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INSIGHT

Recent Executive Actions Related to Gain-of-Function Research and Laboratory Biosafety

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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. A partial exception is the Federal Select Agent Program (FSAP), which covers only the possession, use, and transfer of types of biological agents and toxins. Privately funded research is generally not covered by federal policy or agency guidance beyond what is pursuant to FSAP. Congress, scientists, and the public have debated how to balance the potential benefits of high-risk biological research, such as advancements in scientific discovery and public health, with related safety and security concerns.

In May 2024, the White House Office of Science and Technology Policy (OSTP) released the *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 Policy), which was intended to address "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 established an oversight and review process for two categories that previously had been overseen by separate policies: dual-use research of concern (DURC) and research on pathogens with enhanced pandemic potential (also known as gain-of-function research). The 2024 Policy was scheduled to take effect on May 6, 2025, and institutions that receive federal funding had prepared to implement those requirements.

On May 5, 2025, the White House issued Executive Order (E.O.) 14292, "Improving the Safety and Security of Biological Research," which directed OSTP to revise or replace the 2024 Policy within 120 days. The E.O. also directed OSTP to revise or replace the 2024 *Framework for Nucleic Acid Synthesis Screening*, which established requirements for recipients of federal funding for research related to sources of synthetic nucleic acids.

E.O. 14292 calls for OSTP to establish guidance for relevant agencies to immediately end federal funding of "dangerous gain-of-function research" or other life science research "conducted by foreign entities in countries of concern ... or in other countries where there is not adequate oversight to ensure that the countries are compliant with United States oversight standards and policies." The E.O. also instructed that this guidance apply to foreign biological research "that could reasonably pose a threat to public health,

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public safety, and economic or national security." The E.O. also directs OSTP to establish guidance for federal agencies on how to suspend federally funded "dangerous gain-of-function research" in the U.S. until at least the updates to the 2024 Policy are completed. Notably, the E.O. charges OSTP with the development and implementation of a strategy to govern nonfederally funded research, which previous policies had not covered.

E.O. 14292 defines "dangerous gain-of-function research" as "research on an infectious agent or toxin with the potential to cause disease by enhancing its pathogenicity or increasing its transmissibility." The E.O. also prescribes a list of covered research activities, defined as "those that could result in significant societal consequences," which have similarities to the experimental outcomes classified as DURC under previous policies, including the 2024 Policy.

Until OSTP issues its final policy, it is unclear how, or whether, the distinctions between DURC and gain-of-function research set forth in previous policies will remain or whether a new system of classification, review, and types of allowable research will be developed.

To implement E.O. 14292, on May 7, 2025, the National Institutes of Health (NIH) issued Notice Number NOT-OD-25-112, "Implementation Update: Improving the Safety and Security of Biological Research," which described immediate actions that NIH would be taking in response to E.O. 14292:

> NIH will not accept competitive applications for grants and cooperative agreements submitted for due dates after [May 7, 2025,] and/or [research and development] contract proposals submitted to solicitations issued after [May 7, 2025,] for dangerous gain-of-function research, as defined in Section 8 of the Executive Order.
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> NIH intends to suspend ongoing funding in accordance with guidance developed under Section 3(b) of the Executive Order. All NIH awardees should review ongoing research activities to proactively identify potential dangerous gain-of-function research and identify safe actions to halt such research and to effectively comply with guidance once established.

NIH's notice declared that it is rescinding a previous notice, NOT-OD-25-061, which had described the implementation of the 2024 Policy. As of May 9, 2025, no other federal agency has issued a notice or guidance to institutions receiving federal dollars about how those agencies will be implementing E.O. 14292. Congress may choose to examine how institutions should interpret the directives of the E.O. when applied to current research projects, given that research institutions had developed implementation plans and procedures to meet the requirements of the 2024 Policy scheduled to take effect on May 6, 2025.

Recent bills restricting gain-of-function research include H.R. 1827 in the 118th Congress and S. 738 in the 119th Congress, as well as other legislation related to oversight of high-risk life sciences research. For example, S. 854, the Risky Research Review Act, in the 119th Congress would establish a life sciences research security board within the executive branch to review proposed federal funding for high-risk life sciences research. Congressional consideration of such bills could include how they would interact with the final policy that OSTP issues in response to E.O. 14292.

Stakeholders have taken different views on the potential impacts that E.O. 14292 will have on life sciences research and whether it will improve biosafety and biosecurity risk management, which could also be a subject of congressional oversight.

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