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ONE HUNDRED SEVENTEENTH CONGRESS

**Congress of the United States**  
**House of Representatives**  
**COMMITTEE ON ENERGY AND COMMERCE**

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October 27, 2021

The Honorable Francis Collins, M.D., Ph.D.  
Director National Institutes of Health  
9000 Rockville Pike  
Bethesda, MD 20892

Dr. Collins,

We write again asking the National Institutes of Health (NIH) to be transparent about its relationship with EcoHealth Alliance (EcoHealth) and to provide information and documents related to National Institute of Allergy and Infectious Diseases (NIAID) grant project number R01AI110964, “Understanding the Risk of Bat Coronavirus Emergence.”<sup>1</sup> In 2014, NIH awarded this grant to EcoHealth, the non-profit organization that in turn funneled those funds to the Wuhan Institute of Virology (WIV)<sup>2</sup> and to additional research organizations to support risky research in China.

Since March 2021, we have led a comprehensive examination of how the COVID-19 pandemic started. Understanding the root cause of this pandemic will help us prevent future pandemics. We are examining in connection with this effort whether NIH oversight of risky research conducted by an NIH sub-grantee in China was adequate to prevent or render it implausible that a lab accident could have been involved in the origins of the pandemic. Based on a review of documents and other information recently made available, we have significant

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<sup>1</sup>This is our fourth letter to NIH seeking information related to oversight of NIAID’s grant R01AI110964. Our prior letters dated March 18, 2021, July 21, 2021 and August 24, 2021 are available at <https://republicans-energycommerce.house.gov/the-covid-19-origins-investigation/>. At this time, NIH has yet to respond in writing to any of the questions in these letters, and only produced EcoHealth grant documents to us after HHS had released them to *The Intercept* in response to a Freedom of Information Act lawsuit.

<sup>2</sup> This funding was in addition to USAID funding to EcoHealth that was also funneled to the WIV during this timeframe. USA Spending.gov, *EcoHealth Alliance*, Advanced Recipient Search (Aug. 2, 2021), available at <https://www.usaspending.gov/search/?hash=b2b11ac84d498190e8e69a33c04cdd99>. An April 6, 2016 correction to the Nov. 20, 2015 research article acknowledged the USAID-EPT-PREDICT funding source from EcoHealth Alliance to Zhengli Shi. Menachery, V. et al., *Correction: Corrigendum: A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence*, Nature Medicine (Apr. 6, 2016), available at <https://www.nature.com/articles/nm0416-446d>.

concerns about the adequacy of NIH oversight of EcoHealth and the related research activities at the WIV and other organizations in China.

In 2016, EcoHealth proposed a research project with the WIV using humanized mice to test several chimeric viruses to see if these experiments would show whether these viruses could infect human cells. EcoHealth portrayed the risks of these experiments as if they were not of concern, and the NIH accepted EcoHealth's assertions without a searching inquiry. However, the assessment of the risks by both EcoHealth and the NIH do not seem to square with the understanding of the research risks at that time. Although the engineered viruses at the WIV were far from SARS CoV-2 on the coronavirus family tree, this research reflected a high tolerance for risk.<sup>3</sup> As noted by Stanford University microbiologist David Relman, "[The WIV] were essentially playing Russian roulette with the virus that the world's expert had labelled poised for human emergence. It's the willingness to manipulate them without due concern."<sup>4</sup>

Further, the one condition imposed by the NIH was the requirement that EcoHealth stop the humanized mice experiment and notify the NIH if the result was a virus with enhanced growth by more than ten times (or one log) compared to the parental backbone or strains found in nature. The purpose of this policy was to safeguard against experiments creating viruses that could replicate quickly and had the potential to overwhelm the immune systems of humans. We believe the EcoHealth grant documents indicated such a reportable result from the experiment, but there is no evidence of EcoHealth taking the required actions, or the NIH raising any questions after getting the results of the experiment from EcoHealth. If EcoHealth and NIH could not handle compliance and oversight of such a basic policy, it raises more concerns about the overall adequacy of the oversight of this research, which leaves the public vulnerable to a serious lab accident.

In addition to how NIH examined the research proposal, the funding of EcoHealth by NIH after the suspension of their grant raises serious concerns about NIH's management and oversight of grants. Following an initial grant termination in April 2020, NIH reinstated the grant and then suspended the grant in July 2020 because of EcoHealth's inadequate oversight of the WIV.<sup>5</sup> When NIH asked EcoHealth to provide information related to its subaward to the WIV, EcoHealth refused to comply with most of the requests.<sup>6</sup> Despite EcoHealth's unwillingness to cooperate, NIH paid an additional \$369,819 to EcoHealth on July 13, 2020, a mere five days after its grant was suspended. NIH's payment seems inconsistent with NIH's grant policy and possibly violates other federal laws and regulations.<sup>7</sup>

NIH also failed to report EcoHealth's noncompliance and grant suspension into the www.SAM.gov database that alerts other U.S. Government agencies to risky grant recipients. Remarkably, the NIH, U.S. Agency for International Development (USAID), and Department of Defense (DoD) have paid EcoHealth more than \$23.4 million in new and renewed assistance

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<sup>3</sup> Carolyn Korman, *The Mysterious Case of the COVID-19 Lab Leak Theory*, *The New Yorker* (October 12, 2021), available at <https://www.newyorker.com/science/elements/the-mysterious-case-of-the-covid-19-lab-leak-theory>.

