



June 2023

FEDERAL RESEARCH

NIH Could Take Additional Actions to Manage Risks Involving Foreign Subrecipients

Accessible Version

Why GAO Did This Study

Federal agencies sometimes provide funds to foreign entities, such as universities and laboratories, for research or other purposes. Such collaborations can benefit agency missions and lead to advancements in areas such as public health. At the same time, Congress, the White House, and others have expressed concerns about entities from countries, such as China, exploiting U.S. funded research in ways that could harm U.S. national security or economic competitiveness.

GAO was asked to provide information on federal funds disbursed to three selected Chinese entities—Wuhan University; the Wuhan Institute of Virology; and the Academy of Military Medical Sciences.

This report examines, among other things, the amount of federal funding GAO identified that was provided to the three selected Chinese entities in calendar years 2014 through 2021 and steps agencies and award recipients have taken to assess risks.

GAO searched USAspending.gov and other federal databases and reviewed award agreements, progress reports, payment information, and other documents from federal agencies and U.S.-based award recipients. GAO also interviewed federal officials and the U.S. award recipients.

What GAO Recommends

GAO is recommending that NIH evaluate and, as appropriate, implement actions—such as changes to its internal processes—to more quickly improve its oversight of awards with foreign subrecipients. The agency concurred with the recommendation.

View [GAO-23-106119](#). For more information, contact Candice N. Wright at (202) 512-6888 or wrightc@gao.gov.

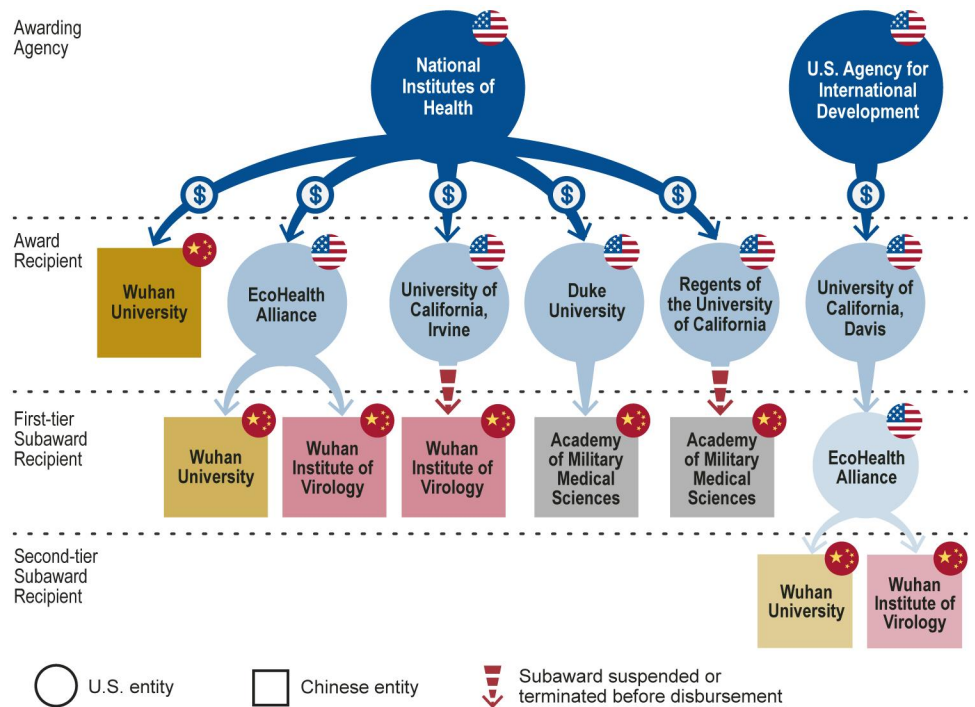
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What GAO Found

All three of the selected Chinese entities GAO was asked to provide information on, received research funds in calendar years 2014 through 2021, whether directly through a federal award or indirectly through subawards to carry out part of the work of a federal award. Specifically, the National Institutes of Health (NIH) provided \$200,000 in grant funding to Wuhan University, the only selected Chinese entity to receive funding directly from a federal agency. However, all three selected entities collectively received seven subawards, totaling over \$2 million, from federal award recipients or a first-tier subrecipient (see figure).

Awards and Subawards Identified to Three Selected Chinese Entities, Calendar Years 2014-2021



Source: GAO analysis of agency and award recipient funding data and documents. | GAO-23-106119

Accessible Data for Awards and Subawards Identified to Three Selected Chinese Entities, Calendar Years 2014-2021

Relationship between awarding agencies and award recipients:

1. National Institutes of Health (awarding agency)
 - a. Wuhan University (award recipient, Chinese entity)
 - b. EcoHealth Alliance (award recipient, U.S. entity)
 - i. Wuhan University (First-tier subaward recipient, Chinese entity)
 - ii. Wuhan Institute of Virology (first-tier subaward recipient, Chinese entity)
 - c. University of California, Irvine (award recipient, U.S. entity)

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Abbreviations

AMMS	Academy of Military Medical Sciences
COVID-19	coronavirus disease 2019
CY	calendar year
DNA	deoxyribonucleic acid
EAR	Export Administration Regulations
EPT	Emerging Pandemic Threats Program
FACTS	Foreign Award and Component Tracking System
FAIN	Federal Award Identification Number
FBI	Federal Bureau of Investigation
FFATA	Federal Funding Accountability and Transparency Act of 2006
FSRS	FFATA Subaward Reporting System
GPS	NIH Grants Policy Statement
HHS	Department of Health and Human Services
HHS-OIG	HHS Office of Inspector General
HIV	human immunodeficiency virus

KSHV	Kaposi's sarcoma-associated herpesvirus
MERS	Middle East respiratory syndrome
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
OMB	Office of Management and Budget
R&D	research and development
RNA	ribonucleic acid
SAM	System for Award Management
SARS	severe acute respiratory syndrome
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
USAID	U.S. Agency for International Development
WIV	Wuhan Institute of Virology

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June 14, 2023

Congressional Requesters

Federal agencies sometimes provide funds to foreign entities, such as universities and laboratories, for research or other purposes. Such collaborations can enhance agencies' ability to carry out their missions, potentially benefiting the U.S. economy or advancing areas such as public health. Further, collaborations with foreign entities can provide the U.S. with access to talent or other resources worldwide and support the acquisition of new scientific knowledge and understanding. In fiscal year 2020, federal agencies obligated about \$1.4 billion for research and development (R&D) with foreign entities.¹

At the same time, Congress, the White House, and others have expressed concerns about entities from certain foreign countries, such as China, exploiting U.S. funded research in ways that could harm U.S. national security or economic competitiveness.² In December 2020, we reported that the Department of Justice had announced the conviction and sentencing of a researcher at a U.S. university, who had failed to disclose conflicts of interest prior to receiving federal funds for biomedical research. Specifically, the researcher did not inform the federal awarding agency of his membership in a Chinese government talent recruitment program or his simultaneous employment at two different Chinese universities where he was conducting similar research. We also reported that some federal agencies lacked clear enforcement procedures for

¹National Science Foundation, National Center for Science and Engineering Statistics, Federal Funds for Research and Development (Alexandria, Va.: Apr. 28, 2022). The U.S. obligated about \$167 billion for R&D in fiscal year 2020. Federally funded research can include basic research, which is experimental or theoretical research to acquire knowledge of fundamental aspects of phenomena and of observable facts. The federal government also funds applied research, which is directed toward a specific practical aim or objective, and funds "experimental development" to improve R&D processes or produce new ones. See Office of Management and Budget, *Preparation, Submission, and Execution of the Budget*, Circular No. A-11 (Washington, D.C.: Aug. 2021).

²See, for example, *National Security Presidential Memorandum 33: United States Government-Supported Research and Development National Security Policy* (Washington, D.C.: Jan. 14, 2021) and GAO, *China: Efforts Underway to Address Technology Transfer Risk at U.S. Universities, but ICE Could Improve Related Data*, [GAO-23-106114](#). (Washington, D.C.: Nov. 15, 2022).

policies aimed at combatting undue foreign influence in U.S. funded research.³

You asked us to provide information on federal funds disbursed to three selected Chinese entities in calendar years (CY) 2014 through 2021—Wuhan University, the Wuhan Institute of Virology (WIV), and China’s Academy of Military Medical Sciences (AMMS). The selected entities are government institutions or laboratories in China that conduct work on infectious diseases, including pandemic viruses, and have had actions taken by federal agencies to address safety or security concerns.⁴ This report describes (1) the funding we identified that was provided to the selected Chinese entities in CY 2014 through 2021, (2) the purpose and results of the funding identified, and (3) agency and award recipient steps to assess risks.

To identify funding, we searched federal award databases, including USAspending.gov and agency databases, for any awards or first-tier subawards made to the three selected Chinese entities in CY 2014 through 2021. USAspending.gov is the official government-wide source of federal spending data; it includes data submitted by agencies on their awards to award recipients and by those award recipients on their first-tier subawards, as applicable. To identify disbursements for the awards and subawards that we identified, we collected and reviewed award and subaward agreements, payment authorizations, budget proposals, and other documents, and we interviewed federal awarding agencies and U.S.-based award recipients that provided funding to the three selected Chinese entities. To describe the purpose and results of funding provided to the selected Chinese entities from CY 2014 through 2021, we reviewed relevant award documents, including research proposals and progress reports. To describe agency and award recipient steps to assess risks,

³Undue foreign influence could include financial conflicts of interest by foreign participants in U.S. funded research or the diversion of knowledge or intellectual property to participants’ home countries. See GAO, *Federal Research: Agencies Need to Enhance Policies to Address Foreign Influence*, [GAO-21-130](#). (Washington, D.C.: Dec. 17, 2020). According to a Department of Justice press release from May 11, 2020, and Department of Health and Human Services (HHS) officials, the FBI and its federal partners, including HHS, co-investigated the U.S. researcher and the National Institutes of Health (NIH) within HHS provided assistance and witness testimony that helped secure the verdict and conviction.

⁴For example, in December 2021, the Department of Commerce added AMMS and 11 AMMS subunits to its “Entity List” of organizations that may be involved in activities contrary to U.S. national security or foreign policy. Additionally, in May 2020, the National Institutes of Health directed a grant recipient to suspend its subaward to WIV, because of reports that work at WIV posed serious biosafety concerns.

we collected agency policies and other documents and interviewed agency officials and U.S.-based award recipients on steps they took to assess risks associated with some of the awards and subawards we identified. See appendix I for more information on the objectives, scope, and methodology.

