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April 25, 2022

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Dr. Tabak,

Our review of EcoHealth Alliance's reports about its humanized mice experiments at the Wuhan Institute of Virology (WIV) using funds from the National Institutes of Health (NIH) shows pervasive discrepancies, inconsistencies, and omissions in its progress reports and renewal application that raise serious questions about scientific and ethical misconduct, violations of NIH policies and regulations, and possible false statements and fraud. Accordingly, we request the NIH investigate Dr. Peter Daszak, the Principal Investigator of R01AIll0964, and other EcoHealth officials to determine whether certain data related to mice deaths and other material information were intentionally withheld during the peer review process for EcoHealth's grant renewal application.

A. History of Grant R01AIll0964

EcoHealth's National Institute of Allergy and Infectious Diseases (NIAID) grant R01AIll0964 was funded for June 2014 to May 2019. During this five-year term, EcoHealth was required to submit annual progress reports to the NIAID. Such submissions typically occurred around mid-April and were required before funding for the following year was provided. On or around November 5, 2018,[1] EcoHealth prepared and submitted a renewal application to NIAID, and the grant was renewed for another five years in May 2019. This renewal award was for $3.7 million plus a $369,819 increase over the first award.[2] At that point, EcoHealth received its funding for Year 6, the first year of its renewal grant. However, the renewal and funding

[1] This is based on what looks like a time stamp at the bottom of the first few pages of the renewal application.
[2] Letter from NIH Deputy Director for Extramural Research Michael Lauer, MD to Drs. Aleksei Chmura and Peter Daszak, EcoHealth Alliance (July 8, 2020) http://downloads.vanityfair.com/lab-leak-theory/Daszak_7_8_20_Reactivation_and_Suspension.pdf

occurred before EcoHealth attempted to submit its Year 5 progress report in late July 2019. EcoHealth claimed that it was locked out of the NIH system for submitting its Year 5 progress report, which remained unsubmitted until 2021.[3] In April 2020, concerns emerged about EcoHealth-funded research at the WIV, and NIH suspended the grant on July 8, 2020, which appears to remain suspended.[4]

B. Peer Review Process

Our concerns over EcoHealth's reporting of the humanized mice experiments and how it affected review of its grant must be seen in the context of the NIH peer review process. Unlike the general review of progress reports by the grant officer, the goal of peer reviewers is to perform an in-depth look at the data to see what the grant would accomplish over the next five years. All NIH grant, fellowship, and cooperative agreement applications undergo review through a two-tiered system of peer review, a competitive and committee-based process to evaluate the applications.[5] The required peer review system was established pursuant to section 492 of the Public Health Service Act (42 U.S.C. §289a), and federal regulations (42 C.F.R. §52).[6]

In the first stage, the applications are received by the NIH Center for Scientific Review (CSR), who then assigns each application that meets basic requirements to both a potential awarding IC and an associated Scientific Review Group (SRG) of the IC.[7] The potential awarding IC (Institutes and Centers) is the one whose mission best aligns with the objectives of the research project.[8] An SRG is a peer-review committee composed of 12 to 22 scientists who are experts in the relevant fields of research. No more than one-fourth of the members of any SRG may be federal employees.[9] The SRG is responsible for evaluating a grant proposal on the basis of scientific merit and potential impact of the research. After discussing the application, each member gives the application a final score, and an overall impact score is determined from the average of members' final scores. The application is also given a percentile ranking, based on how the overall impact score compares to other applications reviewed by the SRG in the past year.[10]

In the second stage, the funding decisions are refined by the National Advisory Councils or Boards of the potential awarding ICs. Advisory Councils and Boards are composed of scientific and lay representatives. These groups examine applications recommended for funding,

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[3] EcoHealth's explanation for the delayed submission of the Year 5 report does not make sense. Dr. Daszak claimed that EcoHealth was ready to submit its Year 5 progress report at the end of July 2019, but EcoHealth was locked out by the NIH's data system. However, even if this were true, the question remains: Why didn't EcoHealth simply submit its Year 5 progress report by email to its grant officer? Even though it would not have been in the eraCommons system used by grantees, EcoHealth at least would have gotten its submission to the NIAID until submission into the eraCommons system could be figured out.
[4] Letter from Dr. Michael Lauer, NIH to Dr. Peter Daszak, EcoHealth Alliance (July 8, 2020).
[5] NIH, Report of the Director of the National Institutes of Health: Fiscal Years 2014 & 2015, p. 25, https://report.nih.gov/biennialreport/NIH_Biennial_Report_2014-15_non508.pdf.
[6] NIH, Peer Review," at https://grants.nih.gov/grants/peer-review.htm (accessed April 4, 2022).
[7] NIH, Peer Review," at https://grants.nih.gov/grants/peer-review.htm (accessed April 4, 2022).
[8] *Id.*
[9] NIH, Peer Review," at https://grants.nih.gov/grants/peer-review.htm (accessed April 4, 2022).
[10] NIH, "Peer Review-Scoring," at https://grants.nih.gov/grants/peer-review.htm#scoring

place their impact scores and percentile rankings in the context of the IC's research priorities, and then make recommendations for final funding decisions.[11]