<sup>4</sup> *Id.*

<sup>5</sup> Mark Moore, *NIH investigating Wuhan lab at center of coronavirus pandemic*, *NEW YORK POST* (Apr. 28, 2020), available at <https://nypost.com/2020/04/28/nih-investigating-wuhan-lab-at-center-of-coronavirus-pandemic/>.

<sup>6</sup> *Id.* EcoHealth did report select subgrant funding data on July 13, 2020 into a public database. NIH had raised concerns that EcoHealth had not accounted for its funding of subgrantees.

<sup>7</sup> USA Spending.gov, *EcoHealth Alliance*, Advanced Recipient Search (Oct. 13, 2021), available at [https://www.usaspending.gov/award/ASST\\_NON\\_R01AII10964\\_7529](https://www.usaspending.gov/award/ASST_NON_R01AII10964_7529).

awards since April 2020, when NIH should have reported the administrative action it took against EcoHealth's grant. To date, NIH has refused to address any of these concerns.

We outline our concerns in more detail about NIH's oversight of the EcoHealth grant in the discussion that follows.

#### Grant Documents and Other Information Made Recently Available

On September 7, 2021, after the Department of Health and Human Services (HHS) produced documents related to the EcoHealth grant because of a Freedom of Information Act (FOIA) lawsuit, HHS shared essentially the same documents with us.<sup>8</sup> On September 29, 2021, Principal Deputy Director Lawrence Tabak briefed bipartisan Committee staff about the EcoHealth grant documents. Unfortunately, HHS and NIH did not accommodate the staff request to include subject matter experts and witnesses with first-hand knowledge from NIAID in this briefing. HHS arranged an in-person bipartisan Committee staff *in camera* review of the printed copies of the four highly relevant letters between NIH and EcoHealth about EcoHealth's humanized mice research proposal. These documents raise significant concerns about NIH's management and oversight of the EcoHealth grant.<sup>9</sup>

#### HHS Oversight Policy of Gain-of-Function Research Was Weakened in Recent Years

On August 30, 2021, the *Washington Post* published an article, *A Science in the Shadows*, detailing how the HHS oversight process over risky research, often referred to as Gain-of-Function (GOF) research, was weakened in recent years from the policy established in 2012.<sup>10</sup> For example, in December 2017, the review process known as the *HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens Care and Oversight* (P3CO) was revised to remove any authority by the HHS P3CO review group to block GOF research proposals.<sup>11</sup> Instead, HHS redefined GOF research, which has given NIH leaders the sole discretion to approve GOF projects without referring them to the HHS P3CO review group.<sup>12</sup>

In a significant policy change, the 2017 policy also narrowed the criteria for review of GOF research to cover only altered pathogens "likely capable of wide and uncontrollable spread in human populations."<sup>13</sup> The review policy that started in October 2014, required experiments to

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<sup>8</sup> Sharon Lerner and Mara Hvistendahl, *New Details Emerge About Coronavirus Research at Chinese Lab*, *The Intercept* (Sept. 6, 2021), available at <https://theintercept.com/2021/09/06/new-details-emerge-about-coronavirus-research-at-chinese-lab/>. The NIH document production appears identical to their production to *The Intercept*, except the documents NIH provided to us do not include FOIA exemption numbers in the redactions and instead include Bates numbered pages.

<sup>9</sup> A bipartisan *in camera* private in-person inspection of the physical copies of four letters dated May 18, 2016, June 8, 2016, July 7, 2016, and July 5, 2018 controlled by NIH was conducted at HHS headquarters on Oct. 5, 2021, monitored by HHS staff.

<sup>10</sup> David Willman and Madison Muller, *A Science in the Shadows*, *The Washington Post* (Aug. 26, 2021), available at <https://www.washingtonpost.com/nation/interactive/2021/a-science-in-the-shadows/>.

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> U.S. Department of Health and Human Services, *Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens, Dual Use Research of Concern* (Dec. 19, 2017), available at <https://www.phe.gov/s3/dualuse/Documents/P3CO.pdf>.

be reviewed if they expected to generate flu and coronaviruses that would be “transmissible among **mammals**” and might accidentally cause human infections.<sup>14</sup> (Emphasis added).

