U.S. SENATE COMMITTEE ON
HEALTH, EDUCATION, LABOR&PENSIONS
RICHARD BURR, NORTH CAROLINA - RANKING MEMBER

Strengthening the Safety and Security of Laboratories

NOVEMBER 5, 2021 *POLICY BRIEF*

The United States is the global leader in public health and biomedical research. Our scientists and researchers are at the forefront of developing innovative products, such as vaccines and therapeutics, which dramatically improve our ability to treat and prevent life-threatening diseases and which protect against man-made and naturally occurring health security threats.

The COVID-19 pandemic, recent Ebola outbreaks, and advances in synthetic biology capabilities all demonstrate the ever-evolving landscape of biological threats and the urgent need to prepare for them, and have renewed Congressional and public interest in regulations regarding high-containment laboratories. Carefully conducted research is necessary to understand and combat these types of threats. Researchers routinely study pathogens to better understand how they work, the risks they pose, and to inform the development of medical countermeasures and other strategies to combat them. These efforts can keep America at the forefront of biomedical innovation, allow us to outpace our adversaries in research, and ensure national health security.

Conducting research without effectively understanding and addressing the risks, however, can pose a threat to public health and safety. Gaps in policies and protocols and the lack of a strategic and measured approach to laboratory practices can lead to devastating results. For example, in 1976, an accidental release of anthrax from a bioweapons facility in Sverdlovsk, Russia killed at least 64 people, including members of the public.[1] In 1995, a microbiologist in the United States was indicted on fraud charges after misrepresenting his reasons for ordering samples of the bacteria that causes plague. In the aftermath of this event and under growing threat of potential bioterror attacks, Congress passed legislation in 1996 requiring the Department of Health and Human Services (HHS) to issue regulations regarding the handling of biological agents and toxins that pose a severe threat to public health and safety and to establish criminal penalties for the illegal possession, use, or transfer of such agents. This law was a precursor to the Federal Select Agent Program (FSAP) we have today. [2, 3]

Policies to mitigate and manage biosafety and biosecurity risks, which are inherent to working with live pathogens, are fragmented and inconsistent. This lack of coordination, particularly between relevant federal agencies and a lack of uniformity in those agencies' policies, has resulted in the accidental release of, and potential exposure to, numerous pathogens and presents a serious challenge for scientists conducting legitimate research in high-containment laboratories.

[1] https://www.pbs.org/wgbh/pages/frontline/shows/plague/sverdlovsk/
[2] https://www.selectagents.gov/overview/index.htm
[3] https://www.congress.gov/104/plaws/publ132/PLAW-104publ132.pdf

As we continue to investigate the origins of COVID-19 and, as a nation, experienced the challenges of contamination of test-kits early in the pandemic, now is the time to implement reforms to improve our biosecurity and safety policies. For years, expert organizations, federal advisory committees, and even the Government Accountability Office (GAO) have advocated for targeted improvements to our laboratory safety protocols – to keep Americans safe and to address rapidly evolving challenges. Congress should act to address these concerns.

Background: Overview of High-Containment Laboratories

Laboratories use a tiered system for the containment of pathogens, based on the biosafety risks of each specific pathogen and the circumstances under which it is being used and handled. The classification system for facilities working with pathogens capable of infecting humans consists of four biosafety levels (BSL). Under this system, level four (BSL-4) is used for research activities that pose the greatest risks and require the highest degree of precautions to ensure containment and safety. The types of precautions taken under each BSL include laboratory practices and protocols, personnel training, physical attributes of the laboratory, and specific equipment that should be used.

High-containment laboratories, which are either BSL-3 or BSL-4 laboratories, are maintained by both public and private entities. The vast majority of high-containment laboratories are classified as BSL-3 and are operated by government agencies, private industry, and academic institutions. While a number of facilities may have BSL-4 capabilities, only four laboratories in the United States were actively operating at the BSL-4 level as of 2018.[4] All four of these active BSL-4 laboratories are either government-owned or academic institutions that receive federal support for the facility.

In the United States, biosafety recommendations for each BSL are developed by subject matter experts and issued jointly by the Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH) in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) manual. NIH policy requires similar biosafety requirements as a condition of research funding.