C. EcoHealth's proposed humanized mice experiment

As noted in our October 30, 2021, letter to NIH, EcoHealth first proposed testing chimeric SARS-like viruses in a humanized mice experiment to evaluate pathogenicity in the spring of 2016. The NIH approved this research in July 2016 with the condition that EcoHealth immediately stop its experiments and report to the NIH if there was more than one log of virus growth in any of mice groups infected with one of the chimeric viruses. Peculiarly, EcoHealth did not specify in its proposal to NIH how pathogenicity would be evaluated in an animal experiment, and NIH did not follow-up to ask for such information.[12]

In addition to gain-of-function research concerns, it appears NIH approved an animal experiment without knowing the number of animals that would be involved and potentially harmed. Despite EcoHealth and NIH's conclusion that there was no potential gain-of-function concern (which seems counter to the purpose of the grant),[13] the results of the experiments showed all three chimeric viruses were more lethal compared to the WIV-1 virus.

Notably, one condition that NIAID did impose on the research proposal related to enhanced virus growth, 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).

However, NIAID requested that EcoHealth clarify the location of the experiment since EcoHealth previously indicated that the experiment would be conducted at the University of North Carolina (UNC). However, on June 27, 2016, Dr. Daszak clarified that the experiment

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[11] NIH, Peer Review," at https://grants.nih.gov/grants/peer-review.htm (accessed April 4, 2022).

[12] This is contrary to animal research reporting guidelines that state, "Clearly define all outcome measures assessed (e.g., cell death, molecular markers, or behavioural changes)." Nathalie Percie du Sert, *et al*, Reporting animal research: Explanation and elaboration for the ARRIVE guidelines 2.0, PLOS Biology (July 14, 2020) available at https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.3000411

[13] "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." June 8, 2016, EcoHealth letter to NIH (per notes taken by Minority Committee staff Oct. 5, 2021, during bipartisan *in camera* review).

would be conducted at the WIV, and he assured NIH that the WIV would immediately notify EcoHealth of such enhanced virus growth:

> You are correct to identify a mistake in our letter. UNC has no oversight of the chimera work, all of which will be conducted at the **Wuhan Institute of Virology**…. We will clarify tonight with Prof. Zhengli Shi[14] exactly who will be notified if we see enhanced replication…**my understanding is that I will be notified straight away**, as [principal investigator], and that I can then notify you at NIAID. Apologies for the error! (Emphasis added).[15]

Even though EcoHealth received approval for the risky research from NIAID in the early weeks of Year 3, EcoHealth and the WIV did not report the experiment until the Year 4 report. It appears that during Year 3, EcoHealth arranged to get the humanized mice for the experiment imported to China. More transgenic mice were then constructed and bred before the experiment was conducted.[16]

D. EcoHealth's Descriptions of Humanized Mice Experiment

As far as we are aware, neither EcoHealth nor the WIV published the details of these experiments in scientific literature, nor are there indications that such publication was even intended. Thus, available details of the experiment are limited to three key documents that described aspects of the mice experiment: the Year 4 progress report, the renewal application for NIAID grant R01AIll0964, and the Year 5 progress report.

i. The Year 4 progress report (June 2017-May 2018)

The experiment involved infecting four groups of humanized mice with different SARS-like bat viruses, with three groups getting infected with chimeric SARS-like viruses. During the Year 4 reporting period between June 2017 and May 2018, the WIV conducted one experiment that caused some Angiotensin-Converting Enzyme 2 (ACE2) Receptor humanized mice to get sick within six days after infection, and some to die within two weeks. However, EcoHealth split the disclosure of the experiment's data into two parts: (1) weight loss data and viral load in lung tissue in the Year 4 report and the renewal application; and (2) the deaths, viral load in brain tissue, and two photos of lung tissue in the Year 5 report.

As we stated in our February 24 letter, EcoHealth claimed in October 2021 that it conducted a single risky virus infection experiment in one year, but split up the reporting into two different years. The wording of the reports and the renewal application can be read as if there were two experiments. The report stated, "we continued with in vivo infection experiments."[17] If the report accurately reflected Dr. Daszak's claim, then the report should have

[14] Dr. Shi leads bat coronavirus research at the WIV.
[15] Katherine Eban, "This Shouldn't Happen": Inside the Virus-Hunting Nonprofit at the Center of the Lab-Leak Controversy, Vanity Fair (March 31, 2022), Inside the Virus-Hunting Nonprofit at the Center of the Lab-Leak Controversy | Vanity Fair
[16] Year 3 Report, at 253.
[17] EcoHealth Alliance Year 5 progress report at 15.

read "we continued data analysis of in vivo infection experiments." The plain meaning of the text does not support Dr. Daszak's assertion.

Further, the term "experiments" is plural, incorrectly suggesting more than one experiment. In the Year 4 progress report, the experiment was characterized as "preliminary," but, interestingly, the word "preliminary" does not appear in the Year 5 progress report description. Yet, more significantly, the Year 5 report makes no mention of the weight loss data from the Year 4 report that would show it was a continuation of the same study.[18]

According to the Year 4 progress report:

> In Year 4, we performed **preliminary** in vivo infection of SARSr-CoVs on transgenic mice that express hACE2. Mice were infected with 10^5 pfu of full-length recombinant virus of WIV1 (rWIV1) and the three chimeric viruses with different spikes. Pathogenesis of the 4 SARSr-CoVs was then determined in a 2-week course. Mice challenged with rW IV1-SHC014S have experienced about 20% body weight loss by the 6th day post infection, while rWIV1 and rWIV-4231 S produced less body weight loss. In the mice infected with rWIV1-WIV16S, no body weight loss was observed (Fig. 35a).[19] (Emphasis added).

