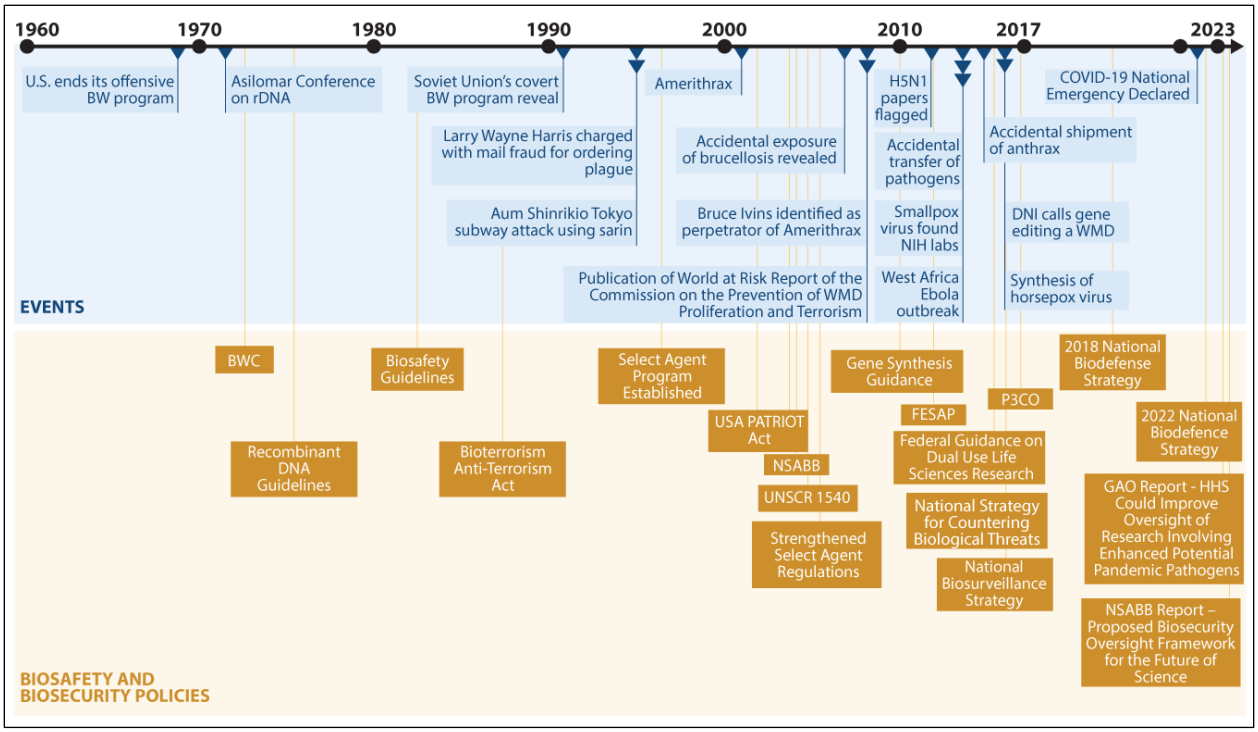


Source: CRS, adapted from National Science Advisory Board for Biosecurity, *Recommendations for the Evaluation and Oversight of Proposed Gain-of-Function Research*, 2016, p. 28.

Notes: BMBL=Biosafety in Microbiological and Biomedical Laboratories; NIH=National Institutes of Health; DURC=Dual-Use Research of Concern; HHS=U.S. Department of Health and Human Services; HHS P3CO Framework=Framework for Guiding Funding Decisions About Proposed Research Involving Enhanced Potential Pandemic Pathogens; and NSABB=National Science Advisory Board for Biosecurity.