The World Health Organization (WHO) and individual countries also maintain their own biosafety guidelines. Some countries, including multiple European Union (EU) member states, follow the leadership of the United States and use BMBL to inform their own domestic biosafety policies.[5] For example, Germany's domestic policies go into more detail than overarching EU directives and are based on BMBL, specifying additional precautions.[6]

Globally, countries vary in whether they have an established biosafety policy. This variation results in differences in the way researchers may handle dangerous pathogens and the ways in which human interaction and human error in laboratories may affect risks of exposure. Even in countries with established biosafety standards and requirements, compliance varies between laboratories, possibly due to differences in biosafety capabilities and challenges with

[4] https://www.niaid.nih.gov/research/biosafety-labs-needed
[5] https://www.liebertpub.com/doi/pdfplus/10.1177/1535676016661772
[6] Ibid.

implementing and understanding policies.[7] This variability across the globe creates vulnerabilities that could be exploited by bad actors or increase the likelihood of accidental releases, to catastrophic effect. Not only do policies and protocols, based on the best available science, need to be in place in every country, but they must be well understood, followed, and exercised with close oversight.

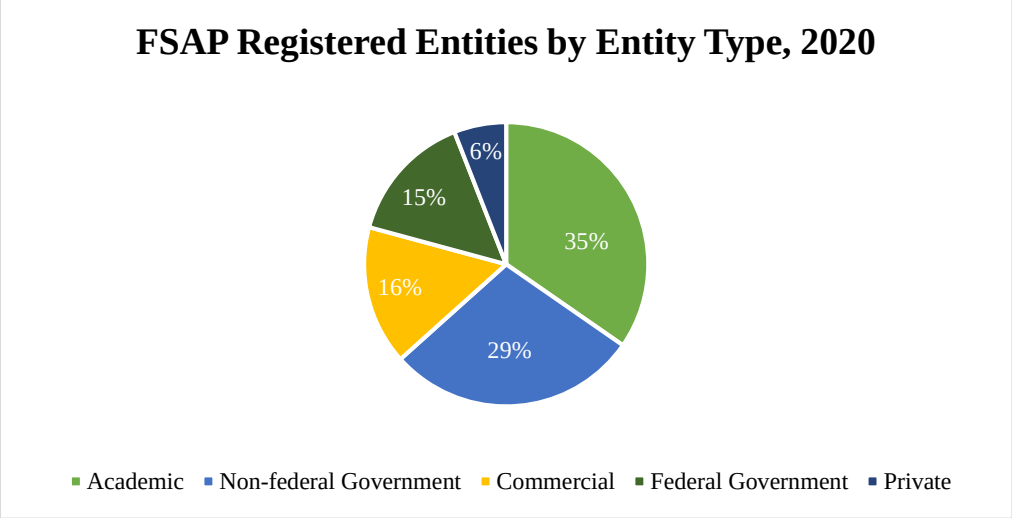
Policy Landscape in the United States

The possession, use, and transfer of certain pathogens and biological toxins are regulated under federal law through FSAP, which is jointly administered by CDC and the U.S. Department of Agriculture (USDA). CDC and USDA establish the specific pathogens and biological toxins, known as "select agents," regulated under the program. CDC is responsible for oversight of agents that pose a threat to public health and safety, and USDA regulates agents that pose a threat to animal and plant health and related products. Currently, 67 pathogens and toxins are on the select agents list, of which 35 are regulated by CDC, 21 are regulated by USDA, and 11 appear on both the USDA and CDC lists because the agents present a threat to both humans and animals or plants.[8] In 2010, President Obama signed Executive Order 13546 to implement a more risk-based approach to FSAP.[9] As part of this effort, the executive order established the Federal Experts Security Advisory Panel (FESAP) to develop recommendations for improving FSAP.[10]

Entities proposing to conduct research involving a select agent must register with FSAP and agree to both announced and unannounced inspections of their laboratories by CDC or USDA. The program also requires registered entities to implement site-specific plans to ensure compliance with FSAP requirements for biosafety and biocontainment, drills and exercises, vetting and training of personnel, information systems and physical security controls, and incident response.[11] In 2020, 244 entities were registered with the program, of which 209 were registered through CDC and 127 were registered to work with the highest risk agents, like the Ebola or Marburg viruses.[12] The breakdown of FSAP registered entities by entity type can be found in Figure 1.

