

U.S. Sen. Johnson, U.S. Rep. Gallagher: Request information on National Institutes of Health's funding of gain of function research

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WASHINGTON — U.S. Sen. Ron Johnson (R-Wis.) on Thursday joined by Sens. Paul (R-Ky.), Lankford (R-Okla.), Scott (R-Fla.), Cotton (R-Ark.), Marshall (R-Kan.), and Rep. Mike Gallagher (R-Wis.) sent a letter to Dr. Francis Collins, Director of the National Institutes of Health (NIH) requesting information on gain of function research and NIH's 2014 moratorium on funding for that research.

The members sent 17 information requests asking NIH to explain what prompted the establishment of a moratorium on gain of function research in 2014. They also requested NIH to explain why the moratorium stated that, "[a]n exception from the research pause may be obtained if the head of the USG funding agency determines that the research is urgently necessary to protect the public health or national security."

The members asked the following questions:

- Who requested that the moratorium include this exception?
- Who was involved in drafting the moratorium document?
- Who gave final approval of the moratorium document?
- How many studies received an exception during the moratorium period (2014-2017)?

- Who approved these exceptions?

A full copy of the letter can be found [here](#) and below.

May 20, 2021

The Honorable Francis Collins, M.D., Ph.D.

Director

National Institutes of Health
9000 Rockville Pike
Rockville, MD 20892

Dear Director Collins,

Since the beginning of the pandemic, the exact origin of SARS-CoV-2 has remained elusive. Recently, in response to the World Health Organization's study of SARS-CoV-2's origins, a group of eighteen scientists published a letter in Science Magazine stating that a leak of the virus from a lab is a "viable" theory and should be thoroughly investigated.[1] Yet, obtaining information about the research on bat coronaviruses conducted at China's Wuhan Institute of Virology has been very difficult. Such information, including if and when gain of function experiments occurred at the lab, is crucial in determining the viability of the laboratory introduction theory. In light of the many unanswered questions regarding the origins of the SARS-CoV-2, we write to seek information regarding the National Institutes of Health's (NIH) 2014 funding pause on gain of function research (also referred to as the moratorium), exceptions NIH may have granted from that pause to allow gain of function research to continue, and the lifting of that pause in 2017.

In October 2014, following several high profile biosafety incidents at labs, as well as public scrutiny of gain of function research studies, the Department of Health and Human Services and NIH instituted a pause on funding research of gain of function experiments "involving influenza, SARS, and MERS viruses." [2] The U.S. government (USG) noted, though, that "[a]n exception from the research pause

may be obtained if the head of the USG funding agency determines that the research is urgently necessary to protect the public health or national security.”[3] This pause did not apply to currently-funded research at the time, but the moratorium did urge “the USG and non-USG funded research community to join in adopting a voluntary pause.”[4]

One of the notable NIH-funded studies that was already underway prior to the funding moratorium was Dr. Ralph Baric’s work on a “lab-made coronavirus related to SARS.”[5] In this 2015 study, researchers reportedly created a chimeric virus “related to SARS [that] can infect human cells.”[6] Dr. Zhengli-Li Shi, “China’s leading expert on bat viruses” from the Wuhan Institute of Virology, contributed to this research.[7] An article noted that NIH allowed this study “to proceed while it was under review by the agency.”[8] Baric reportedly added that “NIH eventually concluded that the work was not so risky as to fall under the [gain of function] moratorium.”[9] It is unclear why NIH apparently concluded that this study was not “risky” enough to fall under the moratorium.

In addition to Baric’s apparent gain of function research in 2015, NIH and the National Institute of Allergy and Infectious Diseases (NIAID) also reportedly funded similar coronavirus research conducted by EcoHealth Alliance, which subcontracted with Shi.[10] Because of Shi’s research and her connection to the Wuhan lab, Dr. Richard Ebright, a molecular biologist and infectious disease expert, stated, “[i]t is clear that the Wuhan Institute of Virology was systematically constructing novel chimeric coronaviruses and was assessing their ability to infect human cells and human-ACE2-expressing mice.”[11] In fact, Dr. Peter Daszak, the president of EcoHealth Alliance, spoke about changing coronaviruses in a lab. In an interview Daszak stated, “Well I think . . . coronaviruses—you can manipulate them in the lab pretty easily.”[12]

In December 2017, NIH lifted the funding pause and established a multi-disciplinary review process, known as the P3CO Framework, to ensure that federally funded gain of function experiments are “conducted responsibly.”[13] It is unclear whether EcoHealth Alliance or any of its subcontractors was granted an exception to the moratorium or whether NIH reviewed those studies in connection with the P3CO Framework.[14]

Given the unanswered questions surrounding SARS-CoV-2's origin, as well as both the 2014 moratorium on gain of function research and the 2017 P3CO Framework, we request that NIH provide the following information as well as all records responsive to Representative Cathy McMorris Rodgers' March 18, 2021 letter to NIH by June 3, 2021:

1. The 2014 moratorium defines gain of function research as "research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have *enhanced pathogenicity and/or transmissibility in mammals via the respiratory route*." [15] Is Dr. Baric's research that reportedly created a chimeric virus related to SARS that could infect human airway cells [16], or research that is "systematically constructing novel chimeric coronaviruses and [is] assessing their ability to infect human cells" [17] considered gain of function research under the 2014 moratorium definition? If not, please explain why not.
2. Please explain what prompted the establishment of a moratorium on gain of function research in 2014.
3. Who was involved in drafting the moratorium document?
4. Who gave final approval of the moratorium document?
5. Please explain why the moratorium stated that, "[a]n exception from the research pause may be obtained if the head of the USG funding agency determines that the research is urgently necessary to protect the public health or national security." [18]
6. Who requested that the moratorium include this exception?
7. How many studies received an exception during the moratorium period (2014-2017)?
8. Please list all requests for exceptions and indicate what exceptions NIH granted.
9. Who approved these exceptions?
10. Please explain whether research connected to EcoHealth Alliance or Dr. Shi required an exception? If so, was an exception: a) requested; b) granted or denied? If so, who was involved in those evaluations and decisions?
11. Was any EcoHealth Alliance grant ever forwarded for review pursuant to the P3CO Framework? If not, why not?

12. Please explain whether NIH reviewed Dr. Baric's 2015 study[19], as reported in the November 12, 2015 *Nature* article.[20] If NIH reviewed this study, please explain how NIH evaluated the study's risk level and how NIH reportedly determined the study was not "so risky as to fall under the moratorium."[21]
13. Did NIH request that Dr. Baric voluntarily comply with the 2014 moratorium? Please explain.
14. Were any of Dr. Baric's grant proposals ever forwarded for review pursuant to the P3CO Framework? If not, why not?
15. After the moratorium went into effect, how many studies, which were already funded at the time, adopted a "voluntary pause on research"?[22] Please provide a list of those studies.
16. Provide the total number of grant proposals or projects that have been forwarded for review pursuant to the P3CO Framework since its establishment? How many of those grants have been approved?
17. Provide an explanation of what processes or procedures NIH used to ensure that a grant recipient was complying with the moratorium, including voluntary compliance.

Thank you for prompt attention to this matter.