The 2023 NSABB Recommended expansion is a visual representation based upon the recommendations found in the National Science Advisory Board for Biosecurity report *Proposed Biosecurity Oversight Framework for the Future of Science*, 2023, and should not be interpreted as an estimate of actual expansion. Other recommendations in the NSABB report, if implemented, could expand or combine DURC oversight with HHS Framework for Guiding Funding Decisions about Proposed Research Involving Potential Pandemic Pathogens (P3CO). See the "Recent Recommendations from GAO and NSABB" section below. The Government Accountability Office (GAO) made three recommendations in its 2023 report *HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens*, which could also expand P3CO/DURC oversight if implemented.

Figure 2. Select Biosafety and Biosecurity Events and Associated U.S. Policy Implementation Through 2023



Source: CRS, adapted from Diane DiEuliis et al., "Biodefense Policy Analysis—A Systems-Based Approach," *Health Security,* vol. 17, no. 2 (2019).

Notes: Figure represents a selection of major events and should not be interpreted as a comprehensive list. BW=Bio weapons; BWC=U.N. Bioweapons Convention; DNI=Director of National Intelligence; FESAP=Federal Experts Security Advisory Panel; GAO=Government Accountability Office; HHS=U.S. 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=U.N. Security Council Resolution; WMD=Weapon of Mass Destruction.

U.S. Policies for Biosafety and Biosecurity Oversight

Biosafety in Microbiological and Biomedical Laboratories (BMBL) 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 serves as 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.[3] Some federal agencies include adherence to the BMBL as a condition for receiving certain federal grants. It is also recommended as guidance to assist entities subject to

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

the Federal Select Agent Program (FSAP) and others in the development of biosafety/biocontainment plans.

The BMBL describes biosafety levels (BSLs), which are designations applied to projects or activities conducted in laboratories, in ascending order of containment based on the degree of the health-related risk associated with the work being conducted.[4] Each biosafety level (BSLs 1-4) builds upon the previous level (see **Table 2** for descriptions of the BSLs). Each level describes a minimum set of safety practices and procedures, required safety equipment, and administrative and engineering controls. The appropriate BSL for a research project is determined by the institution in which the work is being conducted, in consultation with the principal investigator, and based on a risk assessment of the specific organism (see **Table 3**) and types of experiment to be performed. In 2021, 187 entities with BSL-3 laboratories and 8 entities with BSL-4 laboratories were registered in the FSAP in the United States; they were operated by a variety of actors (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]

While the BMBL serves as an "advisory document recommending best practices for the safe conduct of work in biomedical and clinical laboratories,"[7] the GAO reported in 2013 that there are 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]

Table 2. Laboratory Biosafety Levels

BSL Level	Description
Biosafety Level 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 related science.

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

[5] Federal Select Agent Program, *2021 Annual Report of the Federal Select Agent Program*, 2021, https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2021_508.pdf.

[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.

[7] Biosafety in Microbiological and Biomedical Laboratories (BMBL), p. iii, https://www.cdc.gov/labs/BMBL.html.

[8] U.S. Government Accountability Office, *High-Containment Laboratories: Assessment of the Nation's Need Is Missing*, 2013, https://www.gao.gov/products/gao-13-466r.

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

BSL Level	Description
Biosafety Level 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 in that (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.
Biosafety Level 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.
Biosafety Level 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 related agents 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: CRS, adapted from Paul J. Meechan and Jeffrey Potts, *Biosafety in Microbiological and Biomedical Laboratories*, 6th Edition, 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.

Table 3. Classification of Biohazardous Agents by Risk Group

Risk Group Number	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*, 2019, https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

Notes: The NIH guidelines require a risk assessment to 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.

