EcoHealth Alliance

October 26th 2021

Dear Dr Lauer (cc'ing Dr. Tabak),

I am responding to your letter requesting IACUC information and unpublished data from our original R01. As I read your letter, I realized that this request is likely related to a letter from Dr. Tabak to Congressional member Comer released publicly on the 20th October *(PDF attachment #1)*. In his letter Dr. Tabak referred to a mouse infection experiment in our FoIA'd year 5 report, and stated that *"EcoHealth failed to report this finding right away, as was required by the terms of the grant"*. The experiment referred to is, in fact, the same one we reported in our Year 4 Report on April 13, 2018. There was just the one experiment conducted, with results from follow-up analyses included in the Year 5 Report. **Thus, EcoHealth did in fact comply with all reporting requirements**. We respectfully would like to clarify this below:

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). 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.** Proof of submission on that date is attached *(PDF attachment #2)*. It is very important that these facts be acknowledged, as they clearly show that EcoHealth Alliance is *not* out of compliance with our oversight and reporting obligations, and in fact reported this experiment over 3 years and 6 months ago.

In our modified NoA, we were instructed to *"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"*. The Year 4 report was filed in the NIH system on April 13th 2018 and a copy emailed to our Program Officer at NIAID on April 25th 2018 *(PDF attachment #3)*. At no time did program staff indicate to us that this work required further clarification or secondary review. In fact, our report was deemed sufficient for the Year 5 to be awarded without delay. Our relationship with NIH has always been that if we are asked for information, we respond and follow up in a timely manner. If NIH had indicated to us at any point that any issues needed further clarification, we would of course have complied immediately with any request, as we have always done. On June 8th 2016, we wrote to NIH to explain the rationale for these planned experiments and suggested alternative approaches involving non-infectious virus-like particles *(PDF attachment #4)*. Had NIH reviewed our 2018 report and found a need to change the nature of this work, we could have simply shifted to that alternative strategy. No such review or request was reported or made to us.

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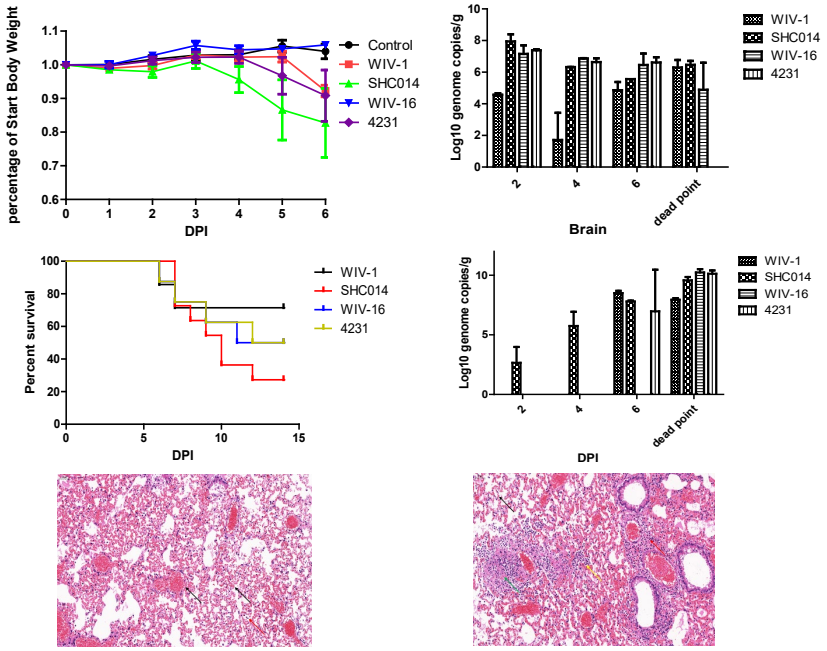

Year 4 report Figure 35 (Top 2 graphs). *In vivo infection of SARSr-CoVs in hACE2-expressing mice. Left: Body weight change; Right: Viral genome copies per gram in lung tissue*

Year 5 report Figure 13 (Below)**:** *In vivo infection of SARSr-CoV in hACE2-expressing mice. Survival rate, viral genome copies/gram, histopathology WIV-1, histopathology rWIV1-SHC014 S.*

Secondly, the direction in our revised Year 3 NoA, was that we should report experiments in which *"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"*. In virological terms, "virus growth" normally refers to viral titer measuring the concentration of infectious viruses by plaque assay. The experiment we reported to NIH actually shows genome copies per gram *not* viral titer. We have been advised by senior virologists that data on genome copies per gram usually do not accurately equate to viral titer, since genomic material from inactivated, incompletely formed, or dead virus are also measured. Viral titers were not conducted in this experiment. We also note that the genome copy data for SHC014 are only enhanced relative to the WIV1 backbone at the earliest part of the experiment and by day 6-8, there was no discernably significant difference among the different viral types. This suggests that differences, if real, were transient. Given the small number of mice, it is also uncertain whether the survival and weight loss data were statistically relevant, and as no further replications of this experiment were performed, we are unable to corroborate these initial results. We assume that these were the rationale NIH used at the time for *not* highlighting this work as requiring further clarification or secondary review.