The Year 4 (2017-2018) progress report disclosed weight loss results in the infected mice (Figure 35(a) included below) and a graph showing virus growth in mice lung tissue for the first few days during the two-weeks and then from the "dead point" (Figure 35(b) included below). However, the graph showing the weight loss results only showed results up to 6 days post-infection, even though it was a two-week experiment. Notably, it was on the sixth day of the experiment that the first mouse death occurred according to Figure 13(a) in the Year 5 report. For example, there is no weight loss data for days 8, 10, 12, and 14 post-infection.[20]

The graph showing the viral load in lung tissue also only showed measurements up to six days (again without data for days 8, 10, 12, and 14) but then included measurements at the "dead point." However, the "dead point" was not defined or explained. Most significantly, the lung graph did not imply mice deaths from the virus. The mice deaths could have reflected the sacrificed mice made either to obtain the lung tissue samples or to prevent further suffering from the mice during the experiment in accordance with animal welfare requirements.

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[18] The Year 5 report included two photographs of lung tissue sections to showcase the difference in pathogenicity between the most lethal virus and the least lethal virus. However, such a visual would have attracted more attention at the study panel review into the extent of the virulence that EcoHealth appeared to be trying to conceal. EcoHealth should have linked this photographic evidence with the viral load in the lung tissue graph in the Year 4 report, but no linkage was made between the photographs in the Year 5 report and the graph in the Year 4 report.

[19] HHS docs at 297, Year 4 report at 24. EcoHealth grant documents *available at* https://theintercept.com/document/2021/09/08/understanding-the-risk-ofbat-coronavirus-emergence/.

[20] EcoHealth may have chosen not to report additional weight loss results because the mice were dying at such a high rate, the data would be biased toward the heavier, healthier mice that survived. On the other hand, if the mice mounted an immune response to the virus, then that data was not shared.

Additionally, Figure 35(b) showed viral growth in the experiment that implicated the NIH policy of stopping the experiment if more than one log of viral growth occurred. There is no evidence that EcoHealth complied with NIH's condition to stop this experiment since it continued past the point of excessive viral growth and there was no evidence of stoppage or any notification to NIAID. EcoHealth apparently reported the experiment in the Year 4 progress report well after the experiment was completed. Overall, EcoHealth vaguely characterized the experiment: "These results demonstrate varying pathogenicity of SARSr-COVs with different spike proteins in humanized mice."

ii. EcoHealth's renewal application (November 2018).

EcoHealth's application for competitive renewal sent later in 2018 for its grant included the same Year 4 report data but conspicuously omitted the word "dead" from the lung tissue graph. But this time EcoHealth provided some interpretation. EcoHealth pointed out that the results demonstrated that "pathogenicity of SARSr-CoVs in humanized mice differs with divergent S proteins, thus confirming the value of this model in assessing novel SARSr-COV pathogenicity."[21] In addition, EcoHealth mentioned that the WIV had vaccinated the humanized mice infected with the SHC014 chimeric virus and the WIV-1 virus. The renewal application stated that the vaccine did not reduce clinical symptoms in the SHC014-infected mice, but the vaccine cross-neutralized two out of the four monoclonal antibodies in the WIV-1–infected mice. However, none of this data was actually shown nor any other substantiating details provided.[22]

Most significantly, EcoHealth used the experiment results to help make the case for grant renewal. EcoHealth asserted that its humanized mice work had three implications for its R01 renewal:

> (1) some SARS related CoVs currently circulating in bats in southern China **are likely able to infect and replicate within people**; (2) clinical outcomes of infection may include SARS-like illness that is **not treatable with monoclonal antibodies nor preventable with experimental vaccines**; (3) SARS related coronavirus ability to bind human ACE2 is lost with S protein divergence between 10 and 24 percent. **Although no viruses within this range have so far been described, these strains likely used hACE2 but could escape existing vaccines and immunotherapeutics and represent significant public health threats.** In our R01 renewal proposal, we will actively seek to identify viruses with this level of S protein divergence, characterize their binding targets in vitro, and their capacity to produce SARS-like disease that evade immunotherapy and vaccination in vivo. (Bolded in original).

[21] EcoHealth Alliance grant renewal application at 162 *available at* Understanding the Risk of Bat Coronavirus Emergence - The Intercept

[22] Again, since there has been no publication of the experiment and publication does not appear to have been intended. EcoHealth could make these assertions in NIH documents without substantiation.

iii. Year 5 progress report (June 2018 – May 2019).

