



VIA ELECTRONIC MAIL AND FED EX

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DETERMINATION OF UNCONTESTED SUSPENSION/DEBARMENT

BACKGROUND

In the matter of Wuhan Institute of Virology, Chinese Academy of Sciences Capital Construction (WIV), the U.S. Department of Health and Human Services (HHS) transmitted an Action Referral Memorandum (ARM) to WIV by:

- () Notice of Suspension
- () Notice of Proposed Debarment
- (X) Notice of Suspension and Proposed Debarment

The July 17, 2023, Notice of Suspension and Proposed Debarment (Notice) and ARM informed WIV that HHS had suspended and proposed WIV for debarment from participating in United States Federal Government (Government) procurement and nonprocurement programs. The suspension is pursuant to 2 C.F.R. § 180.700(b) and (c) and the debarment is pursuant to 2 C.F.R. 180.800(d) – “Any other cause of so serious or compelling nature that it affects your present responsibility.” HHS invited WIV to submit information and argument in opposition to the suspension and proposed debarment within 30 days after receipt of the Notice and ARM.

Pursuant to 2 C.F.R. § 180.615, in order for notice to be effective, the suspending and debarring official must send a written notice to the “last known street address, facsimile (fax) number, or e-mail address of” the respondent or the respondent’s identified counsel, or alternatively, the respondent’s “agent for service of process, or any . . . partners, officers, directors, owners, or joint venturers.”

On July 17, 2023, HHS transmitted the Notice and ARM to WIV by electronic mail (e-mail) to the e-mail address: wiv@wh.iov.cn, which was obtained from the “Contact” page on WIV’s website, found at: http://english.whiovcas.cn/About_Us2016/Contact2016/. On July 18, 2023, HHS received an electronic notification from Microsoft Office 365 that the e-mail was

undeliverable due to a “policy violation or system error” and that the user - wiv@wh.iov.cn - was not found.

On July 17, 2023, HHS also attempted to transmit the Notice and ARM to WIV by fax at the following number: 027-87998612. This fax number was obtained from the “Contact” page on WIV’s website, found at: http://english.whiovcas.cn/About_Us2016/Contact2016/. HHS, however, was not able to successfully transmit the documents via fax after three attempts resulting in no answer.

Based on the undeliverable e-mail and fax attempts, on July 18, 2023, HHS identified Dr. Yanyi Wang as WIV’s Director General/Principal Investigator and located her e-mail address as wangyy@wh.iov.cn from WIV’s website, found at: http://www.whiovcas.cn/sourcedb_whiovcas/yw/rck/201203/t20120307_3450260.html. Additionally, HHS identified Dr. Zhengli Shi as WIV’s Principal Investigator under the 2014 through 2018 subcontract/consultant agreements between EcoHealth Alliance, Inc. (EcoHealth) and WIV (signed/dated October 28, 2014; September 1, 2015; August 1, 2016; August 1, 2017; and July 1, 2018 by Dr. Zhengli Shi, as WIV’s representative). The subcontract/consultant agreements identified her e-mail address as zlishi@wh.iov.cn. HHS later verified this e-mail address on WIV’s website, found at: http://www.whiovcas.cn/sourcedb_whiovcas/yw/rck/200907/t20090718_2100074.html. Subsequently, HHS transmitted the Notice and ARM in an e-mail to both of these e-mail addresses on July 18, 2023. HHS received electronic communication from Microsoft Office 365 that the e-mail delivery to wangyy@wh.iov.cn and zlishi@wh.iov.cn was complete as of this date.

Since the e-mail addressed to Dr. Wang and Dr. Shi was successfully delivered, HHS satisfied the notice requirements of 2 C.F.R. § 180.615. As a courtesy, HHS also sent the Notice and ARM to WIV by international mail via DHL Express on July 27, 2023 (tracking number 7897442851). HHS used the following mailing address: Wuhan Institute of Virology, Chinese Academy of Sciences Capital Construction, No.44, Xiaohongshan Middle Area, Wuhan, Hubei, 430071 CHINA¹. According to the DHL Express tracking information, on August 1, 2023, delivery of the package was attempted, and the package was scanned as “Delivery not accepted.” On August 11, 2023, the package was marked as “Return to sender,” and on August 14, 2023, the package was returned to HHS.