Thirdly, regarding the timing of our year 5 (final) report. As we informed you previously, and as is documented by the NIH receipt system itself *(PDF attachment #5)*, we first uploaded this report on time, in July 2019 (the final allowable date for submission would have been September 30th 2019). However, by the time we tried to officially submit, our R01 grant had been renewed (July 24th 2019) and the system locked us out from submitting a normal annual final Year 5 report at that point. On July 30th 2019, we requested further information about the submission of the Year 5 report from the NIH Grants Management Specialist who had been dealing with our renewal, but we did not receive a response to

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our questions (*PDF attachment #6)*. NIH also did not send any subsequent request to us for the Year 5 report, despite the reality that we were in frequent communication with staff during that period. Because the new award had been made and the work was permitted to commence we had no indication there was anything missing, and assumed that the Year 1 report for the renewal grant would provide all of the relevant information. It is standard NIH policy to contact a grant recipient if additional information of reporting is required. We heard nothing further from NIH in the period subsequent to this until your letter in April 2020 requesting that we not fund work at WIV, which we complied with, and then the termination notice you sent a few days later. We presumed at that point that no further reporting was required of us, however when we received a request from your office on July 23rd 2021 for the year 5 report, we immediately took steps to file the report. We were finally able to get the system to accept our report within 11 days, but only after considerable efforts from NIH staff to circumvent the system's lockout. Note also that, even though the grant was terminated and then suspended, and funding is not available to us to work on this, we have continued to comply with NIH reporting requests, and submitted reporting for Years 6 and 7 of this grant.

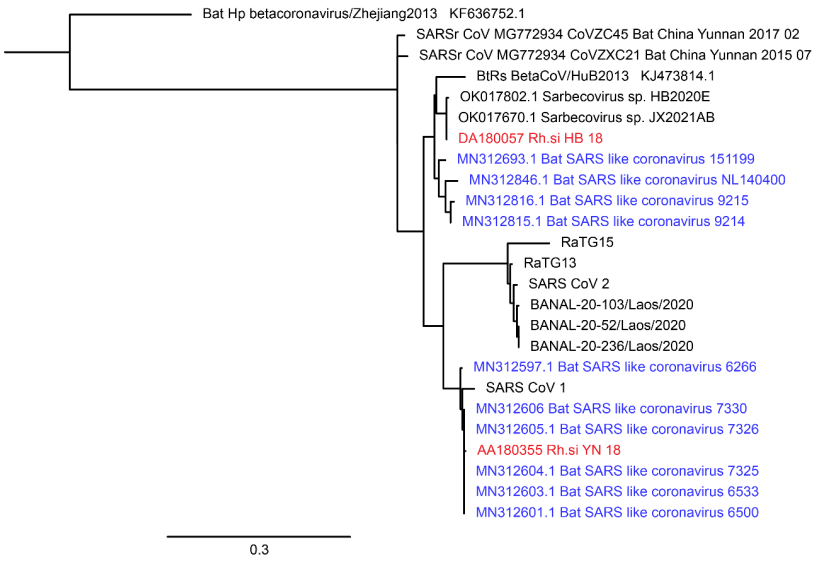
We take our compliance oversight role very seriously at EcoHealth Alliance, and hope you understand our need to correct these misinterpretations. We have cc'd Dr. Tabak so that he is aware, and we hope he understands that we are making these comments respectfully, and that we acknowledge these are complex technical issues that can be easily misinterpreted. We would like to point out that these types of mistakes about the timing or nature of our reporting can be better addressed by contacting us to request clarification prior to responding to any congressional inquiry. This will help ensure factually correct responses and will save our organization and staff from undue disparagement and unjustified accusation of inappropriate behavior that have now ensued in the press. We believe it is very important that the impressions the Congressional inquiry may take away from the incorrect information provided them be addressed quickly and clearly. We remain, of course, ready to respond to any future questions you or Dr. Tabak may have. We are also available to work with program staff at NIAID on any future technical questions – as would be normal procedure for a grantee.

Request for IACUC information and unpublished data.