[7] Ibid.
[8] https://www.selectagents.gov/sat/list.htm
[9] https://irp.fas.org/offdocs/eo/eo-13546.htm
[10] https://www.phe.gov/Preparedness/legal/boards/fesap/Pages/default.aspx
[11] Ibid.
[12] https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2020_508.pdf

Figure 1.



Source: https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2020_508.pdf

In addition to regulating laboratory protocols, the Federal Select Agent Program works with the Federal Bureau of Investigation (FBI) to assess the security risks posed by each individual seeking access to a select agent through a registered entity. If an entity is found to be out of compliance with program requirements, potential actions include establishing a voluntary Corrective Action Plan, suspending or revoking the entity's registration (which effectively halts any ongoing work with select agents), and notifying relevant agencies, like the FBI, for further investigation, which could result in civil monetary penalties or criminal prosecution.[13]

In 2020, entities reported to FSAP 158 releases, 13 losses, and zero thefts of select agents, compared to 199 releases, 12 possible losses and zero thefts of select agents reported in 2015.[14,15] Releases may be due to equipment failures, spills, needle-sticks, contact with an infected laboratory animal, or human error. Losses are often related to misplaced samples or inconsistencies between recorded inventory and the amount of a sample actually on-hand; they are referred to FBI for further investigation.

Apart from facilities under the jurisdiction of FSAP, research laboratories are generally self-regulated by their institution, subject to federal and state laws or regulations and any applicable requirements related to the use of federal funds or receiving pathogen samples from federal sources. Laboratories can also choose to undergo a voluntary accreditation process through ABSA International, a biosafety professional association based in the United States.[16]

Research with Enhanced Potential Pandemic Pathogens: Federal policies have also been established to oversee a subset of federally-funded research involving enhanced potential pandemic pathogens. Following a three-year moratorium on federal funding for certain types of experiments involving influenza, SARS, or MERS viruses (often called "gain-of-function

[13] Ibid.
[14] Ibid.
[15] https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2015.pdf
[16] https://absa.org/lab-accred/

research of concern"), in 2017 the White House Office of Science and Technology Policy (OSTP) issued guidance on Potential Pandemic Pathogens Care and Oversight (P3CO). This guidance provided criteria for how departments should review certain research proposals.[17] Later that year, HHS issued its *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*, which established a process, led by the Office of the Assistant Secretary for Preparedness and Response (ASPR), to review HHS projects and work with the relevant subagency and investigators to incorporate additional safeguards and changes to experiments as a condition of funding.[18] To date, only three reviews of HHS-funded projects have been completed through this process.[19] Apart from HHS, no other departments and agencies have publicly established a policy in response to the OSTP guidance.

The Problem: Recent Biosafety Lapses

The lack of an overarching strategy and coordination among domestic high-containment laboratories, including among federally owned and operated laboratories, has resulted in policy gaps that create unnecessary occupational, public health, and security risks. GAO has found there is no federal agency responsible for the strategic planning and oversight of high-containment laboratories, and there is no coordinated strategy for their expansion.[20, 21] Further, GAO noted that "no one agency is responsible for determining the aggregate or cumulative risks associated with the continued expansion of high-containment laboratories…the oversight of these laboratories is fragmented and largely self-policing."[22]

Compounding the risks is the fact that, even in recent years, federal laboratories have continued to experience contamination issues and lapses in biosafety. These issues and lapses have led to questions over whether the purported culture of responsibility within federal research laboratories has given way to a culture of complacency.

As noted in the timeline to the right, in 2014, a cascade of biosafety lapses in federal laboratories occurred, beginning with

Timeline for Selected Domestic Laboratory Accidents and Events:

May 2014: USDA researchers discover that CDC accidentally mixed samples of avian influenza with a highly pathogenic, more dangerous strain of the virus.