A GOF Experiment Warning by Dr. Ralph Baric and Others

In 2015, Dr. Ralph Baric of the University of North Carolina – Chapel Hill, Dr. Zheng-Li Shi of the WIV, and others published a study in *Nature*, titled *A SARS-Like Cluster Of Circulating Bat Coronaviruses Shows Potential For Human Emergence*.<sup>15</sup> Dr. Baric and Dr. Shi have each collaborated previously with EcoHealth. Importantly, EcoHealth, through its funding from USAID, helped support Dr. Shi of the WIV in this particular study.<sup>16</sup> Near the end of this publication, the authors issued a warning about a potential threat of certain viruses identified with the SHC014 reference number:

We consider viruses with the SHC014 spike a potential threat owing to their ability to replicate in primary human airway cultures, the best available model for human disease. In addition, the observed pathogenesis in mice indicates a capacity for SHC014-containing viruses to cause disease in mammalian models, without RBD adaptation.<sup>17</sup>

In the next paragraph, the authors explain the context of GOF research and how their expectation that the viruses they created would not increase pathogenicity turned out to be wrong after they conducted the experiments:

In addition to offering preparation against future emerging viruses, this approach must be considered in the context of the U.S. government–mandated pause on gain-of-function (GOF) studies. On the basis of previous models of emergence, the creation of chimeric viruses such as SHC014-MA15 was not expected to increase pathogenicity. Although SHC014-MA15 is attenuated relative to its parental mouse-adapted SARS-CoV, similar studies examining the pathogenicity of CoVs with the wild-type Urbani spike within the MA15 backbone showed no weight loss in mice and reduced viral replication. Thus, relative to the Urbani spike–MA15 CoV, SHC014-MA15 shows a gain in pathogenesis.<sup>18</sup>

The authors then explain that scientific review panels may determine that similar studies would be too risky, so any further research may be limited going forward:

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<sup>14</sup> The White House, *Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research*, Blog (Oct. 17, 2014), available at <https://obamawhitehouse.archives.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research>.

<sup>15</sup> Menachery, V. et al, *A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence*, *Nature Medicine* (Nov.20, 2015), available at <https://www.nature.com/articles/nm.3985>.

<sup>16</sup> An April 6, 2016 correction to the Nov. 20, 2015 research article acknowledged the USAID-EPT-PREDICT funding source from EcoHealth Alliance to Zhengli Shi. Menachery, V. et al, *Correction: Corrigendum: A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence*, *Nature Medicine* (Apr. 6, 2016), available at <https://www.nature.com/articles/nm0416-446d>.

<sup>17</sup> Menachery, V. et al, *A SARS-like cluster of circulating bat coronaviruses shows potential for human emergence*, *Nature Medicine* (Nov.20, 2015), available at <https://www.nature.com/articles/nm.3985.pdf>.

<sup>18</sup> *Id.*

On the basis of these findings, scientific review panels may deem similar studies building chimeric viruses based on circulating strains too risky to pursue, as increased pathogenicity in mammalian models cannot be excluded. Coupled with restrictions on mouse-adapted strains and the development of monoclonal antibodies using escape mutants, research into CoV emergence and therapeutic efficacy may be severely limited moving forward.<sup>19</sup>

Finally, the authors advise that the purpose of their study – to prepare potentially for and mitigate future outbreaks – must be carefully weighed against dangers posed by the experiments creating more dangerous pathogens. Notably, the authors considered whether similar studies should be pursued:

Together, these data and restrictions represent a crossroads of GOF research concerns; the potential to prepare for and mitigate future outbreaks must be weighed against the risk of creating more dangerous pathogens. In developing policies moving forward, it is important to consider the value of the data generated by these studies and whether these types of chimeric virus studies warrant further investigation versus the inherent risks involved.<sup>20</sup>

#### Letters Reveal NIH and EcoHealth Discussed GOF Research Concerns

HHS allowed bipartisan Committee staff to see three letters from NIH to EcoHealth (May 18, 2016, July 7, 2016, and July 5, 2018) and one letter from EcoHealth to NIH (June 8, 2016) in an *in camera* review.<sup>21</sup> To our knowledge, NIH has not publicly disclosed these letters, although some of the contents in these letters appear to have been used in NIH correspondence to U.S. Senators.<sup>22</sup>

During the 2014 GOF moratorium in the United States, EcoHealth submitted its Year Two progress report dated May 13, 2016, to NIAID for grant R01AI110964. EcoHealth disclosed it would conduct experiments in humanized mice using two chimeric bat coronaviruses.<sup>23</sup> In response to the experiment descriptions in EcoHealth's research progress report, NIH wrote to EcoHealth on May 28, 2016,<sup>24</sup> to advise that NIAID determined the R01AI110964 grant research project may include GOF experiments subject to the 2014 GOF research pause.<sup>25</sup>

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<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> A bipartisan *in camera* private in-person inspection of the physical copies of four letters dated May 18, 2016, June 8, 2016, July 7, 2016, and July 5, 2018, was conducted at HHS headquarters on Oct. 5, 2021, monitored by HHS staff. Information presented as letter excerpts are produced from detailed staff notes because NIH refused to release copies of the letters to the Committee.

<sup>22</sup> See July 28, 2021, letter from NIH Director Francis Collins to U.S. Senator Charles Grassley, *available at* [https://www.grassley.senate.gov/imo/media/doc/national\\_institutes\\_of\\_health\\_to\\_grassley\\_-\\_covid\\_origins\\_grant\\_oversight.pdf](https://www.grassley.senate.gov/imo/media/doc/national_institutes_of_health_to_grassley_-_covid_origins_grant_oversight.pdf).

<sup>23</sup> Sharon Lerner and Mara Hvistendahl, *New Details Emerge About Coronavirus Research at Chinese Lab*, *The Intercept* (Sept. 6, 2021), *available at* <https://theintercept.com/document/2021/09/08/understanding-the-risk-of-bat-coronavirus-emergence/>.