The Year 5 progress report disclosed death data, a graph of virus load in brains of infected mice, and two photographs of viral load impact on lung tissue of infected mice.[23] However, the submission of EcoHealth's progress report for Year 5 that included the mice death data was delayed and not received by the NIH until August 2021.[24] The Year 5 progress report (due in September 2019, but submitted to NIH in August 2021) stated:

> In Year 5, we **continued** with in vivo infection **experiments** of diverse bat SARSr-CoVs on transgenic mice expressing human ACE2. Mice were infected with 4 strains of SARSr-CoVs with different S protein, including the full-length recombinant virus of SARSr-CoV WIV1 and three chimeric viruses with the backbone of WIV1 and S proteins of SHC014, WIV16 and Rs4231, respectively. Pathogenicity of the 4 SARSr-CoVs was evaluated by recording the survival rate of challenged mice in a 2-week course. All of the 4 SARSr-CoVs caused lethal infection in hACE2 transgenic mice, but the mortality rate vary among 4 groups of infected mice (Fig. 13a). 14 days post infection, 5 out of 7 mice infected with WIV1 remained alive (71.4%), while only 2 of 8 mice infected with rWIV1-SHC014 S survived (25%). The survival rate of mice infected with rWIV1-WIV16S and rWIV1-4231S were 50%. (Emphasis added).

E. Dr. Daszak Claimed There Was Only a Single Experiment

The wording in the progress reports and the renewal application appeared to show two experiments in different reporting years.[25] As a result, in October 2021, NIH wrote to EcoHealth mentioning the experiment discussed in the Year 5 progress report and informed EcoHealth that the research violated the one log virus growth policy.

In its defense, EcoHealth claimed that it complied with the policy because EcoHealth now claimed it was a single experiment conducted in Year 4 in which some of the results were reported in the Year 4 progress report, with the deaths results reported in the Year 5 progress report. In his October 26, 2021, response,[26] Dr. Daszak claimed the humanized mice experiment discussed in both progress reports was one study:

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[23] EcoHealth grant documents *available at* https://theintercept.com/document/2021/09/08/understanding-the-risk-ofbat-coronavirus-emergence/.

[24] *Id.*

[25] According to one expert contacted by staff who is familiar with such studies, two different experiments would have been standard practice. The Year 4 experiment would have been a preliminary small study assessing weight loss (probably with four or fewer mice per group, which is a number of mice sufficient to provide interpretable weight-loss data but not sufficient to provide interpretable survival-rate data), and a follow-up large study (perhaps with 10 or more mice per group). However, this experiment was conducted in China, not in the U.S.

[26] EcoHealth Oct. 26, 2021, letter to NIH *available at* https://www.documentcloud.org/documents/21097880-ecohealth-letter-contesting-claims.

> Firstly, Dr. Tabak's letter appears to refer to our year 5 report, and we note that in your email accompanying you also refer to a Figure 13 from that year 5 report. However, as is visible in the pattern of viral genome measurements, this figure closely resembles Figure 35 from our year 4 report, but with follow-up histopathological and survival data added (both are inserted, below).[27] The reason for this is that both figures are from the same experiment – conducted in 2018 and, as noted above, reported rapidly to NIH on 13th April 2018 in our Year 4 report.[28]

In his March 2022 interview with *The Intercept*, Dr. Daszak further explained how there was only one humanized mice experiment. [29] First, he stated that EcoHealth Alliance essentially cut and pasted the report section sent by the WIV on the experiment:

> Here's what happens, it's a very standard procedure: We are subcontracting to a lab in China to do some work. Every year we have to file a report to NIH to tell them what we've done for the year, how we've spent the money, and whether we've achieved the goals of the grant. So, we contact our subcontractees and we say, 'Send us the information. Let us know what successes you've had this year and whether you've had problems and issues. Put it all in a report and send it to us.' And then we use that to produce a report for NIH. That's why there are some editing issues around that. We move them around a bit, and we send a final report.

He then detailed how the reporting of one humanized mice experiment was split between two progress reports:

> This is a simple issue of Chinese nationals writing a report and then us drafting our report to NIH. So there's a word in there where they say we continued the studies. That doesn't mean they continued infecting mice with new viruses. No. What it means is they continued doing the research on the one experiment that they've done. And that continuation is a lot of work. So they did all the pathology, which means at the end of the experiment, you take all the mice, and you look at every organ in the body. You

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[27] While Dr. Daszak depicted the "pattern of viral genome measurements" and the results in Figure 35 in the Year 4 report and in Figure 13 in the Year 5 report as "closely" resembling each other, a closer examination revealing data discrepancies shows otherwise. This is discussed in a latter section of the letter.

[2828] EcoHealth grant documents posted by *The Intercept* (Oct. 21, 2021) *available at* https://theintercept.com/document/2021/09/08/understanding-the-risk-ofbat-coronavirus-emergence/. As we noted in a previous letter, EcoHealth was not in compliance with the NIH policy even with the Year 4 progress report because the experiment was not stopped when the excessive virus growth occurred while it was being conducted. Instead, EcoHealth reported the experiment after it had been completed.