June 2014: A CDC BSL-3 laboratory accidentally sent possibly live anthrax samples to a lower security lab without the proper safety measures in place to handle a live select agent.

July 2014: Decades-old smallpox and other vials are found in a FDA storage space on the NIH campus.

December 2014: A CDC laboratory sent possibly live Ebola samples to another, lower security lab.

July 2015: CDC testifies before Congress that the Department of Defense (DoD) provided and shipped possibly live anthrax to 192 laboratories over a ten-year period.

June – July 2019: CDC conducts an inspection of U.S. Army Medical Research Institute of Infectious Diseases' (USAMRIID) high-containment laboratories and subsequently issues an order to suspend work with select agents because of structural problems in the facility and insufficient training and adherence to standard operating procedures of laboratory personnel.

February 2020: FDA conducts an inspection of CDC's laboratory that developed and manufactured COVID-19 test kits, finding that the laboratory had multiple breaches of protocol and contamination was the likely source of faulty tests.

[17] https://www.phe.gov/s3/dualuse/documents/p3co-finalguidancestatement.pdf
[18] https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf
[19] https://www.phe.gov/s3/dualuse/Pages/ResearchReview-PPP.aspx
[20] https://www.gao.gov/assets/gao-14-785t.pdf
[21] Ibid.
[22] Ibid.

a discovery by USDA researchers that samples received from CDC of a low-pathogenic avian influenza virus had been accidentally contaminated with a high-pathogenic strain.[23] However, when USDA informed CDC of the incident, CDC personnel did not appropriately report it to their branch supervisor until a month later. It took several more weeks for the incident to be reported to FSAP.[24] Around the same time, CDC found that a BSL-3 laboratory had sent possibly live anthrax samples that may not have been successfully inactivated to a BSL-2 facility, leading to a potential release of live anthrax, although later reviews determined this was a false alarm.[25] Six months later, a similar incident occurred with possibly live samples of Ebola.[26] In response to these incidents, CDC stopped all transfers of samples out of its high-containment laboratories, closed its BSL-4 laboratory, and conducted internal reviews to determine the cause of each lapse and to make recommendations to improve standard operating procedures within CDC laboratories. CDC also established a new entity, the Office of Laboratory Science and Safety, within the agency to provide agency-wide oversight of its laboratories, which is housed separately from the division that administers FSAP. Additionally, USDA's Animal and Plant Health Inspection Service (APHIS) conducted a review and inspection of the CDC laboratories in response to the incidents.

During the same period, boxes of viable smallpox and other decades-old vials were found in a storage space in a Food and Drug Administration (FDA) laboratory located on the NIH campus.[27] In August 2014, the Obama Administration directed all federal departments and agencies to conduct an inventory of biological agent samples in their possession, a clear demonstration of the scope of the problem and degree of concern within the highest levels of government.[28] Smallpox was declared eradicated globally in 1980.[29] The last known samples are held under high security at the CDC in Atlanta and in Russia's VECTOR laboratory in Novosibirsk.[30] Biosafety lapses in federal laboratories are not limited to CDC, or even HHS. The DoD reported biosafety lapses involving the shipment of possibly live anthrax the following year.[31] A 2016 GAO report assessing the biosafety practices of eight departments that operate biological laboratories found that "most department and agency policies were not comprehensive and did not contain all six elements for managing high-containment laboratories."[32]

In the immediate wake of the incidents of early 2014, FESAP was reconstituted and charged by the National Security Council to develop recommendations for the improvement of biosafety and biosecurity in research more broadly.[33] Concurrently, the White House established a Fast Track Action Committee for the Select Agent Regulations (FTAC-SAR) to engage the broader community of stakeholders in select agent policy deliberations.[34] In December 2014, FESAP issued its report in response to this directive, which included recommendations to improve

[23] https://www.gao.gov/assets/680/676248.pdf, p. 60.
[24] Ibid.
[25] Ibid.
[26] Ibid.
[27] Ibid, p. 2.
[28] Ibid.
[29] https://www.cdc.gov/smallpox/vaccine-basics/index.html
[30] https://www.cdc.gov/smallpox/history/history.html
[31] https://www.gao.gov/assets/680/676248.pdf
[32] Ibid, p. 12.
[33] https://www.phe.gov/Preparedness/legal/boards/fesap/Pages/default.aspx
[34] https://www.phe.gov/s3/Documents/ftac-sar.pdf

laboratory practices and culture at the institutional level, bolster the select agent regulations, and engage in a three-step process "to determine the appropriate number of federally funded high-containment U.S. laboratories" working with select agents.[35]