As stated above, HHS considers the Notice and ARM to have been delivered to WIV as of July 18, 2023, which is the date of the successful e-mail delivery to WIV’s Director General/Principal Investigator Dr. Yanyi Wang and WIV’s Principal Investigator Dr. Zhengli Shi. *See also* 2 C.F.R. § 180.725(b)(3) (“The Federal agency taking the action considers the [Notice of Suspension] to be received by you [w]hen delivered, if the agency sends the notice by e-mail”) and 2 C.F.R. § 180.820(b)(3) (“The Federal agency taking the action considers the Notice of Proposed Debarment to be received by you [w]hen delivered, if the agency sends the notice by e-mail”).

¹ This address was obtained from WIV’s entity registration entry in the General Services Administration’s web-based System for Award Management (SAM), available at www.sam.gov.

Upon opportunity to contest the action under the provisions of 2 C.F.R. Part 180, WIV:

- (X) failed to send, or make arrangements to appear and present information and argument in opposition to the Notice of Suspension and Proposed Debarment within 30 days after the receipt of the Notice of Suspension and Proposed Debarment.**
- () the Notice of Suspension and Proposed Debarment was returned to the suspending and debarring official and marked “unclaimed” after repeated notification.
- () failed to leave a forwarding address with the post office.
- () could not be located at the last address known to HHS.
- () other

WIV is deemed to have not contested the Notice and ARM. Absent information from WIV to the contrary, this determination concludes that the information in the ARM, dated July 17, 2023, which was transmitted by the Notice, is accurate and the conclusions drawn are warranted.

DISCUSSION

Pursuant to 2 C.F.R. §180.865, if the suspending and debarring official determines that a period of debarment is necessary, the length of the period of debarment will be based on the seriousness of the cause(s) upon which the respondent’s debarment is based. While the typical debarment period should not exceed three years, if circumstances warrant, the suspending and debarring official may impose a longer period of debarment. This is particularly applicable in cases involving 2 C.F.R. 180.800(d) as the debarment cause for fact-based cases – “Any other cause of so serious or compelling nature that it affects your present responsibility.” In these types of cases, the suspending and debarring official considers the seriousness of the conduct (“acts or omissions”) and its effect on the respondent’s present responsibility and any mitigating or aggravating factors identified in the record. *See* 2 C.F.R. § 180.845(a).

The appropriateness of the mitigating and aggravating factors provided in 2 C.F.R. §180.860 are evaluated in the context of the seriousness of the cause(s) and conditions that gave rise to the suspension and proposed debarment. Here, as the HHS Suspension and Debarment Official (SDO), I may also consider other factors, as appropriate, in light of the circumstance of a particular case. In considering the information in the record, I determined that the following factors are relevant to my decision to debar WIV for a ten-year period:

- *2 C.F.R § 180.860(a) – The actual or potential harm or impact that results or may result from the wrongdoing.*

As stated in the July 17, 2023, Notice and ARM, the National Institutes of Health’s (NIH’s) review of the Year 5 Interim-Research Performance Progress Report (I-RPPR) for Grant Number 5R01AI110964-05 determined that an experiment by WIV, shown in

Figure 13 of the I-RPPR, had possibly yielded a greater than 1 log increase in viral activity, in violation of the terms of the grant. The NIH gave WIV several opportunities to disprove this finding, but to date, WIV has failed to do so. Due to WIV's disregard of the NIH's requests that WIV provide the required materials to support its research reported in the grant Research Performance Progress Reports (RPPRs) and I-RPPRs, the NIH's conclusion that WIV research likely violated protocols of the NIH regarding biosafety is undisputed. As such, there is risk that WIV not only previously violated, but is currently violating, and will continue to violate, protocols of the NIH on biosafety, as set forth in the NIH GPS, Section 4.1.24 "Public Health Security," and the terms and conditions of the NoA for Grant Number R01AI110964 (e.g., requiring that "Research funded under this grant must adhere to the [Centers for Disease Control (CDC)/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)].")

In summary, the NIH determined that WIV may have conducted an experiment yielding a level of viral activity which was greater than permitted under the terms of the grant. The NIH gave WIV several opportunities to address and/or rebut the NIH determination, but WIV failed to do so. WIV conducted an experiment that violated the terms of the grant regarding viral activity, which possibly did lead or could lead to health issues or other unacceptable outcomes. WIV was an active NIH grant subrecipient from 2014 through 2020. WIV's refusal to acknowledge or provide any information regarding this violation to the United States Government, in accordance with the terms of the grant, constitutes an aggravating factor.

Considering the length of time that lapsed during WIV's performance as a grant subrecipient, the potential health consequences and repercussions stemming from their violations, and their failure to respond to NIH's investigation and this Notice and ARM (as further explained below), represents that there is continued potential harm and health risks caused by WIV's violations. I consider this an aggravating factor for consideration that supports my decision to debar WIV for a period of ten years.