We conducted this performance audit from June 2022 to June 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for any findings and conclusions based on our audit objectives.

Background

Federal research funds are generally provided directly by a federal agency to an award recipient or indirectly through a U.S. or foreign award recipient to a subrecipient. An award recipient is an entity, either foreign or domestic, that receives an award directly from a federal awarding agency.⁵ A subrecipient is an entity that receives funds to carry out part of the work. The subrecipient receives the funds through a subaward from the award recipient, typically through a grant, contract, or cooperative agreement.⁶ This entity is referred to as a first-tier subrecipient. These subrecipients, in turn, can pass on a portion of the funds to other subrecipients (second-tier, third-tier, etc.).

Agencies report information on funds provided to award recipients, which, in turn, is made available to the public on [USAspending.gov](https://www.usaspending.gov), in accordance with the reporting requirements in the Federal Funding Accountability and Transparency Act of 2006 (FFATA), as amended. The website also includes subaward data reported by award recipients in the government-wide FFATA Subaward Reporting System (FSRS). Award

⁵See 2 C.F.R. § 200.1.

⁶See 2 C.F.R. § 200.1.

recipients provide data on first-tier subawards in FSRS to meet the FFATA reporting requirements.⁷

We previously reported that a federal awarding agency has a direct relationship with an award recipient but has no direct relationship with subrecipients.⁸ Information on federal funds provided through subawards is not fully known because of limitations in the data provided in response to federal reporting requirements for subawards.⁹ Specifically:

- Award recipients are required to report information on first-tier subawards that are \$30,000 or more.¹⁰ Information on subawards that

⁷In accordance with FFATA and implementing guidance, agencies are required to disclose certain information about federal awards that equal or exceed the micro-purchase threshold on a single public-facing, searchable website. In addition, award recipients are required to report specified information on first-tier subawards—with some exceptions—associated with these awards in FSRS. The goal of the reporting is to increase transparency and publicly available information on federal spending. Since 2010, agencies have required award recipients to report subaward information in FSRS. Pub L. No. 109-282, 120 Stat. 1186 as amended by The Digital Accountability and Transparency Act of 2014, Pub. L. No. 113-101, 128 Stat. 1146 (codified as amended at 31 U.S.C. § 6101 note); 2 C.F.R. pt. 170. 2 C.F.R. part 170, which includes guidance for FFATA required recipient subaward reporting for grants and cooperative agreements, defines recipient as “a non-Federal entity or Federal agency that received a Federal award.” 2 C.F.R. § 170.332.

⁸See GAO, *Federal Research: Information on Funding for U.S.-China Research Collaboration and Other International Activities*, [GAO-22-105313](#) (Washington, D.C.: Sept. 29, 2022).

⁹In August 2020, OMB issued final guidance revising sections of its Guidance for Grants and Agreements. The Supplemental Information portion of the Federal Register Notice issuing this guidance noted as part of its response to comments that federal agencies do not have a direct relationship with subrecipients. Guidance for Grants and Agreements, 85 Fed. Reg. 49506, 49508 (Aug. 13, 2020) (codified at 2 C.F.R. pts. 25, 170, 183, and 200).

¹⁰2 C.F.R. part 170 includes implementing guidance to federal awarding agencies on recipient reporting of subawards in accordance with the FFATA, as amended, for grants and cooperative agreements. It also includes an award term for inclusion in federal awards that meet the funding threshold regarding recipient subaward reporting requirements. This award term also exempts recipients that, in the previous tax year, had a gross income, from all sources, under \$300,000 from reporting subawards. In addition, the requirements of 2 C.F.R. part 170 do not apply to individuals who receive a federal award and allow for the Office of Management and Budget (OMB) to exempt classes of federal awards or recipients when exceptions are not prohibited by statute. See 2 C.F.R. § 170.110 (b), (c). Effective November 12, 2020, OMB raised the first-tier subaward reporting threshold for grants and cooperative agreements from \$25,000 to \$30,000, as part of a revision to its guidance. See Guidance for Grants and Agreements 85 Fed. Reg. 49506, 49526 (Aug. 13, 2020) (codified at 2 C.F.R. pt. 170 Appendix A).

fall below \$30,000 and those below the first tier (e.g., second tier or third tier) is not required to be reported in government-wide systems.

- According to OMB guidance, the quality of data that award recipients report in FSRS is the legal responsibility of the award recipient.¹¹ The guidance further provides that agencies are not required to certify the quality of subaward data reported in FSRS and made available on USAspending.gov.¹²

We have issued several reports that identify opportunities to enhance the quality of agencies' spending data.¹³ For example, in July 2022, we reported that Offices of Inspector General (OIG) identified a variety of issues with the quality of agency spending data reported in systems such as USAspending.gov. GAO previously recommended in March 2022 that Congress consider amending the Digital Accountability and Transparency Act of 2014 to extend the requirement for OIGs to review the completeness, timeliness, quality, and accuracy of their agencies' spending data submissions periodically. Extending the requirement for ongoing OIG oversight through periodic reviews could help ensure the quality of data reported in USAspending.gov continues to improve and provide transparency about where federal dollars are being spent.

All Three Selected Chinese Entities Received Funds

One of the three selected Chinese entities, Wuhan University, received a total of \$200,000 from NIH during the period from CY 2014 through 2021,

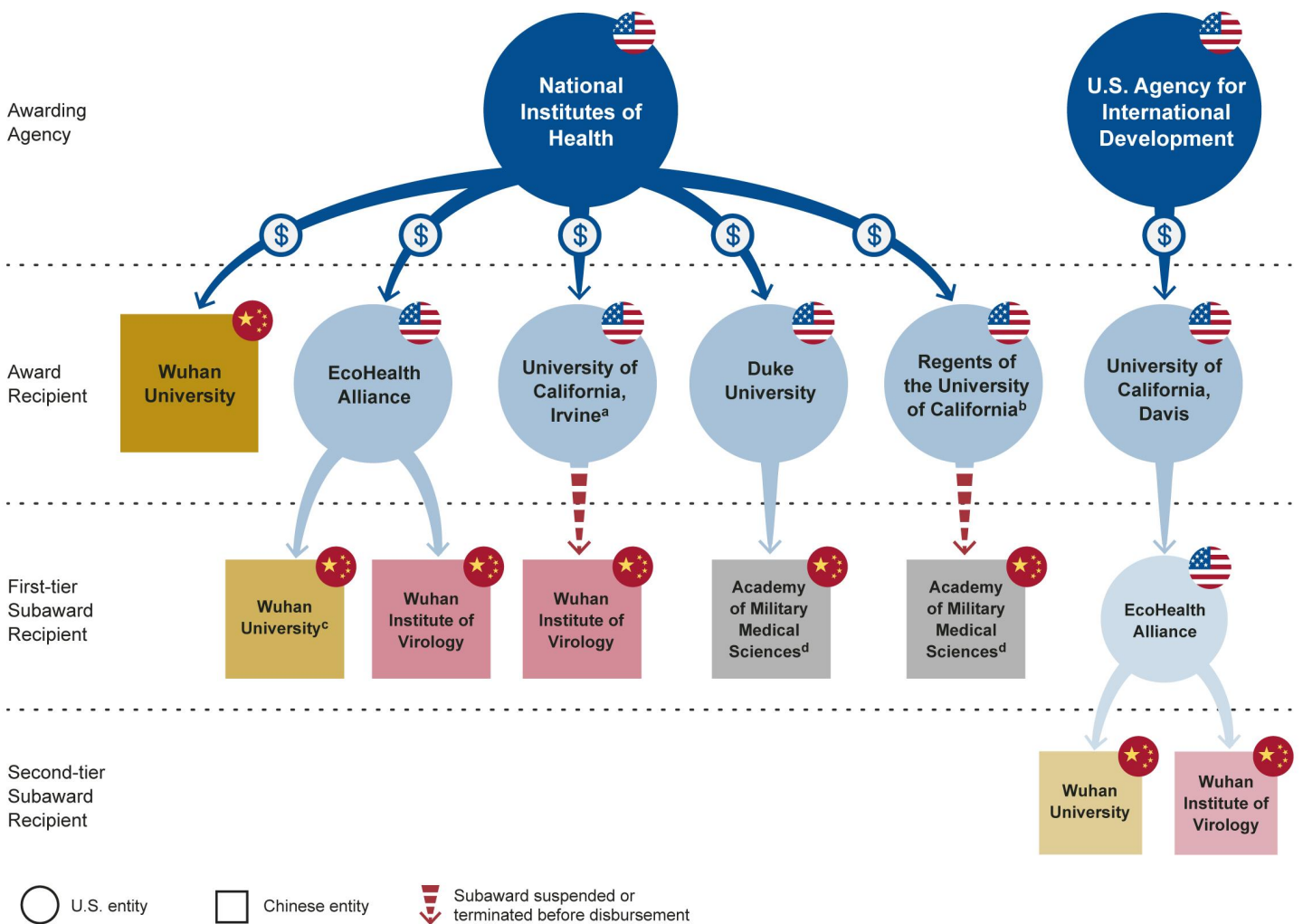
¹¹See OMB, *Management of Reporting and Data Integrity Risk*, Appendix A to OMB Circular No. A-123, M-18-16 (June 6, 2018).

¹²OMB, *Management of Reporting and Data Integrity Risk*, Appendix A to OMB Circular No. A-123, M-18-16 (June 6, 2018). According to the same OMB guidance, agencies are responsible for resolving audit findings that may indicate if recipients are not complying with subaward reporting requirements. In addition, certain audits undertaken in accordance with the Single Audit Act include a compliance review of FFATA required subaward data. 2 C.F.R. pt. 200, Appendix XI, 3-L-1, July 2022. (This Compliance Supplement identifies compliance requirements expected to be considered as part of an audit required by the 1996 Amendments to the Single Audit Act.)

¹³See GAO, *Federal Spending Transparency: OIGs Identified a Variety of Issues with the Quality of Agencies' Data Submissions*, GAO-22-105427, (Washington, D.C.: July 12, 2022); *Federal Spending Transparency: Opportunities Exist to Further Improve the Information Available on USAspending.gov*, [GAO-22-104702](#) (Washington, D.C.: Nov. 8, 2021); *Data Act: Quality of Data Submissions Has Improved but Further Action Is Needed to Disclose Known Data Limitations*, [GAO-20-75](#) (Washington, D.C.: Nov. 8, 2019).

according to our analysis. During the same period, all three Chinese entities received over \$2 million, combined, through seven subawards we identified which were made by award recipients or another subrecipient (see fig. 1).

