

# CRS Insights

A Federal Pause in Potentially Risky Influenza Research

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November 24, 2014 (IN10184)

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## Overview

Over several decades, Congress has enacted legislation to fund research into the origins and mechanisms of the causes and transmission of disease with the intent to spur the development of treatments and to improve public health. It has also enacted legislation in order to improve the security of biological pathogens. A recently implemented federal research moratorium has highlighted concerns about the general appropriateness of this research and the sufficiency of these biosecurity efforts. Policymakers focused on the intersection of public health and scientific research may question whether a moratorium appropriately balances federal interests in developing disease countermeasures with concerns over the potential of altered pathogens escaping research laboratories.

On October 17, 2014, the White House Office of Science and Technology Policy (OSTP) and the Department of Health and Human Services (HHS) announced a [government moratorium](#) on certain research projects involving influenza, Middle East respiratory syndrome (MERS), or severe acute respiratory syndrome (SARS) viruses. The moratorium applies to projects in which the intent of the research is to impart to the virus enhanced pathogenicity or transmissibility in mammals. Such research is known as "gain-of-function" research. As written, the moratorium will last until the executive branch adopts a new gain-of-function research policy. The HHS has established the deliberative process that will develop this policy. The process will have several parts: the development of draft recommendations by the [National Science Advisory Board for Biosecurity \(NSABB\)](#) and a subsequent review and discussion of these recommendations at [a conference](#) convened by the National Academies. The NSABB, informed by this feedback, will then provide its final recommendations to those federal entities that conduct, support, or have an interest in life sciences research. These recommendations will inform the development of the new federal policy. The goal is to complete this process in less than one year.

## Scope

The gain-of-function moratorium affects a small portion of federal research. The primary source of funding for such research is the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#), one of the [National Institutes of Health](#). Federal funding agencies will release no new grant funds for this research, and federal agencies have directed their contractors to cease such work. The moratorium allows the head of the federal funding agency to exempt on a case-by-case basis research deemed urgent for public health or national security. In addition, OSTP and HHS encourage scientists to voluntarily cease nonfederally funded research involving gain-of-function of these viruses until the risks and benefits are more fully addressed.

The current mandatory moratorium follows a [voluntary moratorium](#) undertaken by scientists performing gain-of-function research on H5N1 ("avian") influenza virus in 2012-2013. The voluntary moratorium began after scientific and public debate over gain-of-function research performed in 2011. The scientists involved in that research asserted that all necessary biosecurity and biosafety measures were followed, making this research safe to perform.

Federal officials have discovered recent [biosafety breaches](#) at federal laboratories, including those of the Centers for Disease Control and Prevention (CDC), which regulates certain laboratories for [biosecurity](#). Officials found undeclared pathogens located in insecure laboratories, unprotected workers potentially exposed to pathogens, and breakdowns in approved laboratory policies and procedures. The CDC director [stated](#) that such failures at CDC laboratories might indicate carelessness on the part of scientists who handle such pathogens on a regular basis.

The debate over gain-of-function research has multiple facets. Some scientists argue that such research may improve understanding of and preparation against new virus strains arising in nature. Other scientists express concern that a ban on gain-of-function research may be too broad or poorly defined and might span a wide array of research from aerosol transmission of avian influenza to modification of seasonal influenza for vaccine research. Some critics of gain-of-function research question whether such work should be done at all, given the unknown risks and benefits, and question whether existing biosafety and biosecurity requirements sufficiently reduce the risk of accidental infection or release. Others raise objections to the broad dissemination of gain-of-function research results, arguing that such results might be used for malevolent purposes.

## Impact

The extent and impact of the 2014 federal moratorium is unclear. Such research is predominantly funded by HHS. The NIAID sent [letters regarding the moratorium](#) to at least 14 institutions operating under 18 grants or contracts. That said, NIAID alone issued [1,008 grants](#) in FY2013. Therefore, the impact of the moratorium is likely concentrated in a narrow field. Potential deleterious outcomes of the moratorium might include delay in obtaining research results, movement of researchers out of this type of research due to a lack of available funding, and movement of gain-of-function research to nations with fewer or no such restrictions.

Arguably, the broader impact may lie in the potential applicability of such a federal moratorium to other research areas. Federal funding moratoria are relatively uncommon. The federal government has not used moratoria to address concerns raised since 2001 over the prospects of various types of biological research being used by malicious actors to cause harm. Instead, it has approached this issue by releasing guidance and guidelines for review of such research. For example, HHS has released [screening guidance](#) for synthetic DNA and a [guide](#) for identifying, assessing, managing, and communicating dual use research of concern (DURC). This approach has generally placed the requirement for review at the institutional level, where proposed research would be individually assessed. The use of a federal funding moratorium may indicate an increased willingness to restrict such research at the federal level rather than relying on a case-by-case analysis of projects at the institutional level.