Federal Select Agent Program (FSAP)

FSAP is one of the federal regulatory programs addressing biosecurity. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188) requires the Department of Health and Human Services (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

USDA to establish and regulate a list of biological agents that have the potential to pose a severe threat to animal health and safety, plant health and safety, or to the safety of animal or plant products. FSAP is managed by the Division of Select Agents and Toxins at the 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. 42 U.S.C. §262a and 7 U.S.C. §8401 require CDC and USDA to review and republish the lists of select agents and toxins on at least a biennial basis.[10]

FSAP focuses on both the people who have access to select agents and the facilities where select agents are used and stored. Entities possessing select agents are required under 42 U.S.C. §262a and 7 U.S.C. §8401 to develop explicit biosecurity and biosafety plans and procedures, which are reviewed and certified by FSAP.[11] Some have argued that a list-based approach "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.[12]

The select agent regulations (7 C.F.R. Part 331, 9 C.F.R. Part 121, and 42 C.F.R. Part 73) require entities to develop and implement a written biosafety and biocontainment plan as well as an incident response plan. FSAP provides guidance documents that describe attributes that each plan must have.[13]

Dual-Use Research of Concern (DURC)

The U.S. Government Policy for the Institutional Oversight of Life Sciences Dual Use Research of Concern went into effect on September 24, 2015. The policy articulates the practices and procedures required to ensure that dual-use research of concern is identified at the institutional level and risk mitigation measures are implemented as necessary.[14] It defines dual-use research of concern as

> life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

It covers research that uses one or more of the 15 agents or toxins listed within the policy and 7 categories of experiments. The policy applies to:

1. all U.S. government departments and agencies that fund or conduct life sciences research; and
2. institutions within the United States that both

[10] Federal Select Agent Program, https://www.selectagents.gov/sat/index.htm.

[11] An entity is defined as any government agency (federal, state, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity. 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.

[12] Sam Weiss Evans et al., "Embrace Experimentation in Biosecurity Governance," *Science*, vol. 368, no. 6487 (2020).

[13] 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.

[14] The United States Government, *United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern*, September 25, 2015, https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf.

a. receive U.S. government funds to conduct or sponsor life sciences research, and
b. conduct or sponsor research that involves one or more of the 15 agents or toxins listed within the DURC policy, even if the research is not supported by U.S. government funds.

Institutions or private companies that do not receive U.S. government funding are not subject to the DURC policy.

The terms biosafety and biosecurity are used differently in various international regulations and frameworks. Global consensus around what DURC should consist of or what the appropriate safety levels for DURC experiments should be is lacking, except that these types of experiments should be conducted under the safest conditions practicable.[15] Some have argued that instead of developing DURC policies that prohibit or limit certain types of experiments, the focus should be on reviewing the scientific questions proposed.[16]

See the "Recent Recommendations from GAO and NSABB" section, below.

Framework for Guiding Funding Decisions About Proposed Research Involving Enhanced Potential Pandemic Pathogens

In January 2017, the White House Office of Science and Technology Policy (OSTP) released *Recommended Policy Guidance for Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO)*,[17] which described attributes of federal agency review and reporting processes for the additional oversight of federally funded research that is anticipated to create, transfer, or use enhanced pathogens with pandemic potential. Agency implementation of a review and reporting process with the described attributes would allow an agency to support gain-of-function (GOF) research on potential pandemic pathogens.[18] Responding to the OSTP guidance, HHS released the *Framework for Guiding Funding Decisions About Proposed Research Involving Enhanced Potential Pandemic Pathogens* in December 2017.[19]

Sections III and IV of the HHS P3CO framework establish an additional review process for HHS-sponsored research proposals that have gone through the normal scientific review process, have been determined to be scientifically sound, and are reasonably anticipated to create, transfer, or use enhanced potential pandemic pathogens (ePPPs). An ePPP is defined as a potential pandemic pathogen resulting from the enhancement of the transmissibility and/or virulence of a pathogen, which can occur via GOF-type research. To be subject to this extra scrutiny, an ePPP must satisfy two criteria:

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[15] Michael J. Imperiale and Arturo Casadevall, "A New Approach to Evaluating the Risk-Benefit Equation for Dual-Use and Gain-of-Function Research of Concern," *Frontiers in Bioengineering and Biotechnology*, vol. 6 (2018).

[16] Ibid.