Figure 1: Awards and Subawards Identified to the Three Selected Chinese Entities, Calendar Years 2014–2021



Source: GAO analysis of agency and award recipient funding data and documents. | GAO-23-106119

Accessible Data for Figure 1: Awards and Subawards Identified to the Three Selected Chinese Entities, Calendar Years 2014–2021

- Relationship between awarding agencies and award recipients:
1. National Institutes of Health (awarding agency)
 - a. Wuhan University (award recipient, Chinese entity)

- b. EcoHealth Alliance (award recipient, U.S. entity)
 - i. Wuhan University (First-tier subaward recipient, Chinese entity)
 - ii. Wuhan Institute of Virology (first-tier subaward recipient, Chinese entity)
 - c. University of California, Irvine (award recipient, U.S. entity)
 - i. Wuhan Institute of Virology (first-tier subaward recipient, Chinese entity), subaward was suspended before disbursement
 - d. Duke University (award recipient, U.S. entity)
 - i. Academy of Military Medical Sciences (first-tier subaward recipient, Chinese entity)
 - e. Regents of the University of California (award recipient, U.S. entity)
 - i. Academy of Military Medical Sciences (first-tier subaward recipient, Chinese entity), subaward was terminated before disbursement
2. U.S. Agency of International Development (awarding agency)
- a. University of California, Davis (award recipient, U.S. entity)
 - i. EcoHealth Alliance (first-tier subaward recipient, U.S. entity)
 - 1. Wuhan University (second-tier subaward recipient, Chinese entity)
 - 2. Wuhan Institute of Virology (second-tier subaward recipient, Chinese entity)

Note: The figure may not reflect all funds to the three selected Chinese entities in calendar years 2014 through 2021, in part, because information on subawards that fall below \$30,000 and those below the first tier (e.g., second tier or third tier) is not required to be reported in government-wide systems.

³According to documents and a University of California, Irvine, representative, the University suspended the subaward at the direction of the National Institutes of Health in May 2020 due to biosafety concerns at the Wuhan Institute of Virology (WIV) cited by the agency. The University did not disburse funds to WIV, including for work already performed from August 2019 and through February 2020.

⁴According to documents and University of California representatives, the subaward—which was provided to the Beijing Institute of Microbiology and Epidemiology, a subunit of the Academy of Military Medical Sciences (AMMS)—was terminated and no funds were disbursed.

⁵The Wuhan University School of Public Health, a subunit of Wuhan University, received funds for this subaward.

⁶The Beijing Institute of Microbiology and Epidemiology, a subunit of AMMS, received funds for this subaward.

Federal Funding Provided Directly to the Selected Chinese Entities through Awards

NIH reported providing an award to one selected Chinese entity—Wuhan University—in the CY 2014 through 2021 period. The other two selected Chinese entities, WIV and AMMS, did not receive any awards directly from federal agencies during the same period, according to our review of federal award databases (see fig. 2).

Figure 2: Federal Funding Provided Directly from Agencies to the Three Selected Chinese Entities, Calendar Years 2014–2021

Selected Chinese Entity	Awarding Agency	Period of Performance	Award Mechanism	Number of Awards	Total Funds Disbursed
Wuhan University <i>Federal Award Identification Number: R01AI116442</i>	National Institutes of Health (NIH)	March 2018 - February 2020	Grant	1	\$200,000 ^a
Wuhan Institute of Virology	—	—	—	—	—
Academy of Military Medical Sciences	—	—	—	—	—

Source: GAO analysis of federal data. | GAO-23-106119

Accessible Data for Figure 2: Federal Funding Provided Directly from Agencies to the Three Selected Chinese Entities, Calendar Years 2014–2021

Selected Chinese Entity	Awarding Agency	Period of Performance	Award Mechanism	Number of Awards	Total Funds Disbursed (in dollars)
Wuhan University <i>(Federal Award Identification Number: R01AI116442)</i>	National Institutes of Health (NIH)	March 2018 – February 2020	Grant	1	200,000 ^a
Wuhan Institute of Virology	no federal awards reported	no federal awards reported	no federal awards reported	no federal awards reported	no federal awards reported

Selected Chinese Entity	Awarding Agency	Period of Performance	Award Mechanism	Number of Awards	Total Funds Disbursed (in dollars)
Academy of Military Medical Sciences	no federal awards reported	no federal awards reported	no federal awards reported	no federal awards reported	no federal awards reported

Note: (-) indicates no federal awards reported by federal agencies.

³According to NIH officials and documents, NIH initially awarded the grant in 2015 to the Institut Pasteur of Shanghai. From March 2015 through January 2018, NIH disbursed \$310,230 to the Institut Pasteur of Shanghai. The award was transferred to Wuhan University in 2018, when the Principal Investigator changed institutions.

According to NIH officials and documents, the NIH-funded award to Wuhan University was initially awarded in 2015 to the Institut Pasteur of Shanghai. From March 2015 through January 2018, NIH disbursed \$310,230 to the Institut Pasteur of Shanghai for the award. In 2018, the Principal Investigator moved to Wuhan University, and NIH approved the award's transfer. NIH officials stated that the Institut Pasteur of Shanghai agreed to the transfer in a statement indicating the institute did not wish to replace the Principal Investigator in order to keep the grant. From March 2018 through the award's completion in February 2020, NIH disbursed \$200,000 to Wuhan University for the award.

NIH officials told us the agency did not provide other awards to any of the three selected Chinese entities during the CY 2014 through 2021 period, and we did not identify any other federal funds directly from NIH or other federal agencies to the three entities for this period.

Subaward Funding Identified to the Three Selected Chinese Entities

All three selected Chinese entities received first-tier subawards from award recipients or second-tier subawards from another subrecipient.¹⁴ Specifically, we identified seven subawards to the three entities:

- **Wuhan University:** Two subawards totaling \$240,496 disbursed,
- **WIV:** Three subawards totaling \$1,413,720 disbursed, and
- **AMMS:** Two subawards totaling \$514,129 disbursed.

¹⁴This list of subawards may not be comprehensive. It includes subawards we were able to identify through government-wide systems or interviews.

We obtained the information on disbursements to the three selected Chinese entities from the U.S.-based institutions, including universities and EcoHealth Alliance, which made the subawards. Funding was disbursed under five of the seven subawards to the selected entities in calendar years 2014 through 2021. Two of the subawards—one from the University of California, Irvine, was suspended and one from the Regents of the University of California was terminated—before any funding was disbursed to the selected Chinese entities, according to award documents and written responses from university representatives (see fig. 3). Five of the seven subawards we identified were first-tier subawards provided by award recipients of NIH-funded grants. The other two subawards—which were funded through a cooperative agreement from the U.S. Agency for International Development (USAID)—were second-tier subawards provided by a first-tier subrecipient, EcoHealth Alliance.

Figure 3: Subaward Funding Identified to the Three Selected Chinese Entities, Calendar Years 2014–2021

Selected Chinese Entity	Awarding Agency	Award Recipient	Subaward Level	Subaward Period of Performance	Subaward Funds Disbursed	Total Subaward Funds Disbursed
Wuhan University	NIH	EcoHealth Alliance <i>FAIN: R01AI110964</i>	First-tier	June 2015 - May 2017	\$201,221 ^a	\$240,496
	USAID	University of California, Davis <i>FAIN: AIDOAAA1400102</i>	Second-tier ^b	September 2016	\$39,275	
Wuhan Institute of Virology	NIH	EcoHealth Alliance ^c <i>FAIN: R01AI110964</i>	First-tier	June 2014 - May 2019	\$598,611	\$1,413,720
		University of California, Irvine <i>FAIN: RF1MH120020</i>	First-tier	August 2019 - May 2020	\$0 ^d	
	USAID	University of California, Davis <i>FAIN: AIDOAAA1400102</i>	Second-tier ^b	October 2014 - September 2019	\$815,109	
Academy of Military Medical Sciences ^e	NIH	Duke University <i>FAIN: R01AI108993</i>	First-tier	August 2014 - July 2019	\$514,129	\$514,129
		Regents of the University of California <i>FAIN: R01AI125842</i>	First-tier	February 2017 - January 2018	\$0 ^f	

FAIN Federal Award Identification Number
 NIH National Institutes of Health
 USAID U.S. Agency for International Development

Source: GAO analysis of award recipient documents and interviews. | GAO-23-106119

Accessible Data for Figure 3: Subaward Funding Identified to the Three Selected Chinese Entities, Calendar Years 2014–2021

Selected Chinese Entity	Awarding Agency	Award Recipient	Subaward Level	Subaward Period of Performance	Subaward Funds Disbursed (in dollars)	Total Subaward Funds Disbursed (in dollars)
Wuhan University	National Institutes of Health (NIH)	EcoHealth Alliance <i>Federal Award Identification Number (FAIN): R01AI110964</i>	First-tier	June 2015 – May 2017	201,221 ^a	240,496
Wuhan University	U.S. Agency for International Development (USAID)	University of California, Davis <i>(FAIN: AID0AAA1400102)</i>	Second-tier ^b	September 2016	39,275	240,496
Wuhan Institute of Virology	NIH	EcoHealth Alliance ^c <i>(FAIN: R01AI110964)</i>	First-tier	June 2014 – May 2019	598,611	1,413,720
Wuhan Institute of Virology	NIH	University of California, Irvine <i>(FAIN: RF1MH120020)</i>	First-tier	August 2019 – May 2020	0 ^d	1,413,720
Wuhan Institute of Virology	USAID	University of California, Davis <i>(FAIN: AID0AAA1400102)</i>	Second-tier ^b	October 2014 – September 2019	815,109	1,413,720
Academy of Military Medical Sciences ^e	NIH	Duke University <i>(FAIN: R01AI108993)</i>	First-tier	August 2014 – July 2019	514,129	514,129
Academy of Military Medical Sciences ^e	NIH	Regents of the University of California <i>(FAIN: R01AI125842)</i>	First-tier	February 2017 – January 2018	0 ^f	514,129

Note: This figure reflects subawards we identified through government-wide systems or interviews and may not reflect all subawards provided to the three selected Chinese entities.

^aThe Wuhan University School of Public Health, a subunit of Wuhan University, received funds for this subaward.