<sup>24</sup> May 18, 2016, NIH letter to EcoHealth (per notes taken by Minority Committee staff Oct. 5, 2021 during bipartisan *in camera* review).

<sup>25</sup> On Oct. 17, 2014, the White House Office of Science and Technology Policy and the U.S. Department of Health and Human Services instituted a pause on funding research of Gain-of-Function (GOF) experiments involving influenza, SARS, and MERS viruses following multiple biosafety accidents at U.S. laboratories. The White House, *Doing Diligence to Assess the Risks and Benefits of Life Sciences Gain-of-Function Research*, Blog (Oct. 17, 2014), *available at* <https://obamawhitehouse.archives.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research>, and *available at* <http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf>.

Under the signature of Dr. Peter Daszak, its president, chief scientist, and grant principal investigator, EcoHealth replied to NIH on June 8, 2016, asserting their research was not GOF.<sup>26</sup>

These 2 chimeric bat-like CoVs were constructed on Sept. 24, 2015. They use the backbone of a group 2b SARS-like bat CoV WIV1 and the spike proteins of two newly discovered bat SL-CoVs (Rs7327 and RsSHC014). The construction of these chimeric viruses aims to understand the receptor usage and infectivity of bat SL-CoVs that may be progenitors of SARS-CoV. We have not yet tested the pathogenicity of these viruses in animals.<sup>27</sup>

There was no discussion of how the RsSHC014 differed from the SHC014 spike protein of concern in the 2015 Baric *et al* warning. If there was no difference between these viruses, then there was no assessment of a known risk. In addition to the potential threat of the RsSHC014 spike, the WIV1 backbone was already known to be potentially dangerous to humans.<sup>28</sup> Nevertheless, EcoHealth stated that its research would not be considered GOF because the virus it was using had never previously infected humans:

We believe that this work would not be considered GOF because the pause specifically targeted experiments that related to the pathogenicity or transmissibility of SARS-CoV, MERS CoV and any influenza virus. Our molecular clone is WIV1, which is a group 2b SARS-like bat coronavirus that has never been demonstrated to infect humans or cause human disease.<sup>29</sup>

EcoHealth also argued that because the virus was ten percent different from the original SARS-CoV, their research did not qualify being subject to the GOF moratorium. EcoHealth continued its justification by explaining that because EcoHealth and/or the WIV would progressively introduce spike proteins that were progressively more distant from the original SARS-CoV, that the research was not subject to the GOF pause. EcoHealth also explained that its theory was supported by the 2015 publication of Dr. Ralph Baric's study:

Moreover, we are introducing progressively more distant S glycoproteins into WIV1 (The RBD of Rs7327 differs from WIV1 in several amino acid residues while RsSHC014 is even more distantly related phylogenetically), so it seems progressively less likely that any of these viruses would be more pathogenic or transmissible than the SARS-CoV. This is further supported by the fact that

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<sup>26</sup> June 8, 2016, EcoHealth letter to NIH (per notes taken by Minority Committee staff Oct. 5, 2021 during bipartisan *in camera* review).

<sup>27</sup> *Id.*

<sup>28</sup> Carolyn Korman, The Mysterious Case of the COVID-19 Lab Leak Theory, *The New Yorker* (October 12, 2021), available at <https://www.newyorker.com/science/elements/the-mysterious-case-of-the-covid-19-lab-leak-theory>. (“Shi’s lab developed its own platform for creating chimeric viruses. She crossed another bat coronavirus from Yunnan—named wiv1—with clones of different novel spike proteins and tested the creation in humanized mice. The viruses quickly replicated. One made the mice emaciated, a sign of severe pathogenesis. **What made this work especially risky was that wiv1 was already known to be potentially dangerous to humans.** Baric himself had made this clear in a 2016 study titled ‘SARS-Like WIV1-CoV Poised for Human Emergence.’”) (Emphasis added).

<sup>29</sup> June 8, 2016, EcoHealth letter to NIH (per notes taken by Minority Committee staff Oct. 5, 2021, during bipartisan *in camera* review).

Professor Ralph Baric's group (Menachery et al 2015, Nature Medicine 21, 1508-1513...PNAS, 113 (11): 3048-3053) took WIV1 spike and inserted it onto a SARS-CoV backbone and showed reduced pathogenicity in mice with human ACE-2 relative to SARS-CoV (mortality rates were much lower, therefore this is loss of function). This strongly suggests that the chimeric bat spike/bat backbone viruses should not have enhanced pathogenicity in animals.<sup>30</sup>

#### NIH Agreed with EcoHealth's Self-Assessment and Added Grant Conditions

In a July 7, 2016, response letter to EcoHealth, NIH replied that NIAID agreed with EcoHealth's determination that its work was not subject to the GOF pause based on its review of the original grant application, and cited two of the justifications provided by EcoHealth as the basis for its agreement:

NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is not subject to the GOF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore, it is not reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.<sup>31</sup>

As a result, the NIAID added the following award condition, per the grant documents:

NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show **evidence of enhanced virus growth greater than 1 log over the parental backbone strain**, Dr. Daszak will immediately stop all experiments w/ these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional biosafety Committee, with the relevant data and information related to these unanticipated outcomes. (Emphasis added).<sup>32</sup>

In a revised grant award notice for Year Three, NIAID added the following in the special terms and conditions section:

Per the letter dated July 7, 2016 to Mr. Aleksei Chmura at EcoHealth Alliance, should any of the MERS-like or SARS-like chimeras generated under this grant show **evidence of enhanced virus growth greater than 1 log over the parental backbone strain** you must stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute

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<sup>30</sup> *Id.*

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

of Virology Institutional Biosafety Committee with the relevant data and information related to these unanticipated outcomes.<sup>33</sup> (Emphasis added). Neither EcoHealth nor NIAID discussed alternative approaches that could have been less risky but may have been able to achieve the same research goals.

#### EcoHealth's Progress Report for Year Four Raises Question of Cover-up

EcoHealth submitted a Year Four progress report in September 2020, two years after when the report should have been submitted to receive Year Five funding.<sup>34</sup> The original EcoHealth's Year Four progress report that was presumably revised should have been submitted to NIH in spring 2018. However, this report was not included in the production to *The Intercept* or to us.

Sometime during Year Four of the grant (June 1, 2017-May 31, 2018), the humanized mice experiments with the chimeric viruses were carried out.<sup>35</sup> The Year Four progress report discussing these experiments are controversial because of the rarity of a progress report being submitted two years late. Given the strict NIH rules regarding the release of grant funds, it is believed that the Year Four progress report may have replaced an earlier version of the Year Four progress report.<sup>36</sup> It is highly unusual for a grantee to replace a progress report.

Contrary to Dr. Tabak's stated belief to bipartisan Committee staff during the June 28, 2021, briefing that all of EcoHealth's grant-supported research was published, and thus it was unlikely that EcoHealth would have much unpublished data, Minority Committee staff was unable to find any published studies for EcoHealth's humanized mice experiment discussed in the grant. The humanized mice experiment results EcoHealth reported to NIH, as described in the grant documents, showed that the SHC014S virus seriously infected the mice and caused them to lose 20 percent of their body weight in six days.<sup>37</sup> EcoHealth and the WIV infected humanized mice with the WIV1 parental virus and three chimeric viruses containing SHC014S, WIV16S and Rs4231S.<sup>38</sup> At two and four days post-infection, "viral loads in lung tissues of mice challenged with all three chimeras reached  $>10^6$  genome copies per/g, significantly higher than related WIV1 infection (Fig. 6b). This demonstrates that pathogenicity of SARS-related coronaviruses in humanized mice differs with divergent S proteins, **confirming** the value of this model in assessing novel SARS related coronavirus pathogenicity."<sup>39</sup> (Emphasis added).

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<sup>33</sup> EcoHealth grant documents at 189, available at <https://theintercept.com/document/2021/09/08/understanding-the-risk-of-bat-coronavirus-emergence/>.

<sup>34</sup> Mara Hvistendahl and Sharon Lerner, *NIH Bat Coronavirus Grant Report Was Submitted More Than Two Years Late*, *The Intercept*, (Oct. 1, 2021), available at <https://theintercept.com/2021/10/01/nih-bat-coronavirus-grant-ecohealth-alliance/>.

<sup>35</sup> EcoHealth grant documents at 485-486 available at <https://theintercept.com/document/2021/09/08/understanding-the-risk-of-bat-coronavirus-emergence/>.

<sup>36</sup> Mara Hvistendahl and Sharon Lerner, *NIH Bat Coronavirus Grant Report Was Submitted More Than Two Years Late*, *The Intercept*, (Oct. 1, 2021), available at <https://theintercept.com/2021/10/01/nih-bat-coronavirus-grant-ecohealth-alliance/>.

<sup>37</sup> EcoHealth grant documents at 486, available at <https://theintercept.com/document/2021/09/08/understanding-the-risk-of-bat-coronavirus-emergence/>.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* The use of the word "confirming" suggests a previous belief that the experiment would demonstrate increased pathogenicity seen in the experiment's results rather than simply showing reduced pathogenicity, which was the purported justification that the experiment was not GOF.

### NIH's Re-Review of EcoHealth Grant Found Research Was Not Subject to the P3CO Risk Analysis Framework Policy

Despite the documents NIH produced to us in which EcoHealth's Year Four progress report, dated September 16, 2020, more than two years after when it should have been submitted, NIH approved EcoHealth's Year Five grant renewal with a Notice of Award dated June 18, 2018.