[29]Sharon Lerner and Mara Hvistendahl, Peter Daszak Answers Critics and Defends Coronavirus Research, The Intercept (March 11, 2022), Peter Daszak Answers His Critics, Defends EcoHealth Alliance (theintercept.com)

> do detailed microscopical analysis. It takes months. So that's why it dragged on because you've got months of after-the-experiment analysis. And we included the mortality data as part of the pathology data. That's completely normal."[30]

F. Financial Pressures on EcoHealth

As recently reported by *Vanity Fair*,[31] EcoHealth faced a "brewing financial crisis" in 2017 and 2018 leading up to the time EcoHealth submitted its grant renewal application to the NIAID in 2018. Ninety-one percent of EcoHealth's funding came from the federal government, with 71 percent of that funding from the PREDICT grant from the U.S. Agency for International Development. The renewed PREDICT II grant was scheduled to end in two years. EcoHealth did not know if this grant would be reauthorized. This looming possibility was known within EcoHealth as the "PREDICT cliff." These financial concerns consumed EcoHealth in meeting after meeting.[32]

To offset this potential loss of funding, EcoHealth sought a grant with the Defense Advanced Research Projects Agency (DARPA) in March 2018, which was ultimately declined. However, at a March 29, 2018, EcoHealth staff meeting, Dr. Daszak expressed his concerns about the amateur nature of the DARPA submission, calling it "a major failure on all accounts"[33] and he demanded a "change in culture" as "part of [a] mentality [sic] to get money."[34] Notably, it was during this time of financial urgency and the push for a culture "to get money" that EcoHealth submitted its Year 4 progress report on April 13, 2018, and its grant renewal application in November 2018.

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[30] Dr. Daszak's statement is contradicted by the Year 4 report that included the lung pathology data but not the mortality data.
[31] Katherine Eban, "This Shouldn't Happen": Inside the Virus-Hunting Nonprofit at the Center of the Lab-Leak Controversy, Vanity Fair (March 31, 2022), Inside the Virus-Hunting Nonprofit at the Center of the Lab-Leak Controversy | Vanity Fair
[32] *Id.*
[33] *Id.*
[34] *Id.*

G. The mice death cover-up

The renewal application for the EcoHealth grant concealed the mice deaths by reproducing the two figures from the Year 4 report, but deleting the word "dead" from the term "dead point" in the lung tissue graph:

Figure 35 – Year 4 Report (with "dead point")

B.2 (Year 4 NIAID CoV Report_Final for eRA Commons.pdf)

1R01AI110964 Year 4 Report PI: Daszak, Peter

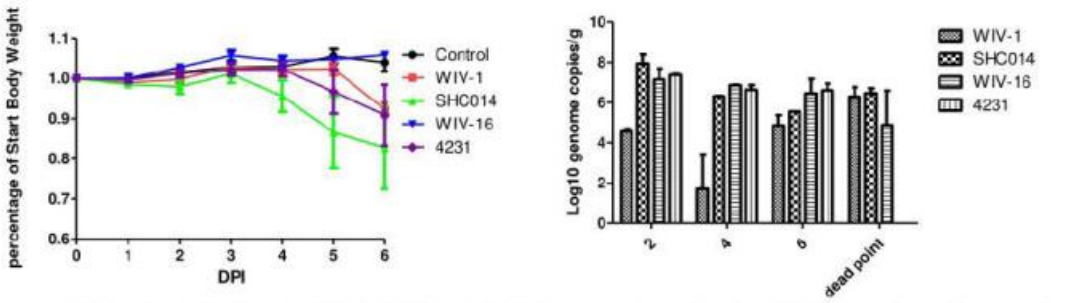


Figure 35. *In vivo infection of SARSr-CoVs in hACE2-expressing mice. (a, left) Body weight change after infection; (b, right) Viral load in lung tissues*

However, the renewal application for the EcoHealth grant shows that the word "dead" was defaced and deleted, but still includes the DPI line for the weight loss graph (Figure 6(b) is reproduced and enlarged for readability):

Figure 6 – Renewal Application (with defaced and deleted "dead" from "dead point")

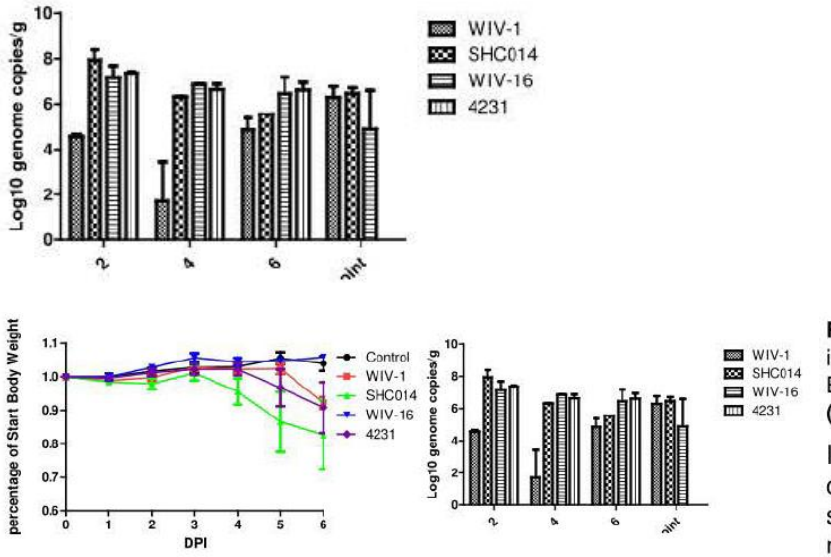
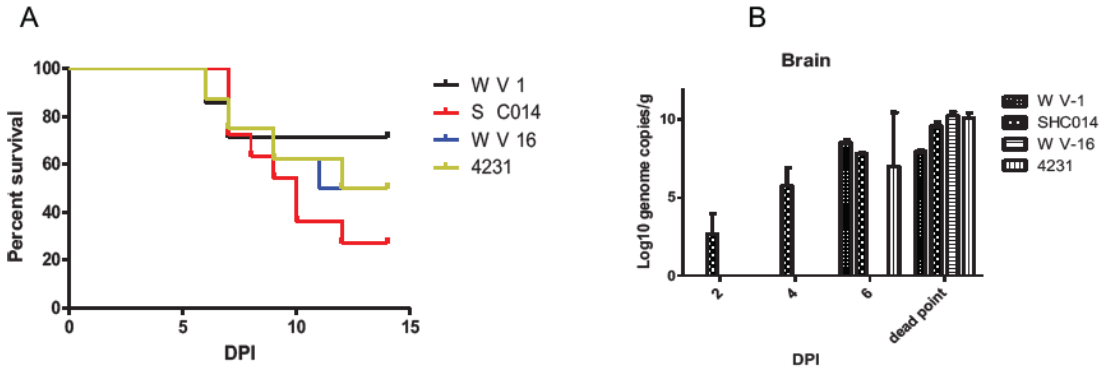