[17] Office of Science and Technology Policy, *Recommended Policy Guidance for Potential Pandemic Pathogen Care and Oversight (P3CO)*, 2017, https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/p3co-finalguidancestatement.pdf.

[18] Gain-of-function (GOF) research is a broad area of scientific inquiry involving organisms that gain a new property or have an existing property altered. A key area of GOF research is the study of both naturally occurring and experimentally induced changes in viruses to better understand transmission, infection, and pathogenesis. Current U.S. policy focuses on GOF research involving enhanced potential pandemic pathogens.

[19] U.S. Department of Health and Human Services, *Framework for Guiding Funding Decisions About Proposed Research Involving Enhanced Potential Pandemic Pathogens*, 2017.

1. it is likely highly transmissible and likely capable of wide and uncontrollable spread in human populations; and
2. it is likely highly virulent and likely to cause significant morbidity and/or mortality in humans.

The HHS P3CO review process examines both what is being experimented on (a PPP) and what the experiment will produce (an enhanced PPP). If a research proposal meets these criteria, it may be required to go through an independent, HHS-level, multidisciplinary P3CO review committee to determine, in part, whether:

- the research is scientifically sound;
- the pathogen is considered to be a credible source of a potential future human pandemic;
- the potential risks compared with the potential benefits to society are justified;
- there is no feasible alternative method to address the same question in a manner that poses less risk;
- the investigators have demonstrated the capacity and commitment to conduct the research safely and securely;
- the research results are expected to be responsibly communicated;
- the research will be subject to ongoing federal oversight; and
- the research is ethically justifiable.

Based on this review, the P3CO review committee reports to the HHS funding agency (e.g., NIH) whether the research is acceptable, not acceptable, acceptable on the condition that certain experiments are modified, or acceptable on the condition that certain risk mitigation measures are employed at the federal and institutional level. The funding agency makes the final determination on whether the project will be funded and must report its decision to HHS and OSTP.

See the "Recent Recommendations from GAO and NSABB" section, below.

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.

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.[20] Compliance with the NIH Guidelines is a condition of grant awards for recipients of funding from the NIH and certain other federal agencies. The guidelines are structured in a manner that can apply to an entire research institution, even if a particular research project/experiment was 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

[20] Department of Health and Human Services, *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, 2019, https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

assign their IBCs the responsibility of reviewing a variety of experimentation that involves biological materials and other potentially hazardous agents. This additional responsibility is assigned entirely at the discretion of the institution.[21] The guidelines classify organisms into four risk groups based on their pathogenicity towards humans (see **Table 3** above).

Recent Recommendations from GAO and NSABB

Two reports released in 2023, one from GAO and another from the NSABB, evaluated current U.S. polices related to research with ePPPs, DURC, FSAP, and broader biosafety and biosecurity issues related to life-sciences research.[22]

The NSABB made 13 recommendations based on 13 findings focused on the implementation of P3CO and DURC. GAO made three recommendations to improve HHS's oversight of research related to P3CO and FSAP.

While each report provided a separate set of recommendations based on its findings, when considered together, three broad themes emerge:

1. clarifying language and developing standards to identify research that requires review under the P3CO policy;
2. increasing transparency around the P3CO review and approval processes; and
3. expanding oversight to include privately funded research.

How these recommendations are considered by federal agencies with oversight responsibilities for life sciences research could impact the guidance and oversight mechanisms described in the preceding sections.

For additional information on these reports, see CRS Insight IN12109, *Improved Oversight of Pathogen Research: Recent Recommendations*, by Todd Kuiken.

Policy Considerations

Status Quo

Policymakers may choose to continue the current oversight system for life sciences research. Supporters of the status quo have argued that existing policies are sufficient and 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), 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. Conversely, some critics of the status quo argue either that additional requirements are needed to ensure safety and security, or that the number and overlap of current policies already

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

[22] U.S. Government Accountability Office, *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.

creates a burden on affected institutions, potentially impacting their ability to conduct scientific research effectively, and thus that existing requirements should be reduced or streamlined.[23]

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.[24] 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.
3. A committee review by fellow researchers evaluating the research on behalf of the institution.[25]

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.[26] Programs of this type vary widely among institutions based on each institution's expertise, resources, and biosafety/biosecurity cultural norms.