Even though the proposed humanized mice experiment would have been already conducted during 2016 to 2017, NIH wrote on July 5, 2018, to EcoHealth reaffirming its July 7, 2016, determination that EcoHealth's proposed research was not a GOF experiment under the HHS P3CO framework. In its July 2018 letter, NIH did not cite any new or additional evidence to show the research was not subject to the HHS P3CO framework<sup>40</sup>

The experiments to generate MERS-like or SARS-like chimeric coronaviruses, are not subject to the HHS P3CO framework. The terms and conditions of the award have been revised to indicate that should experiments proposed in this award result in a virus with enhanced growth by more than 1 log compared to wild type strains, you must notify your NIAID Program Officer, and Grants Management specialist immediate and that further research involving the resulting virus(es) may require review by the DHHS in accordance with the HHS PC30 Framework.<sup>41</sup>

In its November 5, 2018, progress report to NIH for the period of June 1, 2014 through May 31, 2019, EcoHealth reported that the strains of the viruses it was using in its experiments could represent a significant threat to public health because they could escape existing vaccine and therapeutic treatments.<sup>42</sup>

### Preliminary Observations

Based on the totality of these studies and reports made available so far, we make the following preliminary observations:

- The revised 2017 HHS definition of GOF research appears to be too narrow because it does not capture SARS-like or MERS-like viruses that are very similar to SARS or MERS. On January 23, 2020, Dr. Christian Hassell, the Chair of the HHS P3CO review group, expressed concern about the narrow definition in the most recent meeting of NIH's National Science Advisory Board for Biosecurity (NSABB): "I'll just probably be more frank than may be appropriate - I think that's too narrow. My view on this thing is, don't

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<sup>40</sup> July 5, 2018, NIH letter to EcoHealth (per notes taken by Minority Committee staff Oct. 5, 2021 during bipartisan *in camera* review).

<sup>41</sup> *Id.*

<sup>42</sup> EcoHealth grant documents at 486, available at <https://theintercept.com/document/2021/09/08/understanding-the-risk-of-bat-coronavirus-emergence/>.

use too fine a filter.”<sup>43</sup> No additional meetings or communications have been taken in a year and nine months by NIH to address Dr. Hassell’s concerns.<sup>44</sup>

- Both EcoHealth’s and NIAID’s assessments that the experiment would be expected to show less pathogenesis seem at odds with the stated goals of the research project to look for dangerous viruses with pandemic potential. The assessments also turned out to be wrong. Specifically, the humanized mice experiment with the SARS-like coronaviruses showed more pathogenesis with three of the viruses, especially the one labeled SHC014, which produced a 20 percent weight loss in the humanized mice.<sup>45</sup> As previously mentioned, Baric *et al* warned about viruses containing SHC014 in their 2015 publication.
- After the results of the 2015 Baric *et al* paper, which showed an increase in pathogenesis with some viruses, EcoHealth and NIAID should have examined the research proposal more closely before reaching the conclusion that the expected results of the experiment would be less pathogenic.
- It seems unlikely that EcoHealth and NIAID were unaware of the findings in the 2015 paper. Thus, we are left with the impression that both chose to document the research as less dangerous so that EcoHealth could continue to receive its funding and NIAID could avoid outside oversight of that research proposal.
- Neither the EcoHealth nor the NIAID assessments reflected the careful weighing of risks and benefits of the proposed potential GOF research.<sup>46</sup> In particular, NIAID’s assessment in 2016 did not explain the benefits of the proposed research and how such benefits outweighed the risks, nor did NIAID consider any biosafety and risk mitigation measures. The NIAID determination in 2018 that the research was not subject to the HHS P3CO framework lacked any analysis or explanation supporting its determination and failed to address how it concluded that there was no pandemic potential.
- Based on the available documents, EcoHealth violated the terms of its grant. The chimeric virus used in the humanized mice experiment produced more than one log of virus growth compared to the WIV1 parental backbone.<sup>47</sup> In fact, it appears the experiment with the virus listed as SHC014 produced more than 3 logs of comparative growth. Per their grant terms, EcoHealth was to stop their experiment and notify NIAID.<sup>48</sup> It does not appear it

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<sup>43</sup> David Willman and Madison Muller, *A Science in the Shadows*, The Washington Post (Aug. 26, 2021), available at <https://www.washingtonpost.com/nation/interactive/2021/a-science-in-the-shadows/>.

<sup>44</sup> Confirmed with Dr. Hassell on August 13, 2021 in a bipartisan Committee staff briefing.

<sup>45</sup> Sharon Lerner and Mara Hvistendahl, *New Details Emerge About Coronavirus Research at Chinese Lab*, The Intercept (Sept. 6, 2021), available at <https://theintercept.com/document/2021/09/08/understanding-the-risk-of-bat-coronavirus-emergence/>.

<sup>46</sup> June 8, 2016 EcoHealth letter to NIH (per notes taken by Minority Committee staff Oct. 5, 2021 during bipartisan *in camera* review); July 7, 2016 NIH letter to EcoHealth (per notes taken by Minority Committee staff Oct. 5, 2021 during bipartisan *in camera* review).

<sup>47</sup> See Andrew Kerr, *Fauci-Funded Wuhan Lab Viruses Exhibited Over 10,000 Times Higher Viral Load Than Natural Strain*, Daily Caller (September 9, 2021), available at <https://dailycaller.com/2021/09/09/ecohealth-alliance-gain-of-function-higher-viral-load-anthony-fauci/>.