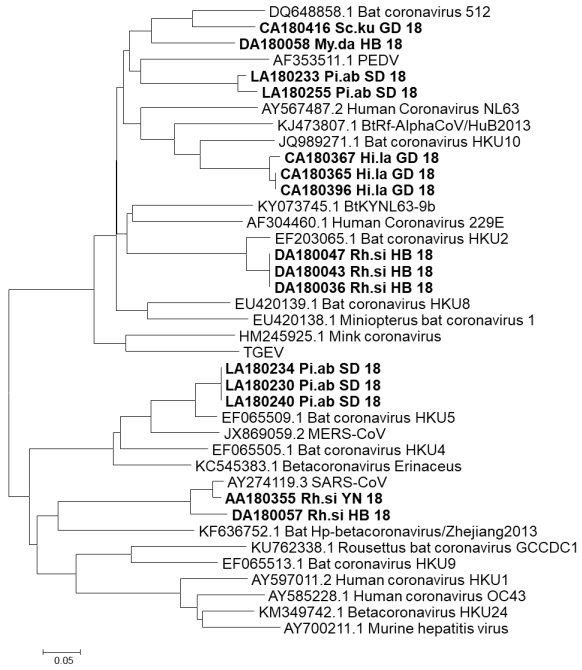
As requested in your letter, we have provided unpublished data below and in pdf attachments. We would like to respectfully point out that our NIH grant funding for this work was terminated in a letter from you in April 24th 2020. The grant was then suspended and the funds remain unavailable to us due to the logistically near-impossible conditions that NIH has placed on us, and that we have addressed in previous correspondence. In your letter of April 24th 2020, you instructed us to discontinue all of our contractual work with WIV. Both the lack of funding, and the instruction to cease contractual work with WIV have led to significant disruption of the normal interactions and dialog among collaborating scientists. Despite these challenges, we have continued to comply with all requests from your office. We have also made significant efforts to analyze data we have access to, and to draft papers and publish our work in international peer-reviewed journals, and to upload sequence data to Genbank. We strongly believe doing whatever we can to collate, analyze, and publish data we have from our prior efforts is critical to advancing science and protecting US citizens and people of all nations from future pandemic threats. However, because of the limitations placed on us by NIH our progress has been substantially

slowed. What we have provided below within the 5-day time limit given to us by Dr. Tabak and yourself, is a good-faith attempt to supply available data as quickly as we are able. These include:

1. A phylogenetic tree of two new SARSr-CoV RdRp sequences reported in ***Figure 5*** *from our 5 year report.* These are from *Rhinolophus sinicus* bats sampled in Hubei and Yunnan provinces, respectively, in 2018. The tree below clearly demonstrates they these viruses (shown in red) are not related closely to SARS-CoV-2, and that the recently-described BANAL coronaviruses are the closest relatives of the pandemic strain. The RdRp sequences for these two viruses are now going through approval process by Chinese authorities so that they can be uploaded to Genbank at the earliest possible opportunity.



2. We have requested that the 13 other novel RdRp sequences (in bold) included in Figure 5 of our year 5 report to be uploaded to Genbank. These are now going through the approval process by the Chinese authorities so that that they can be uploaded to Genbank at the earliest possible opportunity.



Year 5 report Fig. 1 (left): Phylogenetic analysis of partial RdRp gene of CoV (440-nt partial sequence)

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3. We supply new analyses of our work on SADSr-CoVs and HKU2-CoVs *(PDF attachment #7)* that was referred to in our Year 5 report. These viruses are alpha-coronaviruses, not the beta-coronavirus group that contains the viruses responsible for SARS or COVID-19. We are currently drafting a paper on this work for submission to an international peer-reviewed scientific journal. All SADSr-CoV and HKU2 sequences have been uploaded to Genbank, and following widely-accepted scientific standards and norms, will be released publicly once the paper is accepted for publication. Considering that none of these viruses are related to either SARS-CoV or SARS-CoV-2, we believe this is an appropriate balance between public health interests and the need to maintain integrity of the scientific process of discovery, analysis, peer-review, and publication.

4. We supply a manuscript submitted for review that cites our R01 grant *(PDF attachment #8)*. This paper analyzes hotspots for SARSr-CoV spillover in China, Southeast Asia and South Asia. It identifies a large geographic area that acts as an interface for bat-to-human spillover of CoVs, with spillover hostspots in southern China, Myanmar, Laos, Vietnam, and further potential for viral emergence across the whole region. It also estimates the number of people infected annually with novel bat-SARSr-CoVs as a median of 50,000 and a mean of 400,000. This highlights a substantial public health risk, further consolidates our underlying assumption that viruses like SARS-CoV-2 are far more likely to have emerged via a so-called 'natural' pathway than a so-called 'lab-leak', and provides a much-needed road-map for targeting sample collection and surveillance for future spillover events. The analyses are new, but based on already-published data.

5. We provide our DHHS/NIH Office of Laboratory Animal Welfare Interinstitutional Agreement for the WIV animal work on this grant *(PDF attachment #9)*. As required by DHHS/NIH and NIH Grants Policy, the Interinstitutional Agreement document for R01AI110964 was approved and signed by the NIH/OLAW Assured Institution (WIV) IACUC chairperson, the WIV Director, and the NIH Office of Laboratory Animal Welfare Division of Assurances Director. The effective date of our Interinstitutional Agreement is 07 May 2014 for our award (R01AI110964) that started on the 1st of June 2014. Both the Interinstitutional Agreement and the confirmatory email from NIH copying our NIH/NIAID program grants management specialist are included here.

Please let me know if you have additional questions or if it would be helpful to schedule a meeting to review the information submitted with this letter.

Yours sincerely,

Dr. Peter Daszak, President

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