^bUniversity of California, Davis, provided a first-tier subaward to EcoHealth Alliance, which provided funds to selected Chinese entities.

^cIn July 2019, NIH approved a 5-year renewal of the award to EcoHealth Alliance. Subsequently, in 2020, the award was terminated then reinstated and suspended. In November 2022, an EcoHealth Alliance representative told us that no new subaward under the renewal grant was made to Wuhan Institute of Virology (WIV), and there was no current relationship between EcoHealth Alliance and WIV for the NIH grant. For more information, see appendix II.

^dAccording to documents and a University of California, Irvine, representative, the University suspended the subaward at the direction of NIH in May 2020 due to biosafety concerns at WIV cited by the agency. The University did not disburse funds to WIV, including for work already performed from August 2019 through February 2020. The figure reflects the period of performance of the subaward through its suspension in May 2020. Because of the suspension, this period ended about 2 months earlier than the originally planned period of performance.

^eThe Beijing Institute of Microbiology and Epidemiology, a subunit of the Academy of Military Medical Sciences, received the two subawards we identified.

^fAccording to documents and University of California representatives, the subaward was terminated and no funds were disbursed, because the Principal Investigator chose to redirect funding toward project work at the University of California, Berkeley, where research for the NIH award was being conducted. The figure reflects the period of performance of the subaward, which, because of the termination, ended about 4 years earlier than the originally planned period of performance.

As noted above, two of the seven subawards to the three selected Chinese entities were suspended or terminated in 2020, and no funds were disbursed. The subaward from the University of California, Irvine, was suspended, and the subaward from the Regents of the University of California was terminated. The University of California, Irvine, informed WIV in May 2020 that it was suspending the award at the direction of NIH due to biosafety concerns cited by the agency.¹⁵ The University did not disburse funds for work performed by WIV from August 2019 through February 2020. A representative from the University told us in November 2022 that NIH approved the University's request to replace WIV with one of its own researchers; as a result, the University does not expect to resume the subaward to WIV.¹⁶ For the award from the Regents of the University of California to AMMS's Beijing Institute of Epidemiology and Microbiology, the Principal Investigator terminated the subaward before disbursing funds to the selected Chinese entity and redirected the funds for other project work, according to University representatives.

The figure above may not reflect all subawards provided to the three selected Chinese entities. As previously noted, not all subawards are required to be reported in FSRs, including subawards below \$30,000 or those that are below the first tier. In addition, the selected Chinese entities or their subunits may have received funds under another name, as was the case with the two subawards to AMMS. In these two instances, the subaward was made to the Beijing Institute of Microbiology and Epidemiology, a subunit of AMMS.

¹⁵In a letter to WIV, the University of California, Irvine, stated that it was suspending all subaward activities, effective May 20, 2020, at the direction of NIH. According to the letter, NIH had directed the University to suspend the subaward because of reports that WIV "has or is conducting research at its facilities that pose serious biosafety concerns." Further, NIH froze funding for the subaward, directed the University not to provide funds to WIV, and disallowed WIV expenses under the subaward.

¹⁶According to USAspending.gov in April 2023, the NIH grant to the University of California, Irvine, was ongoing and will end in July 2023.

Awards to the Three Selected Chinese Entities Funded Research on Viruses, Disease Surveillance, and Treatments


Funding to the three selected Chinese entities provided directly by NIH or through subawards supported research on therapeutic development, viruses, and disease surveillance. This work included collection and analysis of biological samples, genetic engineering, and surveys of study participants.

NIH Funded Wuhan University to Conduct Research on Therapeutics

Based on our review of NIH award documents, we determined that Wuhan University focused on new therapeutics to treat malignancies associated with Kaposi's sarcoma.¹⁷ According to award documents, Wuhan University researchers studied Kaposi's sarcoma-associated herpesvirus (KSHV), a health problem prevalent among individuals infected with HIV (see fig. 4). Wuhan University researchers identified a new host protein, providing unique and novel clues for targeted therapeutic developments to treat KSHV-related malignancies. This project also resulted in publications in peer-reviewed journals on the replication and persistence of KSHV.

¹⁷Kaposi's sarcoma is a type of cancer in which lesions grow in the skin, lymph nodes, lining of the mouth, nose, and throat, and other tissues of the body. It is caused by Kaposi's sarcoma-associated herpesvirus.

Figure 4: Reported Purpose, Activities, and Results of Federal Funding Provided Directly from Agencies to the Three Selected Chinese Entities, Calendar Years 2014–2021

Selected Chinese Entity	Awarding Agency	Type of Research	Purpose	Examples of Research Activities	Results
Wuhan University <i>Federal Award Identification Number: R01AI116442</i>	National Institutes of Health (NIH)	Basic	Therapeutic development	Study molecular mechanisms leading to Kaposi's sarcoma-associated herpesvirus to facilitate the development of new therapeutics. Study and identify viral genes and host interactions and functions of Kaposi's sarcoma-associated herpesvirus genome.	 Publications

Source: GAO analysis of NIH award documents. | GAO-23-106119

Accessible Data for Figure 4: Reported Purpose, Activities, and Results of Federal Funding Provided Directly from Agencies to the Three Selected Chinese Entities, Calendar Years 2014–2021








Selected Chinese Entity	Awarding Agency	Type of Research	Purpose	Examples of Research Activities	Results
Wuhan University <i>(Federal Award Identification Number: R01AI116442)</i>	National Institutes of Health (NIH)	Basic	Therapeutic development	Study molecular mechanisms leading to Kaposi's sarcoma-associated herpesvirus to facilitate the development of new therapeutics. Study and identify viral genes and host interactions and functions of Kaposi's sarcoma-associated herpesvirus genome.	Publications

Award Recipients Funded the Three Selected Chinese Entities to Collect Biological Samples, Analyze Viruses, and Study Disease Surveillance

Based on our review of award documents and interviews with award recipients and subrecipients, we determined that these recipients funded Wuhan University, WIV, and AMMS to conduct research activities such as collecting biological samples from study participants in China, administering questionnaires to Chinese participants, and conducting genetic research (see fig. 5).¹⁸

¹⁸NIH funding to the three selected Chinese entities, made directly or through subawards, supported therapeutic development, disease surveillance, and genetic engineering. USAID's funding to the selected entities, through second-tier subawards to Wuhan University and WIV, supported pathogen detection and disease surveillance activities.

Figure 5: Reported Purpose, Activities, and Results of Subaward Research Conducted by the Three Selected Chinese Entities, Calendar Years 2014–2021

Selected Chinese Entity	Awarding Agency	Award Recipient	Type of Research	Purpose	Examples of Research Activities	Subaward Results
Wuhan University	NIH	EcoHealth Alliance <i>FAIN: R01AI110964</i>	Basic	Disease surveillance	Collect biological samples from individuals in China with high levels of exposure to bats for Wuhan Institute of Virology to conduct further screening. Administer questionnaire and collect data from study participants in China.	 Publications
	USAID	University of California, Davis <i>FAIN: AIDOAAA1400102 (First-tier subrecipient: EcoHealth Alliance)</i>	Basic	Disease surveillance	Collect biological samples from 1,500 individuals with a range of exposure to bats, other animals and domestic wildlife. Administer questionnaire to collect data from individuals in high-risk communities. Collaborate with Wuhan Institute of Virology on viral detection.	 Publications
Wuhan Institute of Virology	NIH	EcoHealth Alliance <i>FAIN: R01AI110964</i>	Basic	Assess transmission of bat coronaviruses to humans	Conduct RNA extractions and DNA sequencing on bat samples. Conduct biological experiments on pathogen spillover from bats to humans. ^a	 Publications  Workshops
	NIH	University of California, Irvine <i>FAIN: RF1MH120020</i>	Basic	Genetic engineering and neural circuit analysis	Develop and test novel viral tools for neuronal tracing and gene delivery. ^b	No results identified; subaward was suspended.
	USAID	University of California, Davis <i>FAIN: AIDOAAA1400102 (First-tier subrecipient: EcoHealth Alliance)</i>	Basic	Pathogen detection	Conduct DNA barcoding of bat and rodent samples. Test human and animal samples from study sites in Yunnan and Guangdong provinces. Test, clone and sequence bat samples that test positive for viruses such as coronaviruses and influenza viruses.	 Publications  Workshops
Academy of Military Medical Sciences	NIH	Duke University <i>FAIN: R01AI108993</i>	Basic	Assess transmission of swine influenza virus to humans	Conduct focus groups. Collect biological samples from study participants and pigs, and environmental samples. Perform molecular detection of influenza in biological samples from Chinese swine workers.	 Publications
	NIH	Regents of the University of California <i>FAIN: R01AI125842</i>	Basic	Disease surveillance	Collect surveillance data on malaria and tuberculosis infections at the national, provincial, and county levels within China. ^c	No results identified; subaward was terminated.

FAIN Federal Award Identification Number
 NIH National Institutes of Health
 USAID U.S. Agency for International Development

Source: GAO analysis of award recipient and agency documents. | GAO-23-106119

Accessible Data for Figure 5: Reported Purpose, Activities, and Results of Subaward Research Conducted by the Three Selected Chinese Entities, Calendar Years 2014–2021

Selected Chinese Entity	Awarding Agency	Award Recipient	Type of Research	Purpose	Examples of Research Activities	Subaward Results
Wuhan University	National Institutes of Health (NIH)	EcoHealth Alliance <i>Federal Award Identification Number (FAIN): R01AI110964</i>	Basic	Disease surveillance	Collect biological samples from individuals in China with high levels of exposure to bats for Wuhan Institute of Virology to conduct further screening. Administer questionnaire and collect data from study participants in China.	Publications
Wuhan University	U.S. Agency for International Development (USAID)	University of California, Davis <i>(FAIN: AID0AAA1400102)</i> <i>(first-tier subrecipient: EcoHealth Alliance)</i>	Basic	Disease surveillance	Collect biological samples from 1,500 individuals with a range of exposure to bats, other animals and domestic wildlife. Administer questionnaire to collect data from individuals in high-risk communities. Collaborate with Wuhan Institute of Virology on viral detection.	Publications
Wuhan Institute of Virology	NIH	EcoHealth Alliance <i>(FAIN: R01AI110964)</i>	Basic	Assess transmission of bat coronaviruses to humans	Conduct RNA extractions and DNA sequencing on bat samples. Conduct biological experiments on pathogen spillover from bats to humans ^a	Publications; Workshops
Wuhan Institute of Virology	NIH	University of California, Irvine <i>(FAIN: RF1MH120020)</i>	Basic	Genetic engineering and neural circuit analysis	Develop and test novel viral tools for neuronal tracing and gene delivery ^b	No results identified; subaward was suspended

Letter

Selected Chinese Entity	Awarding Agency	Award Recipient	Type of Research	Purpose	Examples of Research Activities	Subaward Results
Wuhan Institute of Virology	USAID	University of California, Davis (FAIN: AIDOAAA1400102) (first-tier subrecipient: EcoHealth Alliance)	Basic	Pathogen detection	Conduct DNA barcoding of bat and rodent samples. Test human and animal samples from study sites in Yunnan and Guangdong provinces. Test, clone and sequence bat samples that test positive for viruses such as coronaviruses and influenza viruses.	Publications; Workshops
Academy of Military Medical Sciences	NIH	Duke University (FAIN: R01AI108993)	Basic	Assess transmission of swine influenza virus to humans	Conduct focus groups. Collect biological samples from study participants and pigs, and environmental samples. Perform molecular detection of influenza in biological samples from Chinese swine workers.	Publications
Academy of Military Medical Sciences	NIH	Regents of the University of California (FAIN: R01AI125842)	Basic	Disease surveillance	Collect surveillance data on malaria and tuberculosis infections at the national, provincial, and county levels within China. ^c	No results identified; subaward was suspended

^aThe transmission of pathogens from animals to humans is called “zoonotic spillover.”