- *2 C.F.R § 180.860(r) – Whether you have had adequate time to eliminate the circumstances within your organization that led to the cause for the debarment.*

As stated in the July 17, 2023, Notice and ARM, the information in the record established that the NIH requested WIV's original laboratory notebook entries and original electronic files to support the information that was reported relating to Grant Number 5R01AI110964-05 to address the NIH's concern that WIV had yielded a greater than 1 log increase in viral activity in violation of the grant. The NIH requested these materials on at least two documented occasions, November 5, 2021, and January 6, 2022. To date, the NIH has not received the requested materials from WIV through EcoHealth (as the pass-through entity on behalf of WIV).

In summary, nearly two years have passed since the NIH first requested that WIV provide the requested information and materials, and yet WIV has still failed to do so. During this time, WIV did not provide any responses or offer any explanations indicating the reason for its inability or unwillingness to provide the requested materials to the NIH.

WIV's refusal to acknowledge or provide any information regarding this violation to the Government, in accordance with the terms and conditions of the grant, constitutes an aggravating factor.

Therefore, I have determined that WIV's failure to provide the requested grant materials, while having an adequate amount of time to do so, is an aggravating factor for consideration and additionally supports my decision to debar WIV for a period of ten years.

- *2 C.F.R. § 180.860(s) – Other factors that are appropriate to the circumstances of a particular case.*

As stated in the July 17, 2023, Notice and ARM, the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, which are applicable to all HHS awards, require non-Government entities (non-Federal entities) to grant access to any documents, papers, or other records of the non-Federal entity that are pertinent to the federal award, and require that a subrecipient of a federal award permit the pass-through entity and auditors to have access to the subrecipient's records and financial statements as necessary for the pass-through entity. *See* 45 C.F.R. §§ 75.364(a); 75.352. WIV signed the subcontract/consultant agreements with EcoHealth, thereby certifying that it would comply with all applicable Government regulations.

In summary, WIV's failure to provide the NIH or EcoHealth with access to its original laboratory notebook entries and original electronic files to support its research, as discussed above, reflect WIV's noncompliance with Government award regulations. To date, WIV has not acknowledged or corrected this violation, nor has WIV provided any information to demonstrate that it would comply with Government award regulations were it to receive any future HHS awards or subawards. This speaks to WIV's lack of present responsibility to participate in Government procurement and nonprocurement programs, and constitutes an aggravating factor.

Therefore, I have determined that WIV's noncompliance with Government award regulations, and failure to acknowledge and correct this violation, is an aggravating factor for consideration that additionally supports my decision to debar WIV for a period of ten years.

I have reviewed the other factors listed under 2 C.F.R. §180.860(b)-(q) and have determined that these factors are either not applicable or not relevant to the circumstances of this case, or otherwise there is not enough information in the record for me to assess the applicability of these factors to this case. Since WIV did not respond to the July 17, 2023, Notice and ARM, there is no genuine dispute over facts material to the debarment cause at issue here. WIV has not acknowledged the violations, has not cooperated with the Government to address the violations, has not accepted responsibility for the violations, and, therefore, presumably has taken no action to eliminate the risk to the Government in conducting business transactions with WIV presently or into the future.

CONCLUSION

As the HHS SDO, based on information presented in the ARM regarding the seriousness of the misconduct, and the aggravating factors set forth in this document, I have determined that a ten-year debarment period for WIV is necessary to protect the Government's interests.

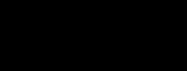
THEREFORE, WIV:

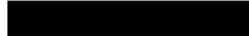
- () remains suspended pending the completion of an investigation or resulting legal or debarment proceeding.
- (X) is debarred, effective upon the date of the suspending and debarring official's endorsement of this Determination from participation in federal procurement and nonprocurement programs as stated in the Notice, dated July 17, 2023.**

As stated in the Notice of Suspension and Proposed Debarment, WIV's name will be published in the General Services Administration's web-based System for Award Management (SAM) at www.sam.gov as:

- () suspended pending the completion of an investigation or resulting legal or debarment proceeding.
- () suspended until [DATE], (which may be extended by six months, under 2 C.F.R. § 180.760(b)).
- (X) debarred until close of business: July 16, 2033. The period of ineligibility during the suspension and proposed debarment, which was effective July 17, 2023, is included in this ten-year period of debarment.**

Approved by:

 Digitally signed by
Date: 2023.09.19
17:47:48 -04'00'


Suspension and Debarment Official and
Deputy Assistant Secretary for Acquisition

cc: Dr. Zhengli Shi
Principal Investigator, WIV
E-mail: zlshi@wh.iov.cn