<sup>48</sup> There is no evidence that EcoHealth stopped the experiment to notify NIAID as required. In discussing the results of this experiment, EcoHealth never explicitly stated in the text of the progress reports the amount of virus growth of the parental backbone, thereby masking the comparison that might have attracted attention from a NIAID reviewer. However, the bar graph in the grant documents shows that the parental backbone, WIV 1, produced about 4.7 log<sub>10</sub> genome copies per gram, two days after

did either. As a result, NIAID's oversight of the grant failed to detect the viral growth issue and, notably, did not hold EcoHealth accountable for violating the terms of its grant.

### NIH Funded the EcoHealth Grant After Suspending It

Since April 2020, NIH has suspended all activities for NIAID grant R01AI110964 due to EcoHealth's grant award non-compliance.<sup>49</sup> Among other infractions, NIH advised EcoHealth in a July 8, 2020, letter that EcoHealth had not satisfied its obligations to monitor the WIV's activities and had not reported its subawards as required. The grant activities remain suspended and, as a result of such suspension, NIH made clear in its letter that "no funds from grant R01AI110964 may be provided to or expended by EcoHealth Alliance" until EcoHealth provides information and materials to NIH's satisfaction.<sup>50</sup>

On July 13, 2020, NIH issued a revised award approval notice to EcoHealth for the sixth year of the suspended project, despite NIH's suspension of all grant activities.<sup>51</sup> Not only did NIH approve the award, but based on a letter from EcoHealth, NIH apparently increased the award amount by an additional \$369,819. Despite NIH's notification to EcoHealth on July 8, 2020, that no funds would be provided, NIH issued the payment of that increase to EcoHealth on July 13, 2020, even though EcoHealth was not allowed to conduct activities under this grant during the suspension. In its revised award notice to EcoHealth issued on the same date as the \$369,819 payment, NIH designated specific allocations of \$76,301 for the WIV, and \$75,600 for the Institute of Pathogen Biology in Beijing, China.<sup>52</sup>

This raises significant concerns regarding NIH's oversight of grantees. This also raises concerns that NIH funding of a suspended entity is contrary to the Public Health Service Act and is possibly an Anti-Deficiency Act violation.<sup>53</sup> At a minimum, this expenditure is inconsistent with competent stewardship of federal funds, and subverts compliance with the NIH suspension letter and the NIH Grant Policy, which states: "Organizations or individuals that are suspended... cannot receive NIH grants, be paid from NIH grant funds, whether under a primary or lower-tier transaction (including trainees on NIH-supported training grants), or otherwise participate during the period of suspension...."<sup>54</sup>

On June 10, 2021, we wrote to you about our concerns that NIH issued a new \$2 million award to EcoHealth in August 2020, while EcoHealth was a noncompliant grantee with a

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infection compared to about 8 log<sub>10</sub> genome copies per gram produced by the SHC014 strain - more than three logs of growth, much more than one log threshold specified in the grant terms.

<sup>49</sup> Committee staff have confirmed the grant status on multiple occasions with NIH leadership.

<sup>50</sup> NIH terminated the grant on April 24, 2020. On July 8, 2020, NIH simultaneously reinstated and suspended the grant activities, pending EcoHealth's cooperation and compliance. Katherine Eban, *The Lab Leak Theory: Inside the Fight to Uncover COVID 19's origins*, Vanity Fair (June 3, 2021), available at <https://www.vanityfair.com/news/2021/06/the-lab-leak-theory-inside-the-fight-to-uncover-covid-19s-origins>.

<sup>51</sup> 2R01AI110964-06 is the renewal number assigned to the sixth year of the NIH R01AI110964 grant project.

<sup>52</sup> EcoHealth grant documents at 321, available at <https://theintercept.com/document/2021/09/08/understanding-the-risk-of-bat-coronavirus-emergence/>.

<sup>53</sup> 31 U.S.C. 1341.

<sup>54</sup> National Institutes of Health, *Debarment and Suspension*, NIH Grants Policy Statement (Oct. 1, 2020), available at [https://grants.nih.gov/grants/policy/nihgps/html5/section\\_4/4.1.6\\_debarment\\_and\\_suspension.htm](https://grants.nih.gov/grants/policy/nihgps/html5/section_4/4.1.6_debarment_and_suspension.htm).

suspended NIH grant.<sup>55</sup> In the same letter, we also detailed our concerns that EcoHealth had never met its requirements to report publicly its subawards to the WIV or to the Wuhan University School of Public Health until NIH specifically instructed them to do so during communications between April and July 2020. The effect of EcoHealth withholding its financial reporting is that prior to and at the time of the COVID-19 pandemic outbreak, the financial relationship between EcoHealth, NIH, and the WIV was hidden from the public and not included in USASpending.gov.