^bAccording to documents and a University of California, Irvine, representative, the University suspended the subaward at the direction of the National Institutes of Health in May 2020 due to biosafety concerns at the Wuhan Institute of Virology (WIV) cited by the agency. The University did not disburse funds to WIV, including for work already performed from August 2019 through February 2020.

^cAccording to documents and University of California representatives, the subaward was terminated and no funds were disbursed.

All three selected Chinese entities collaborated with U.S. researchers on a range of research activities, which resulted in publications and workshops, as noted in figure 5. Specifically:

Wuhan University. The two subawards received by Wuhan University focused on disease surveillance. According to subaward documents, for

the first-tier subaward funded through NIH's grant to EcoHealth Alliance, Wuhan University was tasked with administering a questionnaire that includes questions on experiences with unusual illness and a range of human-animal contacts and collecting biological samples such as stool, sputum, and blood samples from study participants. For the second-tier subaward funded through USAID award recipient, University of California, Davis, Wuhan University was tasked with collecting biological samples from roughly 1,500 individuals in the Yunnan province with exposure to bats, other wildlife, and domestic animals and collaborating with WIV on viral detection. Based on our review of documents provided by awarding agencies and award recipients, we determined that both subawards resulted in publications.

WIV. The three subawards received by WIV focused on genetic engineering, pathogen detection, and the transmission of bat coronaviruses.¹⁹ For the NIH-funded award to EcoHealth Alliance, among other activities, WIV's activities included genetic experiments to combine naturally occurring bat coronaviruses with SARS and MERS viruses, resulting in hybridized (also known as chimeric) coronavirus strains. For the NIH-funded award to University of California, Irvine, according to award documents, WIV had expertise in neurovirology (herpesvirus, H129) and molecular biology and had previously developed a viral toolbox for H129-based anterograde circuit tracing in mice. For the second-tier subaward through USAID-funded award recipient, University of California, Davis, WIV researchers tested bat samples for five priority viral families such as influenza and conducted DNA sequencing of non-human biological samples. As noted in figure 5 above, two of the three subawards to WIV resulted in publications and workshops.²⁰ There were no result activities for the subaward from University of California, Irvine, because the subaward was terminated before funding was disbursed.

AMMS. The two subawards received by AMMS focused on the transmission of swine influenza virus and disease surveillance.²¹ According to research progress reports, AMMS researchers studied

¹⁹Coronaviruses are a family of viruses that can spread from animals to humans. The SARS-CoV-2 virus, which causes coronavirus disease 2019 (COVID-19), is one form of a coronavirus.

²⁰According to annual progress reports and EcoHealth Alliance representatives, EcoHealth Alliance and WIV researchers were invited to present their research at various universities, government agencies, and conferences.

²¹The two subawards were awarded under NIH grants to Duke University and the Regents of the University of California.

swine influenza transmission in confined animal feeding operations in China. Specifically, AMMS researchers conducted monthly sampling of participants to identify individuals who developed influenza-like illnesses. Examples of samples collected include swine fecal specimens, aerosol, water, swine farm environmental swab specimens, and human nasal washes. Based on our review of research progress reports, we determined AMMS's research resulted in several publications. There were no result activities for the Regents of the University of California subaward to AMMS because the subaward was terminated before funding was disbursed (see fig. 5, above).

Based on our review of award recipient documents, we determined that funds provided to the three selected Chinese entities were mainly used for salaries and wages. Additionally, Chinese entities used funds for materials and supplies, travel, and other costs such as staff vaccinations.

Federal Agencies and Award Recipients Described Certain Risk Assessments, but NIH Did Not Fully Consider Timely Actions to Manage Risks

Through agency documents and interviews, NIH and USAID officials and award recipients provided us with examples of risk assessments they conducted before and after funds were awarded for some of the awards or subawards we identified.²² In a January 2023 report, the HHS Office of Inspector General (HHS-OIG) reviewed NIH's actions for one of the awards we reviewed and recommended that NIH implement enhanced monitoring, documentation, and reporting requirements for award recipients with foreign subrecipients. In addition to the HHS-OIG's finding, we found that NIH had not taken near-term steps to manage risks for awards with foreign subrecipients.

²²This section provides examples of risk assessments that NIH and USAID told us they conducted before and after funds were awarded for some of the awards and subawards we identified above. This section also provides, for background purposes, a sample of selected, present-day NIH and USAID pre-award risk assessment policies. We did not review the agencies' policies under which these previous risk assessments were conducted, nor did we assess compliance with those policies or any risk-related grant conditions. As discussed in the body of the report and in appendix II, NIH placed risk-related conditions on the award we identified to EcoHealth Alliance.

Federal Agencies and Award Recipients Described Certain Risk Assessments

Some risk assessments conducted by NIH, USAID, and award recipients before funds were awarded, aimed to identify financial or performance risks or risks related to foreign policy or export controls. For example:

- To assist with identifying financial and performance risks for the 2015 award that was transferred in 2018 to Wuhan University, NIH officials said peer-reviewers, primarily from outside the agency, evaluated the scientific and technical merit of the research proposal.²³ USAID also conducted a merit review process for its award in 2014 to the University of California, Davis. As previously discussed, that award resulted in second-tier subawards from EcoHealth Alliance to Wuhan University and WIV in September 2016 and October 2014, respectively (see fig. 3). USAID also used the federal System for Award Management (SAM.gov) to verify that applicants were not prohibited from doing business with the federal government.²⁴

²³Currently, the *NIH Grants Policy Statement* (GPS) serves as the terms and conditions for NIH grant awards. *Grants Policy Statement* (December 2022) at page ii, Introduction. The current Peer Review Process specified by GPS outlines NIH's peer review requirements for scientific and technical merit of grant applications. *Grants Policy Statement*, sec. 2.4.1 (citing sections 406 and 492 of the PHS Act, as amended by the NIH Reform Act of 2006 and 21st Century Cures Act (see 2 U.S.C. § 289a, 289a-1(a)(2))). The current GPS also specifies when a detailed analysis of proposed costs or a review of applicants' financial systems and controls may be required. *Grants Policy Statement*, sec. 2.5.5.

²⁴For USAID, various sections of its grants policies—found in Chapter 303 of USAID's *Automated Directive System* (December 2022), or ADS—specify current requirements for reviewing proposals and conducting pre-award risk assessments, including reviewing applicants in the Federal Awardee Performance Integrity and Information Systems in SAM.gov and past performance information in USAID's own systems. See ADS sections 303.3.6.1-303.3.6.3, 303.3.9. In addition, prior to approving subawards, USAID staff are currently required to ensure that an applicant or award recipient has conducted its own risk assessment and verified that subaward recipients: (1) do not have active exclusions in SAM.gov, (2) do not appear on the U.S. Treasury Office of Foreign Assets Control List, and (3) are not on the United Nations Security Council Consolidated List. ADS sec. 303.3.9.

- For the award transferred to Wuhan University, NIH officials said the agency requested and obtained a U.S. State Department review of the potential award through NIH's Foreign Award and Component Tracking System (FACTS). In interviews, NIH officials described the general FACTS and State Department review process, as it is currently conducted, and provided current guidance for the process. According to this guidance, in general, NIH staff are to request a State Department review of potential awards involving a "foreign component," in which significant scientific work will be conducted outside of the U.S., whether by a grantee or by a researcher employed by a foreign organization.²⁵ The NIH officials said the results of State Department's reviews are advisory, and NIH institutes are ultimately responsible for deciding whether to make the award. Also according to the NIH officials, a FACTS review is to be conducted for subawards made by U.S. award recipients to foreign entities that meet the definition of "foreign component," regardless of the subaward tier.²⁶

For NIH, current regulations also require NIH officials to review applicants' information in SAM.gov prior to approving awards. 2 C.F.R. § 180.430 as adopted by HHS at 2 C.F.R. pt. 376. In addition, GPS section 2.3.7.8 requires NIH grant recipients to maintain current information in SAM.gov. GPS also currently requires NIH approval of subawards but only subawards for a fixed dollar amount in which the total subaward amount is negotiated up front. GPS sec. 8.1.2.11. A fixed amount award is a type of grant or cooperative agreement under which the federal awarding agency or award recipient with a subrecipient provides a specific level of support without regard to actual costs incurred under the federal award. See 2 C.F.R § 200.1.

²⁵*NIH Staff Guidance for Processing Extramural Awards with Foreign Components* (June 5, 2013) and NIH, *Foreign Award and Component Tracking System (FACTS) State Department User Guide*, (Sept. 28, 2022). According to the guidance, the State Department reviews research involving foreign components or locations. Intramural activities are excluded from FACTS. State Department's reviews are limited to advising that NIH-funded activities, if awarded, will not result in negative U.S. foreign policy implications. In addition, NIH officials knowledgeable about FACTS said that, after requests for State Department review are submitted through FACTS, NIH's Fogarty International Center reviews submissions and forwards the requests. If State Department takes no action within 14 days, a request is considered automatically approved. However, automatic approval does not apply to requests involving potential awards to China or India; those awards must undergo State Department review. Furthermore, NIH officials said that State Department approval is advisory, and NIH institutes and centers are ultimately responsible for deciding whether to make the award.