However, mere months after the issuance of the 2014 FESAP report, biosafety issues made headlines again when it was revealed a DoD facility had unintentionally transferred (both directly and via secondary sources) live anthrax samples to a total of 192 laboratories through 575 separate shipments over a period of ten years, a pattern that one researcher in the field referred to as "gross negligence."[36, 37] This revelation had serious repercussions for FSAP. On July 17, 2015, FedEx notified CDC that it would refuse to transport packages containing select agents moving forward.[38] This move caused concern among members of the public health community, who noted that researchers may face delays shipping specimens collected in the field to laboratories or from public health departments to CDC during a response to an infectious disease outbreak.[39]

In October 2015, FTAC-SAR issued its report, which included recommendations that sought to strike a balance between improving safety and transparency and easing regulatory burdens to facilitate research, particularly during emergencies when medical countermeasures are needed. At the same time, HHS established a Biosafety and Biosecurity Coordinating Council, chaired by the ASPR, to help implement these recommendations, improve biosafety and facilitate coordination, facilitate communication between CDC, NIH, and FDA, and establish systems to increase transparency around HHS laboratory incidents.[40] Additionally, the federal government released an implementation plan for the FESAP and FTAC-SAR recommendations in 2015.[41] GAO noted in its 2016 report, however, that many departments and agencies did not have specific timelines for their individual implementation activities as outlined in the implementation plan.[42] As of June 2021, nine of the total 29 FESAP and FTAC-SAR recommendations were still in the process of being implemented.[43]

Federal entities continue to have problems complying with regulatory requirements and best practices. For example, the high-containment laboratories at USAMRIID have been plagued with issues for a number of years, which resulted in the partial, and eventually full, suspension of its FSAP registration in 2018 and 2019, which was later reinstated in 2020 following corrective action.[44, 45] By comparison, no other FSAP-regulated entities received a full or partial suspension in 2019 or 2020.[46]

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[35] https://www.phe.gov/s3/Documents/fesap.pdf, p. 6.
[36] https://www.cidrap.umn.edu/news-perspective/2015/07/cdc-dod-anthrax-errors-involved-575-shipments
[37] https://www.nature.com/articles/nature.2015.17653
[38] https://www.cidrap.umn.edu/news-perspective/2015/07/fedex-bans-select-agents-after-dod-anthrax-lapses
[39] Ibid.
[40] https://www.gao.gov/assets/680/676248.pdf, p. 101.
[41] https://www.phe.gov/s3/Documents/fesap-ftac-ip.pdf
[42] https://www.gao.gov/assets/680/676248.pdf, p. 2.
[43] "Implementation of Recommendations of the Federal Experts Security Advisory Panel and the Fast Track Action Committee on Select Agent Regulations, Update: June 2021," Report to Congress, p. 7.
[44] https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2020_508.pdf
[45] https://www.fredericknewspost.com/public/operations-at-usamriid-lab-on-fort-detrick-to-resume-on-limited-basis/article_37fba018-9d3e-5eb7-a7d5-bd51f1527923.html
[46] https://www.selectagents.gov/resources/publications/docs/FSAP_Annual_Report_2019_508.pdf

More recently, contaminated test kits produced by CDC during the early days of the COVID-19 response demonstrated there is still room for improvement in federal laboratory practices. In early 2020, CDC was responsible for the development of a test to detect the pathogen that causes COVID-19, SARS-CoV-2. CDC had access to samples of the novel virus that were hard to access at that time and developed a test to be shipped to public health labs around the country. Shortly after the delivery of these test kits, public health labs began to report issues with their trial runs of the tests, and, upon HHS investigation, it was discovered that these test kits were likely contaminated while being manufactured in CDC's laboratories. Until new tests were developed by private sector and laboratory community partners several weeks later, access to testing was extremely limited and negatively impacted the U.S. response. Other countries that relied upon an early WHO test developed in Germany did not experience these issues.