Fig. 6: *In vivo* infection of SARSr-CoVs in hACE2 transgenic mice. **6a (left)** Body weight change after infection; **6b (right)** Viral load in lung tissues.

Infection of rWIV1-SHC014S caused mild SARS-like clinical signs in the transgenic hACE2 mouse model **that weren't**

In the Year 5 report, EcoHealth has no problem including the word "dead" under the brain tissue graph:

Figure 35 – Year 5 Report (with "dead point")



There is no apparent reason why EcoHealth was able to include the word "dead" in the Year 4 and Year 5 report graphs, but not in the graph in the renewal application. Without the word "dead" with Figure 6(b), the lung tissue graph would not have implied mice deaths; it would have implied only increasing viral loads. As such, this looks suspiciously tailored to delete this word in a document that would be reviewed by subject matter experts in the peer review process who were independent of NIAID.

Further, the renewal application, unlike the Year 4 report, stated that the presented information showed that the mice infected with SHC014 only had "mild" SARS-like clinical signs that were not reduced by immune-therapeutic monoclonals that reduce SARS pathogenicity or by vaccines. However, the Year 5 report with the mice death data showed that the SHC014 produced a staggering 75 percent death rate. Thus, the portrayal of the SHC014 infected mice as having mild symptoms when EcoHealth would have known of the 75 percent death rate strongly suggests EcoHealth intended to deceive the peer reviewers.

Finally, the deletion of the word "dead" in Figure 35(b) suggests that EcoHealth believed including "dead point" would have triggered questions from the peer reviewers about the deaths. It appears the word "dead" was taken out to conceal the deaths from the peer reviewers, which raises scientific and ethical concerns.[35]

H. Why Concealing the Mice Deaths Mattered

EcoHealth found itself with unpleasant choices. It could admit that it was doing gain-of-function research, or risk losing money it desperately needed from NIAID. Given the financial pressures it was facing and the culture of "getting money" created by Dr. Daszak, the presentation of the humanized mice data in the renewal application appears intentional.

[35]S. Moran and R. Huneke, The Role of IACUCs in Responsible Animal Research, ILAR Journal (November 2019), https://academic.oup.com/ilarjournal/article/60/1/43/5618668

If the mice deaths had been disclosed, it is reasonable to expect that the peer reviewers would have noted these results and the discrepancies in the data when the data of both Year 4 and Year 5 reports are combined. Had the peer reviewers seen the mice death data from the survival rate graph held back for the Year 5 report, they would have known mice were dying at high rates from the chimeric viruses in a risky experiment. There was a significant probability that reviewers would have wanted to stop such risky research and not continue EcoHealth's funding.

I. Dr. Daszak's Explanation for the Delayed Mice Death Reporting is Suspect

In his March 2022 interview with *The Intercept*, Dr. Daszak stated that the reporting of the mice deaths was delayed because months of pathology work needed to be done. This explanation does not make sense because EcoHealth was able to include lung pathology work in the Year 4 progress report. The renewal application, which appears to have been submitted to the NIH in early November 2018, was seven months after the April 2018 submission of the Year 4 report data, presumably more than enough time to have done pathology work.

Additionally, Dr. Daszak's claims about the length of time needed for pathology work appear dubious. Minority committee staff consulted with scientific experts who are either board-certified in pathology or have conducted humanized mice experiments with coronaviruses and staff found no support for the notion that such pathology work would take months. In fact, two experts indicated that pathology takes a week or so since tissues need to be fixed for 24 hours and then processed and stained. One expert told staff that EcoHealth's assertion that reporting of survival data would need to be deferred until pathology work was done was comical.

Even if Dr. Daszak's assertion were true, there is no basis that we are aware of that justifies holding back the death data that EcoHealth already had. In fact, animal welfare regulations suggest that it would be unethical to withhold or delay reporting the death data. The WIV and EcoHealth could have, and should have, reported the death data and told NIH that the pathology work was continuing.