²⁶A "foreign component" is defined as "the performance of any significant scientific element or segment of a project outside of the U.S., either by the grantee or by a researcher employed by a foreign organization, whether or not grant funds are expended." See *NIH Staff Guidance for Processing Extramural Awards with Foreign Components* (June 5, 2013), and GPS part 1 section 1.2.

- For the August 2014 award from NIH to Duke University, University representatives told us the University’s export control office reviewed the subaward to the Beijing Institute of Microbiology and Epidemiology, a subunit of AMMS. According to a University representative, the subaward was allowed to go forward because the entity did not appear on any U.S. export control restricted party lists at the time, and there were no known military applications for the project, among other reasons.²⁷

Some risk assessments conducted by USAID and NIH before funds were awarded aimed to identify biosafety risks. For example:

- **NIH award to Wuhan University.** As noted in figure 2, above, this award was transferred to Wuhan University in 2018. NIH officials said that prior to awarding the grant in 2015, NIH staff assessed whether the proposed research fell under policies then in place related to specific areas of research requiring additional oversight. In effect at the time of award in 2015 was a temporary government-wide pause, later withdrawn, on new funding for “gain-of-function” research “reasonably anticipated” to enhance the pathogenicity or transmissibility of influenza, MERS, or SARS viruses in mammals via the respiratory route.²⁸ According to NIH officials, the proposed

²⁷In December 2021, after the period of performance of the NIH award to Duke University and the subaward to AMMS, the Bureau of Industry and Security in the Department of Commerce added AMMS and 11 AMMS subunits, including the Institute of Microbiology and Epidemiology, to the End-User Review Committee Entity List (Entity List). According to the final rule in the Federal Register, the Entity List identifies entities that may have been involved in activities contrary to national security or foreign policy interests of the U.S. or pose a significant risk. Addition of Certain Entities to the Entity List and Revision of an Entry on the Entity List 86 Fed. Reg. 71557, 71559 (Dec. 17, 2021) (amending the Export Administration Regulations (EAR) Entity List at 15 C.F.R. Appendix Supplement No. 4 to Part 744).

²⁸*U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses.* The government-wide funding pause was announced on October 17, 2014. The NIH director announced the decision to lift the funding pause for NIH on December 19, 2017. See “NIH Lifts Funding Pause on Gain-of-Function Research.” According to the announcement, the new framework guiding funding decisions, entitled, *Department of Health and Human Services Framework for Guiding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens*, was released on the same day as when NIH lifted the funding pause. We recently made recommendations to HHS on improving its oversight of such research under the framework. For more information, see GAO, *Public Health Preparedness: HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens*. [GAO-23-105455](#). (Washington, D.C.: Jan. 18, 2023).

research did not fall under the funding pause or other policies related to specific areas of research requiring additional oversight.²⁹

- **USAID award to University of California, Davis.** As shown in figure 3, above, this USAID award to the University of California, Davis, resulted in two second-tier subawards from EcoHealth Alliance, one to Wuhan University and the other to WIV. According to USAID’s solicitation for the October 2014 award to the University of California, Davis—which aimed to improve monitoring of zoonotic viruses with pandemic potential in multiple African and Asian countries under its PREDICT-2 project—the agency conducted an initial assessment of potential biosafety and environmental risks.³⁰ In the PREDICT-2 solicitation, USAID also required a mitigation and monitoring plan for such risks prior to the award recipient initiating the work. According to this plan, the University and other partners would be responsible for monitoring sites’ handling and disposal of hazardous medical wastes and for establishing animal and human viral surveillance capacity and plans to respond to an outbreak.³¹

NIH Did Not Take Near-Term Steps to Manage Risks for an Award with Foreign Subrecipients

One biosafety risk assessment conducted by NIH after funds were awarded to EcoHealth Alliance led to new award conditions. NIH subsequently asserted that EcoHealth Alliance had violated these new award conditions, but EcoHealth Alliance stated it had not. In January 2023, the HHS-OIG reviewed NIH’s and EcoHealth Alliance’s actions under this award and found that NIH did not always effectively monitor the

²⁹NIH officials told us that NIH staff also assessed whether the proposed research fell under other biosafety policies, such as an HHS framework on funding research involving avian influenza H5N1 viruses and policies on dual-use research of concern, which apply to research involving at least one of 15 viral agents or toxins. According to the officials, peer reviewers determined that research proposed for the award did not fall under these biosafety policies.

³⁰According to USAID’s April 2014 PREDICT-2 solicitation (request for application), PREDICT-2 is a 5-year project under the agency’s Emerging Pandemic Threats Program (EPT) and supports a follow-on effort of the initial 2009 EPT, which targeted the early detection of new diseases, preparedness and response, and risk reduction.

³¹According to USAID documents and officials, the October 2014 award to the University of California, Davis, began a few weeks prior to the gain-of-function research funding pause. Although the funding pause was not yet in place, according to USAID officials, the agency verified with the award recipient that there were no gain-of-function activities to necessitate a funding pause.

award or take timely action to address compliance with some requirements and made recommendations. We also found that NIH had not taken near-term steps to manage risks for awards with foreign subrecipients. Specifically:

NIH award to EcoHealth Alliance. As shown in figure 3, above, the award to EcoHealth Alliance, which began in 2014, resulted in subawards to Wuhan University and WIV in June 2015 and June 2014, respectively.³² According to a July 2016 letter from the National Institute of Allergy and Infectious Diseases (NIAID) and NIH officials—because the WIV award was in place before the October 2014 government-wide pause went into effect, temporarily, for new funding of certain gain-of-function research—NIH determined that the award did not fall under the funding pause, after reexamining EcoHealth Alliance’s proposal for the award and other information.³³ Nonetheless, in the grant budget period beginning June 2016, NIH added new award conditions on EcoHealth Alliance requiring that it (1) stop experiments with the specified viruses and (2) provide relevant data to NIH if the bat coronaviruses under experiment at WIV showed increased viral growth above a certain threshold.

In October 2021, NIH asserted that EcoHealth Alliance had violated these new award conditions and requested that EcoHealth Alliance submit unpublished data from experiments conducted by WIV. Later, NIH wrote to EcoHealth Alliance that it was terminating the subaward with WIV citing material noncompliance for, among other reasons, WIV’s failure to turn over that data. EcoHealth Alliance representatives told us they had not violated the award conditions. In January 2023, NIH officials told us that the grant remained suspended, and NIAID was renegotiating the renewal grant with EcoHealth Alliance. In April 2023, NIH continued its grant with

³²In July 2019, NIH approved a 5-year renewal of the award to EcoHealth Alliance. Subsequently, the award was terminated in 2020 and then reinstated and suspended. According to NIH officials in late March 2023, the award remained suspended pending a renegotiation with EcoHealth Alliance. In April 2023, NIH continued the award through April 2027. The agency obligated \$576,000 to the award on April 26, 2023, according to USAspending.gov. According to an April 2023 letter from NIH to EcoHealth Alliance, several new specific award conditions to enhance NIH’s oversight of EcoHealth Alliance will apply to the award. For additional information, see appendix II.

³³In a letter to EcoHealth Alliance dated July 7, 2016, NIAID officials stated that they had reexamined EcoHealth Alliance’s original grant application and supplemental information and determined that the research to generate coronaviruses was not subject to the gain-of-function research funding pause. See appendix II for more information.

EcoHealth Alliance through April 2027. See appendix II for more information.

In a January 2023 report, the HHS-OIG reviewed NIH's and EcoHealth Alliance's actions under this award.³⁴ The HHS-OIG found that NIH did not always effectively monitor the award or take timely action to address compliance with some requirements. Among other things, the HHS-OIG reported that:

- It agreed with NIH's assertion that EcoHealth Alliance did not properly notify NIH in a timely manner of research at WIV, which, according to NIH, exceeded the safety threshold outlined in the 2016 award conditions.
- At the same time, the HHS-OIG found that NIH had provided only limited guidance on how EcoHealth should comply with the award conditions and did not outline how to properly notify NIH about results that exceed the safety threshold.³⁵
- While NIH policies and government-wide regulations are designed to have an award recipient manage day-to-day monitoring of subrecipients' activities, according to the HHS-OIG report, NIH and HHS policies also require NIH to monitor award recipients, and NIH had missed other opportunities to more effectively monitor the award with EcoHealth Alliance.³⁶ The HHS-OIG further stated that, "with improved oversight, NIH may have been able to take more timely

³⁴HHS-OIG, *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*. A-05-21-00025. (Jan. 2023).

³⁵According to the January 2023 HHS-OIG report, after learning of the research results that exceeded the safety threshold, NIH requested that EcoHealth Alliance provide data and documentation from WIV. NIH did not receive this data and documentation, according to the HHS-OIG report, and EcoHealth Alliance confirmed that WIV did not cooperate with the request. According to the HHS-OIG report, oversight of subrecipients may depend on the level of cooperation between the recipient and subrecipient, and in certain countries, there may be a risk that larger political or governmental issues may impede cooperation.

³⁶The HHS-OIG noted in the January 2023 report that, while award recipients are responsible for managing the day-to-day operations of grant supported activities, section 8.4 of GPS and Part H, Chapter 2, of HHS's Grants Policy Administration Manual, collectively, require active monitoring of awards by NIH's awarding institutes and centers through reviews of reports, including annual progress reports, and correspondence from the award recipient, annual documentation of award recipients' performance and compliance, and other monitoring.

corrective actions to mitigate the inherent risks associated with this type of research.”

The HHS-OIG made several recommendations, including a recommendation that NIH implement enhanced monitoring, documentation, and reporting requirements for award recipients with foreign subrecipients.³⁷ NIH generally concurred with the recommendation and stated that it will evaluate best practices across the government for overseeing awards issued to domestic recipients that, in turn, oversee foreign subrecipients.

In March 2023, NIH officials told us they did not have a timeline for implementing the HHS-OIG’s recommendation but planned to work with other entities, such as HHS Office of Grants and OMB, to evaluate how to implement it within the existing regulations regarding subrecipient monitoring and management.³⁸ In particular, NIH highlighted that 2 C.F.R. 200.102(c), an existing government-wide regulation, allows a federal awarding agency to adjust requirements to a class of federal awards or nonfederal entities when approved by OMB.³⁹ NIH officials said they are evaluating whether the agency will need additional authority in accordance with 2 C.F.R. 200.102(c) to implement the recommendation.