Oversight of Federally Funded International Research Collaborations

International collaboration is a key component of accelerating scientific breakthroughs and advancing cures. It is also a critical aspect of our work to improve health security, given that many high-consequence pathogens emerge or reemerge in regions around the world, requiring international collaboration to identify, catalog, and understand pathogens. In FY2020, NIH received $41.6 billion in annual appropriations, of which $30.8 billion supported research outside of the agency at academic and other research institutions, including some research conducted in other countries.[47, 48] As part of an application for an award, NIH procedures require investigators to disclose information related to any proposed work with international partner and the agency has additional procedures intended to address and manage any potential risks posed by the research.

NIH has the flexibility to apply additional terms and conditions to an award, including requirements that an investigator promptly notify NIH if their work produces unexpected results that could increase the risks posed by the experiment, such as evidence of increased transmissibility or virulence.[49] This process, when followed, allows NIH to identify projects that may present additional biosafety and security risks and appropriately apply new measures to mitigate these risks in response to the research. NIH award funds are provided annually to researchers and informed by yearly reports submitted to NIH by the investigator, who documents the progress of the funded work, including work conducted by a collaborator under a sub-award.

Emerging information raises questions about whether all of these procedures are followed for all grants. A limitation of this process is that it relies upon the receipt of timely and accurate information from award recipients to inform NIH decision-making. Recent news has brought to light problems that can emerge in the area of international research collaboration when there are biosafety considerations that need to be taken into account. In the case of EcoHealth Alliance, NIH reportedly included an additional term requiring prompt notification of unexpected results; yet, according to NIH, the entity "failed to report this finding right away."[50] EcoHealth Alliance

[47] https://www.niaid.nih.gov/grants-contracts/fy-2020-award-data
[48] Ibid.
[49] https://s.wsj.net/public/resources/documents/NIH%20letter.pdf, p. 1.
[50] Ibid, p. 2.

has disputed this assertion and stated NIH program officers did not inform EcoHealth of the requirement for a secondary review.[51] This disagreement demonstrates the need to improve and clarify communications, expectations, and accountability when it comes to compliance with federal award conditions. Additionally, concerns raised about reports of the conditions under which EcoHealth's international collaborators were conducting experiments show the risks of variation in laboratory safety practices internationally.[52]

Moving Forward: Biosafety and Biosecurity to Address 21st Century Threats

It is imperative for national health security that we address compliance challenges within FSAP, improve the culture of responsibility, including among federal laboratories, and take steps to resolve outstanding biosafety and biosecurity challenges.

Eliminate Gaps in Biosafety and Biosecurity Frameworks: Advances in technology and evolving research capabilities require a fresh look at regulatory frameworks and whether they sufficiently address today's biosafety risks. The implications of synthetic biology should also be considered in the context of laboratory safety and security. Scientists have raised concerns with the increased accessibility of recombinant technology and genetic engineering technologies, which have created potential gaps in FSAP. Because the Federal Select Agent Program relies on a physical sample of a pathogen or toxin, technologies that enable an individual to increase the virulence of a pathogen or synthesize select agents may evade today's regulatory framework.[53]

The National Academies of Science, Engineering, and Medicine echoed these concerns in a 2018 consensus study report commissioned by DoD noting, "synthetic biology expands what is possible in creating new weapons…[and] expands the range of actors who could undertake such efforts and decreases the time required."[54] Further, the National Academies recommended, "the U.S. government, in conjunction with the scientific community, should consider strategies that manage emerging risks better than current agent-based lists and access control approaches," to address their concern that "strategies based on lists, such as [FSAP], will be insufficient for managing risks arising from the application of synthetic biology."[55]

While other policies are in place to support the oversight of federally funded research that poses dual-use concerns, more should be done to align these policies to close gaps in the overarching framework and improve transparency.

- **RECOMMENDATION:** Modernize the Federal Select Agent Program to address current gaps and evolve with scientific progress, while appropriately balancing support for innovation and the research enterprise and taking steps to mitigate risks.