Using the mice death data generated during Year 4 for the Year 5 report also raises questions about how EcoHealth and the WIV actually spent the Year 5 funds for laboratory research since no new mice experiments were apparently conducted in Year 5 given EcoHealth's claim of a single experiment conducted in Year 4. It does not make sense that the pathology work for the lung tissue up to the "dead point" was done in time for inclusion in the Year 4 report, but the pathology work for the viral load in brain tissue up to the "dead point" could not be done in time for the Year 4 report and/or the renewal application. It does not explain why the death data could not have been included in the Year 4 report since lung tissue data with a "dead point" were also submitted in the Year 4 report.

Dr. Daszak's explanation does not explain why the Year 4 report data submitted in April 2018 were not updated with death data for the renewal application that was sent months later in 2018. If Dr. Daszak's statement about the delay in reporting the deaths because of the time needed to do pathology work were true, then there should have been no lung measurements up to

the "dead point" of the experiment included in the Year 4 report. Nor did Dr. Daszak make any distinctions between the lung work and brain work on the length of time to do the pathology work.

J. Discrepancies and Omissions in EcoHealth's Reports

i. "Dead point" Not Defined

As we noted in our previous letter, EcoHealth's Year 5 progress report was riddled with errors, such as mislabeled graphs.[36] Our further examination of the Year 4 and Year 5 reports on the humanized mice research shows the results of the experiment(s) have many discrepancies and omissions. As already noted, the so-called "dead point" in the experiment was not defined or explained.

ii. No Mention of Sample Size

In addition, none of EcoHealth's descriptions of the experiment mention the sample size. For the Year 4 report and renewal application, there is no mention of sample size of any kind, and the Year 5 report only noted that there were 9 mice in the control group and 7 mice in the group that had the most deaths.[37] However, neither the number of mice in the other two groups nor the overall number of mice in the study are mentioned. This is contrary to animal research reporting guidelines that state "Specify the exact number of experimental units allocated to each group, and the total number in each experiment. Also indicate the total number of animals used."[38] By omitting or keeping the mice number vague, EcoHealth was able to hide additional mice deaths resulting from sacrifices made to obtain tissue samples or to mitigate suffering.

iii. Discrepancies in Pathogenicity Results

In the Year 4 report, the WIV 16S infected-mice group had no weight loss, an indication of no pathogenicity. In the Year 5 report, the 16S infected group had a 50 percent death rate while the WIV 1 infected control group had a 29 percent death rate. Thus, for the group infected with the 16S chimeric virus, the experiment in the Year 4 report showed no pathogenesis in terms of weight loss, but the full two-week study in the Year 5 report showed a 50 percent death rate, evidence of pathogenesis. The WIV 1 group had a 29 percent death rate, even though this group had more weight loss (more pathogenesis) than the 16S group had.

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[36] Letter from House Energy and Commerce Committee Republican Leader Cathy McMorris Rodgers, Republican Health Subcommittee Leader Brett Guthrie, and Republican Oversight and Investigations Subcommittee Leader Morgan Griffith to Dr. Lawrence A. Tabak, Acting Director of the NIH (February 24, 2022).

[37] Assuming the other two mice groups were of similar number, the total number of mice used in a single study would have been more than 30, not the typical number in a preliminary in vivo infection study. Given the expense of mice and minimizing the number of mice sacrificed, the number in a preliminary study would be much smaller, according to an expert consulted by staff.

[38] Nathalie Percie du Sert, *et al*, Reporting animal research: Explanation and elaboration for the ARRIVE guidelines 2.0, PLOS Biology (July 14, 2020) available at https://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.3000411

The lung tissue results were not consistent with the weight loss findings. The group with no weight loss and the group with the highest weight loss had nearly the same number of logs of virus growth at the "dead point" of the experiment.[39]

In the Year 4 report, in Figure 35(b), there is no bar for the 4231-infected group at the dead point in the bar graph on the viral loads in lung tissue, although the bar for the 4231 group is represented in measurements taken 2, 4, and 6 days post-infection. As noted before, during the time that mice deaths were accruing, there were no results for days 8, 10, and 12, and it is inexplicable why the 4231-infected mice data for the "dead point" would be missing in Figure 35(b).

The viral load in brain results in Figure 13b were not consistent with the death results in Figure 13a. The group infected with SHC014 that had the highest death rate (75 percent) had less virus growth in the brain than the amount of virus growth in the brain in the two groups that had a 50 percent death rate. Groups with different death rates had similar viral loads in the brain suggesting that the viral loads in brain tissue may not have been as pertinent as viral loads in lung tissues in its association with pathogenicity. But this issue was not distinguished or pursued.

iv. Missing Data

The Year 5 report stated, "Viral replication was confirmed by quantitative PCR in spleen, lung, intestine, and brain of infected mice." However, the PCR viral replication data for the spleen and intestine were not included in the report. Perhaps if EcoHealth and the WIV had published the experiment in scientific literature, complete data sets would have been provided. However, it has been more than four years since the experiment was conducted and we have been unable to find any publication about this experiment. Notably, even Dr. Daszak admitted EcoHealth did not have the lab notebooks or the electronic files for the experiment and claimed that such records were in China.[40]