According to our evaluation, implementing the HHS-OIG’s recommendation could strengthen NIH’s oversight over research funds where there are foreign subrecipients. However, obtaining additional authority in accordance with 2 C.F.R. 200.102(c) could be a lengthy process. Federal internal control standards require that agencies design control activities to respond to risks and take timely corrective actions to

³⁷The HHS-OIG also made a recommendation to EcoHealth Alliance that it ensure that it has the ability to access all records related to its research conducted at subrecipient locations. According the HHS-OIG report, EcoHealth Alliance noted it would, to the best of its ability, ensure that it can access and supply all records related to its research conducted at subrecipient locations. For more information, see the HHS-OIG report.

³⁸See HHS-OIG report pg. 54, (citing 2 C.F.R. §§ 200.331 – 200.333, Subrecipient Monitoring and Management).

³⁹2 C.F.R. § 200.102, Exceptions (Uniform Administrative Regulations).

address deficiencies.⁴⁰ While NIH pursues long-term actions, such as obtaining additional authority from OMB, it has not initiated near-term actions, which could enhance its own internal processes. Examples of such opportunities include expanding its use of special award conditions, enhancing its existing vetting requirements, or engaging diplomatic support from the State Department when a foreign award recipient or subrecipient is no longer cooperating.⁴¹ In a prior report, we highlighted steps taken by USAID to manage risks through additional agency vetting requirements of foreign awards and subawards or mandatory provisions for subawards.⁴² Evaluating opportunities to enhance its existing internal processes, in tandem with other longer-term efforts to implement the HHS-OIG's January 2023 recommendation, would better position NIH to more immediately demonstrate progress to improve its oversight of awards with foreign subrecipients.

Conclusions

Participation by foreign entities in federally funded research can benefit agencies' missions and potentially the U.S. economy, but at the same time, participation by entities from certain countries, such as China, can

⁴⁰GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#). (Washington, D.C.: Sept. 2014). One of the 17 foundational principles of internal controls, Principle 10 – Design Control Activities, specifies that agency management should design control activities to achieve objectives and respond to risks. In addition, Principle 17 – Evaluate Issues and Remediate Deficiencies, requires, among other things, that management completes and documents corrective actions to remediate internal control deficiencies on a timely basis. These corrective actions include resolution of audit findings, such as those discussed in the HHS-OIG's January 2023 report.

⁴¹NIH officials told us in March 2023 that they did not reach out to the State Department to obtain support when WIV—a first-tier foreign subrecipient on the award—failed to respond to requests for data and documents related to the alleged violation. They explained they do not have a formal process for obtaining such support, and GPS provisions to address noncompliance apply whether an entity is domestic or foreign.

⁴²For its West Bank and Gaza mission, USAID adopted a key administrative policy document, referred to as Mission Order 21, which requires that certain individuals and non-U.S. (foreign) organizations undergo vetting, including recipients of grants and cooperative agreements and recipients of subawards. The policy states that USAID's West Bank and Gaza mission is required to ensure that applicable vetting approval by the agency is obtained before a subaward is made and that mandatory provisions are included in subaward documents. The purpose of the policy is to ensure the mission does not inadvertently provide support to entities or individuals associated with terrorism. For more information, see GAO, *West Bank and Gaza Aid: Should Funding Resume, Increased Oversight of Subawardee Compliance with USAID's Antiterrorism Policies and Procedures May Reduce Risks*, [GAO-21-332](#). (Washington, D.C.: March 29, 2021).

bring additional risks—as demonstrated by WIV’s failure to cooperate with NIH’s and EcoHealth Alliance’s requests to turn over documents and data on research involving potentially dangerous pathogens. The HHS-OIG recommendation is focused on enhancing oversight by award recipients with foreign subrecipients. We agree that implementing this recommendation will be key to ensuring appropriate and sufficient oversight over such awards. We also acknowledge that NIH may need to obtain additional authority in accordance with 2 C.F.R. 200.102(c), if it is to enhance its requirements for award recipients to monitor, document, and report on awards with foreign subrecipients.

However, pursuit of this authority should not preclude NIH from evaluating possible changes to its internal processes or other internal actions to improve risk management and oversight of awards with foreign subrecipients. Examples of such actions may already be present in NIH’s special award conditions for certain awards, and NIH has encouragingly stated that it plans to evaluate best practices from across the government.

Recommendation for Executive Action

We recommend that the Secretary of HHS ensure that NIH timely assesses and, as appropriate, implements actions—such as changes to its internal processes—that would allow NIH to more quickly improve its oversight of awards involving foreign subrecipients.

Agency Comments

We provided a draft of this report to HHS and USAID for review and comment. HHS’s comments are reproduced in appendix III. USAID’s comments are reproduced in appendix IV. Both agencies also provided technical comments, which we incorporated into the report as appropriate. In addition, we provided segments of the draft report to the U.S. universities contacted during our review and EcoHealth Alliance to verify the factual accuracy.

In its comments, HHS stated that it concurred with GAO’s recommendation, and NIH will assess potential opportunities to enhance its existing internal processes, while it evaluates whether it needs additional authority under 2 C.F.R. 200 to implement the recommendation.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of HHS, the Administrator of USAID, and other interested parties. In addition, the report is available at no charge on the GAO website at <https://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-6888 or wrightc@gao.gov. Contact points for our Office of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.

A handwritten signature in black ink that reads "Candice N. Wright". The signature is written in a cursive, flowing style.

Candice N. Wright
Director, Science, Technology Assessment, and Analytics

List of Requesters

The Honorable Rand Paul, M.D.
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Ron Johnson
Ranking Member
Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Michael R. Turner
Chairman
Permanent Select Committee on Intelligence
House of Representatives

The Honorable Markwayne Mullin
United States Senate

The Honorable Rick Crawford
House of Representatives

The Honorable Brian Fitzpatrick
House of Representatives

The Honorable Mike Gallagher
House of Representatives

The Honorable Trent Kelly
House of Representatives

The Honorable Darin LaHood
House of Representatives

The Honorable Elise Stefanik
House of Representatives

The Honorable Chris Stewart
House of Representatives

The Honorable Brad R. Wenstrup
House of Representatives

Appendix I: Objectives, Scope, and Methodology

Our objectives were to describe (1) the funding we identified to the selected Chinese entities—Wuhan University, the Wuhan Institute of Virology, and China’s Academy of Military Medical Sciences—in calendar years (CY) 2014 through 2021, (2) the purpose and results of the funding identified, and (3) agency and award recipient steps to assess risks. The selected entities include government institutions or laboratories in China that conduct work on infectious diseases, including pandemic viruses, and have had actions taken by other federal agencies to address safety or security concerns.¹

To identify funding to the three selected Chinese entities in CY 2014 through 2021, we searched in USAspending.gov, a government-wide system providing information about awards made by federal agencies and first-tier subawards made by award recipients. We identified one award made by a federal agency to one of the selected Chinese entities during this period. To verify this result, the Bureau of the Fiscal Service in the Department of the Treasury searched Treasury’s payment systems for evidence of any awards made by federal agencies directly to the three selected Chinese entities. We identified five first-tier subawards provided during this period. In consultation with General Services Administration—which manages the Federal Funding Accountability and Transparency Act Subaward Reporting System and which displays information on USAspending.gov—we confirmed that these were the only first-tier subawards reported in the government-wide systems. Two of the five first-tier subawards were to the Beijing Institute of Microbiology and Epidemiology, which, through addresses and other sources, we confirmed is another name for a subunit of the Academy of Military Medical Sciences. We identified two additional subawards, both second-tier subawards, through an interview with a subrecipient, EcoHealth Alliance. Based on the steps taken, we found the data in

¹For example, in December 2021, the Department of Commerce added AMMS and 11 AMMS subunits to its “Entity List” of organizations that may be involved in activities contrary to U.S. national security or foreign policy interests. In another example, in May 2020, the National Institutes of Health directed a grant recipient to suspend its subaward to WIV, because of reports that work at WIV posed serious biosafety concerns.

USAspending.gov to be sufficiently reliable to assist in identifying federal awards and first-tier subawards for the purposes of this report.

To identify disbursements on awards funded directly by a federal agency, we collected and reviewed award documents and payment information and interviewed the federal awarding agency on the funding provided.² To identify disbursements on the first- and second-tier subawards, we collected and reviewed relevant subaward documents, including subaward agreements, payment authorizations, and budget proposals, and we interviewed award recipients that provided funding to the three selected Chinese entities.

To describe the purpose and results of funding provided to the selected Chinese entities from CY 2014 through 2021, we reviewed relevant award documents, including research proposals and progress reports. To obtain information on the purpose and results, we analyzed the major goals of each award we identified and accomplishments, such as publications or workshops, which resulted from the award. Additionally, we reviewed subaward agreements to identify specific research activities assigned to the three selected Chinese entities.

To describe steps by agencies and award recipients to assess risks, we collected agency policies and award documents and interviewed agency officials and U.S.-based award recipients on steps they took to assess risks associated with some of the awards and subawards we identified.

We conducted this performance audit from June 2022 to June 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

²GAO, *A Glossary of Terms Used in the Federal Budget Process*, [GAO-05-734SP](#) (Washington, D.C.: Sept. 2005). A disbursement is the amounts paid by federal agencies, by cash or cash equivalent, during the fiscal year to liquidate government obligations.

Appendix II: Additional Information on EcoHealth Alliance's Subaward to the Wuhan Institute of Virology

This appendix provides additional information on EcoHealth Alliance's subaward to the Wuhan Institute of Virology (WIV) under its National Institutes of Health (NIH) grant.¹ Figures 3 and 5, earlier in this report, describe the funds, purpose, and results of this subaward.² This appendix summarizes what NIH officials and EcoHealth Alliance representatives told us, and what the documents they provided to us assert, regarding certain biosafety risk assessments conducted by NIH for this award.³

Timeline and Status of the Subaward to WIV

According to NIH and EcoHealth Alliance documents and agency officials and EcoHealth Alliance representatives, the following activities occurred:

- **June 2014–May 2019:** Basic research at WIV on bat coronaviruses and pathogen spillover, including conducting RNA extractions and DNA sequencing on bat samples and experiments on pathogen spillover.