Ensure Appropriate Risk Categorization of Research: We need to improve how we consider the full range of research involving potential pandemic pathogens, including gain-of-function

[51] https://s.wsj.net/public/resources/documents/EcoHealth%20letter%20(1).pdf, p. 1.
[52] https://www.newyorker.com/science/elements/the-mysterious-case-of-the-covid-19-lab-leak-theory
[53] https://www.phe.gov/s3/Documents/ftac-sar.pdf, p. 6.
[54] National Academies of Sciences, Engineering, and Medicine. 2018. Biodefense in the Age of Synthetic Biology. p. 3. Washington, DC: The National Academies Press. https://doi.org/10.17226/24890.
[55] Ibid, p. 7.

research of concern. Questions remain about whether the P3CO process sufficiently captures all projects that should be covered or whether the definition itself is comprehensive enough to ensure appropriate oversight of projects that potentially pose heightened risks.[56] Another challenge is that each department is responsible for establishing its own policy, which creates inconsistencies and silos, and may lead to different interpretations of the scope of the OSTP guidance. The result is confusion, both within government and among the public, about what type of research involving enhanced potential pandemic pathogens is being funded by the federal government. Because the policy only applies to federally funded research, research projects funded through separate sources lack oversight.

- **RECOMMENDATION:** Ensure the definition for research involving enhanced potential pandemic pathogens fully captures the entirety of relevant research and provide ongoing training to ensure such research is appropriately considered under the P3CO framework. Designate an entity that has strategic insight into policies related to such research across departments to consider any such applications.

Improve Oversight of High-Containment Laboratories: Within the existing policy landscape, there is a clear opportunity to improve the expansion, use, and oversight of federally funded, high-containment laboratories. GAO has repeatedly noted the lack of a federal strategy for high-containment laboratories. Enhanced coordination and planning between departments and agencies would better protect the health and safety of both the public and laboratory personnel. This would facilitate the exchange of information and best practices between federal entities, while better leveraging existing high-containment laboratory facilities and stewardship of taxpayer dollars.

- **RECOMMENDATION:** Establish a federal strategy for the management of government-owned, high-containment laboratories to ensure appropriate oversight.

End the Culture of Complacency: Seemingly small missteps or oversights in a BSL-3 or -4 laboratory can have major consequences, which is why protocols and procedures must be updated and adhered to without exception. Too many incidents have occurred in the last decade due to lack of adherence to existing protocols intended to limit accidents and protect researchers and the public health. Multiple advisory bodies have pointed to the need for improved training for researchers and other personnel. The recommended training ranges from specific biosafety topics to FSAP compliance to, more recently, questions surrounding the ability of federal program officers to appropriately recognize and refer proposed research projects that may have higher risks.

- **RECOMMENDATION:** Improve training for both program officers and researchers so they can understand, account for, and appropriately manage and mitigate biosafety and biosecurity risks.

[56] https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-071.html

Conclusion

The research conducted in our high-containment laboratories serves as a front line of defense against biological threats. This work enables the identification of novel pathogens, provides a venue for the development of tests, treatments, and vaccines to mitigate their effects, and allows us to understand the risks associated with the next generation of biological threats. The research conducted in these facilities is one of our foundational biodefense capabilities, ensuring we are better prepared for threats posed by Mother Nature and our adversaries.

In addition, research conducted in laboratories overseas, supported by federal funding, must be held to the same standard as research conducted domestically and receive careful scrutiny. As part of this process, the federal government must ensure consistent policies, across departments and agencies, for reviewing proposals for international research collaborations, making funding decisions, and ensuring that funded projects include appropriate safeguards for biosafety and biosecurity. Working to promote improved biosafety policies and practices within the international community will also help address this issue and ensure that the public health benefits of international collaborations to outweigh the risks.

The United States must remain the global leader in biomedical research and have efficient, modern practices in place to account for any risks associated with this national security endeavor. The recommendations made in this brief lay out a number of steps that can be taken to address gaps in the United States' biosafety and biosecurity frameworks. Ensuring appropriate biosafety and biosecurity in federal and other U.S. laboratories is critical to our nation's health security and preparedness infrastructure.