K. <u>EcoHealth Also Masked Its Violation of NIH Policy on Virus Growth</u>

Even with the Year 4 report's focus on mice weight loss, EcoHealth violated the NIH grant policy that required experiment stoppage when more than one log of viral growth occurred

[39] EcoHealth's Year 4 report description of the mice experiment only focused on the early lung viral loads that were consistent with its assertion that the chimeric virus-infected mice had greater pathogenicity than the WIV1-infected mice. However, EcoHealth's description did not include the later results in the experiment that were inconsistent with this pattern. EcoHealth wrote, "2 and 4 days post infection, the viral load in lung tissues of mice challenged with rWIV1-SHC014S, rWIV1-WIV16S and rWIV1-Rs4231 S reached more than 10 to the 6 genome copies/g and were significantly higher than that in rWIV1-infected mice (Fig. 35b). These results demonstrate varying pathogenicity of SARSr-CoVs with different spike proteins in humanized mice." However, Fig. 35b also showed that 6 days post infection the rWIV1-infected mice had viral loads only slightly less than the other infected mice. In fact, at the dead point, rWIV1-infected mice had higher viral loads in lung tissue than the load in the 4231 S group and almost the same viral load as the SHC014S group.

[40] Letters to EcoHealth Alliance (Jan. 11, 2022) *available at* https://republicans-oversight.house.gov/wp-content/uploads/2022/01/January-2022-EHA-SAC-CAP-letter-final1.pdf.

with the one of the chimera-infected mice groups compared to the viral growth in the control group. The violation is supported by the bar graph in Figure 35(b) showing the excessive viral growth in lung tissue. However, the text of the report does not discuss mice deaths nor quantify the extent of viral growth.[41] Moreover, the weight loss graph stops at 6 days and not for the full two-week period. In contrast, the survival graph in the Year 5 report covered the full 14 days.

It is now apparent how this violation occurred. Contrary to its assurance to NIAID in 2016 about the WIV reporting to Dr. Daszak "right away," EcoHealth had no real-time knowledge of this experiment. It appears EcoHealth simply benefited financially by being a pass-through for the WIV.[42] Based on Dr. Daszak's statement to *The Intercept* about cutting and pasting the WIV excerpts into progress reports, EcoHealth did not know about the virus growth until the WIV sent in its report section for the Year 4 report about the experiment that was already completed.

The concerns raised here have profound implications on the integrity of the peer review process. More investigation needs to be conducted to obtain more complete and accurate information about the humanized mice experiment. In addition to investigating the above concerns, please respond to the following by May 16, 2022:

1. Why did NIAID provide renewal grant funding to EcoHealth before EcoHealth filed its Year 5 Progress Report?

2. Why did NIAID neglect or willfully ignore EcoHealth's missing Year 5 progress report for nearly two years?

3. Why would NIAID fund a study that does not report its sample size? What are the scientific standards for these studies to meet on detailing sample size?

4. Animal experiments are highly regulated, and EcoHealth and the WIV should have very detailed records about the mice experiments. Did NIAID monitor this grant for compliance with animal welfare regulations or ABSL3 (Animal Biosafety Level 3) regulations? Why or why not?

5. When NIAID reviewed EcoHealth's research proposal to study pathogenesis of SARS-related viruses in humanized mice, did the NIAID approve only one experiment? Was EcoHealth authorized by NIH to conduct as many as experiments as it wanted pursuant to the proposal submitted to NIH? Other than the viral growth policy, were there any other restrictions or conditions on EcoHealth's authority in conducting the humanized mice experiment?

[41] EcoHealth only stated that the viral load in mice infected with the three chimeras had "significantly higher" growth than that in the WIV-1 infected mice.
[42] EcoHealth would receive the financial benefit by charging the grant for the WIV overhead and would hold some of that overhead charge for itself.

6. Is it permissible for an NIH grantee to withhold and delay reporting of data on deaths in an animal experiment? If so, under what circumstances?

7. What animal welfare regulations applied to the humanized mice experiment, and was EcoHealth in compliance with those regulations?

8. If a grantee submits a research plan involving an animal experiment on pathogenicity for NIH's review, does the grantee need to specify how pathogenicity is evaluated? Or can the grantee evaluate pathogenicity through a survival study that could result in animal deaths without explicitly informing the NIH?

9. Why did NIAID not seek details on the kind of pathogenicity study that EcoHealth wanted to pursue with the WIV?

10. When was the EcoHealth application reviewed by the SRG for renewal? When did NIAID finalize the decision?

11. What are the implications of grant applicants selectively sharing data that may be material to the funding decision? What is NIH policy in this area?

If you have questions about this correspondence, please contact Alan Slobodin of the Minority Committee Staff.

Sincerely,

Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce

Brett Guthrie
Ranking Member
Subcommittee on Health

H. Morgan Griffith
Ranking Member
Subcommittee on Oversight and Investigations

Cc: The Honorable Frank Pallone, Chair, House Energy and Commerce Committee
The Honorable Anna Eshoo, Chair, Subcommittee on Health
The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations
The Honorable Christi Grimm, HHS Inspector General
Elena Fuentes-Afflick, M.D., M.P.H., Home Secretary, National Academy of Medicine