After paying an illegible grant recipient in July 2020, the NIH in August 2020 announced its award of two multimillion-dollar grants to EcoHealth for NIAID's \$3.05 million project number U01AI151797, and NIAID's \$1.2 million project number U01AI153420.<sup>56</sup> Based on available information, NIH has not recovered the \$369,819 payment to EcoHealth. As recently as July 2021, NIH approved a \$574,984 payment to EcoHealth.<sup>57</sup> Furthermore, over \$23.4 million has been paid to EcoHealth in its status as a potentially ineligible grant recipient, by NIH, USAID, and DoD since the time NIH should have reported its administrative suspension to www.SAM.gov.<sup>58</sup>

In light of our concerns about NIH's grant management and oversight, please respond to the following by November 10, 2021:

1. Does NIH plan to stop funding EcoHealth until it is compliant with NIH's requests? If yes, please identify when you will notify EcoHealth. If not, why not?
2. Does NIH plan to recover the money paid to EcoHealth on its suspended grant? If yes, please identify when you will notify EcoHealth. If not, why not?
3. Please identify who authorized the \$369,819 funding issued to EcoHealth on July 13, 2020, and the specific authority for this funding.
4. Does NIH intend to enter the EcoHealth suspension into the www.SAM.gov database that is intended for agency reporting of temporary or permanent suspensions? If yes, when? If no, why not?
5. Please provide all funded and denied grant applications, progress and final reports for all NIH grants awarded to EcoHealth Alliance as a prime or subgrant recipient in unredacted form.
6. Please provide the following documents related to grant award R01AI110964:

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<sup>55</sup> U.S. House of Representatives Energy and Commerce Committee Republicans, Letter to NIH, Spotlight on COVID-19 Origin Investigation, (June 10, 2021), *available at* <https://republicans-energycommerce.house.gov/wp-content/uploads/2021/06/06.10.21-Letter-to-NIH-Director-Collins.pdf>.

<sup>56</sup> National Institutes of Health, *NIH establishes Center for Research in Emerging Infectious Diseases*, News Releases (Aug. 27, 2020), *available at* <https://www.nih.gov/news-events/news-releases/nih-establishes-centers-research-emerging-infectious-diseases>.

<sup>57</sup> USA Spending.gov, *EcoHealth Alliance*, Advanced Recipient Search (Oct. 13, 2021) *available at* [https://www.usaspending.gov/award/ASST\\_NON\\_U01AI153420\\_7529](https://www.usaspending.gov/award/ASST_NON_U01AI153420_7529).

<sup>58</sup> U.S. House of Representatives Energy and Commerce Committee Republicans, Letter to NIH, Spotlight on COVID-19 Origin Investigation, (June 10, 2021), *available at* <https://republicans-energycommerce.house.gov/wp-content/uploads/2021/06/06.10.21-Letter-to-NIH-Director-Collins.pdf>.

- a. all documents that were not provided to *The Intercept*, including the letter from EcoHealth on which NIH based its decision to increase the award,
  - b. EcoHealth's original application, and
  - c. all other original documents for which only the revised versions were produced.
7. Please provide all correspondence between EcoHealth and NIH, including any letter exchanges about NIH's identification of EcoHealth research that potentially included GOF experiments and EcoHealth's response, dated in May, June, and July of 2016 and July 2018. Please also provide all correspondence between EcoHealth and NIH, including any letter exchanges about humanized mice experiments conducted during Year Five of the grant. Please also include another missing letter from EcoHealth to NIH that was used as the basis to increase the award amount by \$369,819.
8. Please provide an accounting of all EcoHealth subawards, including contracts or any other agreements, to all organizations and scientists located in or sponsored by China from the year 2000 to the present.
9. Please facilitate access for Committee staff and the undersigned to EcoHealth's genomic sequence data and/or database of unpublished and published sequences.
10. Please provide all documentation regarding NIH's resource coordination with USAID, EcoHealth, DoD, and any other communications in which NIH took steps to ensure no overlap of U.S. Government agency funds for the same research was occurring.
11. Please provide EcoHealth's original Year Four progress report for the period of June 1, 2017 to May 31, 2018, that would have been submitted in 2018.
12. Please provide the list of all NIH personnel involved in the development of the HHS P3CO framework with an explanation of each individual's role.
13. What would be the purpose of conducting humanized mice experiments other than to test whether a virus could infect human cells?
14. Please make appropriate NIAID personnel available to Committee staff to address questions about the handling of the EcoHealth grant.
15. When did NIAID first learn that EcoHealth had conducted the humanized mice experiment proposed in 2016?
16. Why did NIAID conduct an HHS P3CO review of the EcoHealth research proposal if the experiment was already conducted?
17. Why were less risky alternative approaches to EcoHealth's proposed experiment not considered and discussed?

18. Please explain why NIAID concluded that the EcoHealth grant was not subject to the HHS P3CO framework.

If you have any questions, please contact Alan Slobodin or Diane Cutler of the Minority Committee staff.

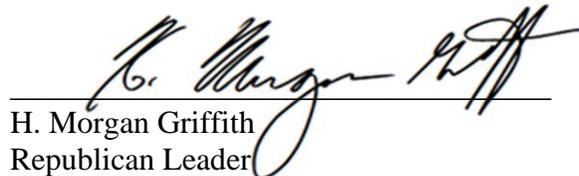
Sincerely,



Cathy McMorris Rodgers  
Republican Leader  
Committee on Energy and Commerce



Brett Guthrie  
Republican Leader  
Subcommittee on Health



H. Morgan Griffith  
Republican Leader  
Subcommittee on Oversight and Investigations

cc: The Honorable Frank Pallone, Chairman  
The Honorable Anna Eshoo, Chair, Subcommittee on Health  
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations  
Ms. Christi Grimm, Principal Deputy Inspector General, U.S. Department of Health and Human Services