Executive Order 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy," 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 R&D, including by providing for research and investment in applied biosafety and biosecurity innovation."[27]

Congress may wish to consider mandating the establishment of an overarching federal biorisk management policy that brings together the recommendations, guidance, and policies shown in **Table 1** into a single common framework. Such an overarching policy could include guidance on how to implement policies, such as the BMBL, in order to address variation in institutional

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[23] Paul W. Duprex et al., "Gain-of-Function Experiments: Time for a Real Debate," *Nature Reviews. Microbiology*, vol. 13, no. 1 (2015), pp. 58-64; Ryan Ritterson et al., "A Call for a National Agency for Biorisk Management," *Health Security*, vol. 20, no. 2 (2022); and Marc Lipsitch and Alison P. Galvani, "Ethical Alternatives to Experiments with Novel Potential Pandemic Pathogens" *PLOS Medicine*, vol. 11, no. 5 (2014).

[24] Sabrina Brizee et al., "Development of a Biosecurity Checklist for Laboratory Assessment and Monitoring," *Applied Biosafety*, vol. 24, no. 2 (2019), pp. 83-89; 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.

[25] 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).

[26] David Gillum and Rebecca Moritz, "Why Gain-of-Function Research Matters," *The Conversation: Science + Technology*, June 21, 2021.

[27] Executive Order 14801, "Advancing Biotechnology and Biomanufacturing Innovation," vol. 87, no. 178 *Federal Register* 56849-56860, September 15, 2022. For additional information on Executive Order 14801, see CRS Report R47274, *White House Initiative to Advance the Bioeconomy, E.O. 14081: In Brief*, by Marcy E. Gallo and Todd Kuiken.

expertise. Such an approach could better align oversight of life science 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 require 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 (NSTC);[28]
- 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
- whether a new regulatory oversight body, independent from agencies funding research, is necessary to coordinate and enforce the policy, as suggested by some experts.[29]

Implementation of Recent NSABB and GAO Recommendations

Congress may wish to consider the GAO and NSABB recommendations (see "Recent Recommendations from GAO and NSABB," above) that suggest expanding U.S. oversight to privately funded research under certain circumstances. This option could require a determination of whether agencies have the authority to make that change or whether additional authorities would be needed. Congress may also choose to examine agencies' ability to conduct oversight of research conducted at private institutions, companies, and international institutions.

Congress could also choose to wait to evaluate how the Administration and relevant federal agencies interpret and implement these recommendations in part, in full, or in a different way. On September 1, 2023, OSTP released a request for information seeking comments on how potential changes to the DURC and P3CO policies could mitigate risks associated with DURC and research with ePPPs while minimizing undue burden on institutions.[30] Congressional committees with jurisdiction could choose to investigate any guidance OSTP provides to agencies on how to implement the GAO and NSABB recommendations and how agencies implement that guidance, in addition to the biosafety and biosecurity priorities put forth in Executive Order 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy."[31]

[28] National Science and Technology Council, https://www.whitehouse.gov/ostp/nstc/.

[29] Ryan Ritterson et al., "A Call for a National Agency for Biorisk Management," *Health Security*, vol. 20, no. 2 (2022).

[30] Office of Science and Technology Policy, "Request for Information; Potential Changes to the Policies for Oversight of Dual Use Research of Concern (DURC) and the Potential Pandemic Pathogen Care and Oversight (P3CO) Policy Framework," 88 *Federal Register* 60513-60515, September 1, 2023.

[31] Executive Order 14801, "Advancing Biotechnology and Biomanufacturing Innovation," vol. 87, no. 178 *Federal Register* 56849-56860, September 15, 2022.

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