¹The project title of the NIH grant to EcoHealth Alliance is "Understanding the Risk of Bat Coronavirus Emergence" (Federal Award Identification Number R01AI110964). EcoHealth Alliance also made a subaward to another of the three selected Chinese entities, Wuhan University. This appendix addresses the subaward to WIV.

²We were asked to provide information on federal funds disbursed to three selected Chinese entities, including WIV, in calendar years (CY) 2014 through 2021. We identified three subawards to WIV in that timeframe. Subawards below \$30,000 or below the first tier are not required to be reported in federal award data systems. See 2 C.F.R. pt. 170. As a result, we may have not identified all subawards to WIV or the other two selected Chinese entities in CY 2014 through 2021.

³We did not perform a comprehensive investigation of events surrounding this subaward or the events as described by NIH and EcoHealth Alliance which conflict in some respects. We did not fully assess the accuracy of the parties' statements.

These activities included genetic experiments by WIV to combine naturally occurring bat coronaviruses with SARS and MERS viruses resulting in hybridized (also known as chimeric) coronavirus strains. As discussed below, NIH analyzed the WIV experiments in 2021 and concluded that the naturally occurring bat coronaviruses were genetically distant from SARS-CoV-2 and could not have been the source of the COVID-19 pandemic.

- **July 2019:** NIH approved a 5-year renewal of the award to EcoHealth Alliance.⁴
- **April 2020:** NIH terminated its 5-year renewal of its award to EcoHealth Alliance, stating the agency believed the project outcomes no longer aligned with program goals and agency priorities.⁵
- **July 2020:** NIH reinstated the renewal award following an appeal from EcoHealth Alliance but immediately suspended the award, specifying award conditions that EcoHealth Alliance would need to meet before NIH would lift the suspension.
- **April 2021:** In a letter to NIH's Deputy Director for Extramural Research, EcoHealth Alliance addressed NIH's reinstatement and immediate suspension of the renewal award and the award conditions. EcoHealth Alliance stated, among other things, that it would be "effectively impossible" to comply with some of the award conditions, including one requiring EcoHealth Alliance to provide a

⁴The Federal Award Identification Number, R01AI110964, and project title, "Understanding the Risk of Bat Coronavirus Emergence," were the same for the initial award period and the renewal. The grant number, which is a separate identifier, changed from 1R01AI110964-01 upon initial award in 2014 to 1R01AI110964-06 upon renewal in 2019.

⁵In an April 24, 2020, notice to EcoHealth Alliance, the NIH Deputy Director for Extramural Research stated that the National Institute of Allergy and Infectious Diseases (NIAID) was terminating the grant for convenience. He stated that the grant was funded as a discretionary grant, as outlined in the *NIH Grants Policy Statement*, and the decision not to award a grant was at the discretion of the agency.

sample of the actual SARS-CoV-2 virus that WIV used to determine the viral sequence.⁶

- **August 2022:** NIH informed EcoHealth Alliance in a letter that it was terminating EcoHealth Alliance's subaward with WIV due to what NIH asserted was EcoHealth Alliance's material non-compliance with grant terms and conditions. NIH's letter further informed EcoHealth Alliance that NIAID would coordinate with EcoHealth Alliance to explore renegotiating the remainder of the award. The letter also stated that if the award could be renegotiated successfully and the remaining work accomplished without the involvement of WIV, EcoHealth Alliance would be required to meet additional award conditions. The additional conditions included conducting on-site inspections of subrecipient facilities every 6 months and submitting semiannual research progress reports and financial reports to NIAID.
- **January through April 2023:** In January, NIH officials told us NIAID was renegotiating the renewal award with EcoHealth Alliance and said the award would remain suspended until it is either resumed under a renegotiated award or terminated. In April 2023, NIH continued the award to EcoHealth Alliance through April 2027. The agency obligated \$576,000 to the award on April 26, 2023, according to USASpending.gov. According to an NIH letter, several new specific award conditions to enhance NIH's oversight of EcoHealth Alliance will apply to the award.⁷

⁶Letter dated April 11, 2021, from the EcoHealth Alliance President to the NIH Deputy Director for Extramural Research, entitled "Response to the reinstatement and immediate suspension of 2R01AI110964 'Understanding the Risk of Bat Coronavirus Emergence.'" The letter stated that it was "effectively impossible" for EcoHealth Alliance to fulfill the award condition, in part, because (1) there was no scientific or administrative rationale for obtaining a SARS-CoV-2 sample, as it was not part of their funded collaboration with WIV, and (2) EcoHealth Alliance scientists were not part of the WIV work to determine the viral sequence of SARS-CoV-2. The letter stated why EcoHealth Alliance believed it could not fulfill other award conditions or that actions to do so had already been taken.

⁷In a letter to EcoHealth Alliance dated April 26, 2023, a director in the NIH Office of Extramural Research stated that NIH was immediately instituting four specific award conditions on NIAID's current awards to EcoHealth Alliance, including the award on bat coronavirus emergence (Federal Award Identification Number R01AI110964). According to the NIAID letter, the award conditions will, among other things, require NIH's prior approval of subaward agreements and remove EcoHealth Alliance's eligibility for unrestricted advance drawdown of grant funds.

Biosafety Risk Assessments

Actions taken by NIH. In a July 2016 letter, NIAID officials stated they had assessed whether the 2014 award to EcoHealth Alliance, including the subaward to WIV, was subject to the temporary government-wide pause on new funding of certain gain-of-function research, even though the award was in place before the pause was in effect.⁸

In the July 2016 letter, the NIAID officials stated they had reexamined EcoHealth Alliance’s original grant application and supplemental information and determined that the research to generate MERS-like or SARS-like chimeric coronaviruses was not subject to the gain-of-function research funding pause for two reasons:

- The chimeric viruses would contain only S glycoprotein genes from phylogenetically distant bat coronaviruses, and
- Published work demonstrated that similar chimeric viruses had exhibited reduced pathogenicity.

⁸Letter dated July 7, 2016, to EcoHealth Alliance from NIAID. According to an October 17, 2014, announcement—*U.S. Government Gain-of-Function Deliberative Process and Research Funding Pause on Selected Gain-of-Function Research Involving Influenza, MERS, and SARS Viruses*—the government-wide pause applied to new funding that was “reasonably anticipated” to increase the pathogenicity or transmissibility of influenza, MERS, or SARS viruses in mammals via the respiratory route. NIH officials told us in January 2023 that the funding pause applied to any experimental method. In addition to gain-of-function, such methods could include serial passaging, RNAi, and recombinant experiments. On December 19, 2017, the NIH director announced that NIH was lifting the funding pause for NIH. See “NIH Lifts Funding Pause on Gain-of-Function Research.”

The director cited the release of the new HHS P3CO Framework—*Department of Health and Human Services Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (2017)—to guide funding decisions on proposed research involving enhancement of potential pandemic pathogens. The P3CO Framework aligned with the *Recommended Policy Guidance for Department Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight* (Jan. 9, 2017). As with the government-wide funding pause, NIH officials told us the framework applies to gain-of-function research and any other experimental method. We recently made recommendations to HHS to improve its oversight of such research under the framework. See GAO, *Public Health Preparedness: HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens*. [GAO-23-105455](#). (Washington, D.C.: Jan. 18, 2023).

In the July 2016 letter, NIAID also stated the agency did not anticipate that the chimeric viruses would have enhanced pathogenicity or transmissibility in mammals via the respiratory route.

NIH officials have stated that, even though the award to EcoHealth Alliance was in place before the pause was in effect, the agency was adding new award conditions out of an "abundance of caution." These added conditions required EcoHealth Alliance to take the following actions:

- Stop all experiments with the viruses, if any of the MERS-like or SARS-like chimeras showed evidence of enhanced viral growth greater than 1 log over the parental backbone strain, and
- Provide relevant data to the NIAID Program Officer, the NIH Grants Management Specialist, and the WIV Institutional Safety Committee upon such an occurrence.

NIAID introduced these new award conditions in its annual notice of award to EcoHealth Alliance for the budget period July 2016 through May 2017.⁹

In October 2021 letters to Representatives McMorris Rodgers and Comer, the NIH Principal Deputy Director stated that:

- EcoHealth Alliance violated an award condition when it failed to immediately report experimental results to NIH showing that

⁹In the July 7, 2016, letter, NIAID specified that the EcoHealth Alliance director would "immediately" stop experiments if any of the MERS-like or SARS-like chimeras showed evidence of enhanced virus growth greater than 1 log over the parental backbone strain and provide the relevant data to NIAID and others. However, the new award conditions included in the NIAID's notice of award for the budget period June 2016 through May 2017 did not specify that EcoHealth Alliance should "immediately" stop the experiments and provide the relevant data upon such an occurrence.

laboratory mice became sicker from one of the bat coronaviruses under experiment at WIV compared to a control cohort of mice,¹⁰ and

- EcoHealth Alliance notified NIH of the experimental results in August 2021, at which point the agency informed EcoHealth Alliance that it had 5 days to submit any unpublished data from the WIV experiments.

The October 2021 NIH letter to the Representatives also stated the following:

- NIH had analyzed the experiments funded in 2014 through 2018 under the grant and determined that the naturally occurring coronaviruses included in the study could not have been the source of the SARS-CoV-2 coronavirus and the COVID-19 pandemic disease,¹¹ and
- Research conducted under the award did not fit the definition of research involving enhanced pathogens of pandemic potential because the viruses being studied by WIV under the subaward from EcoHealth Alliance had not been shown to infect humans.

In an August 2022 letter to EcoHealth Alliance, NIH officials stated that WIV did not turn over unpublished data from the experiments, despite the agency’s request that EcoHealth Alliance obtain any such data and EcoHealth Alliance’s request to WIV. As a result—and as previously discussed—NIH terminated EcoHealth Alliance’s subaward with WIV in August 2022, due to what NIH stated was EcoHealth Alliance’s material

¹⁰Letter dated October 20, 2021, to the Honorable Cathy McMorris Rodgers, Ranking Member, Committee on Energy and Commerce, U.S. House of Representatives from Lawrence A. Tabak, Principal Deputy Director, NIH. An identical letter was sent on that date to the Honorable James Comer, Ranking Member, Committee on Oversight and Reform, U.S. House of Representatives. In the letter, the NIH Principal Deputy Director wrote that NIH was notified of the experimental results in August 2021, when EcoHealth Alliance submitted a research progress report for the June 2018 through May 2019 grant period (year 5 of the NIH grant). According to the letter, a “limited” experiment at WIV aimed to test whether the spike protein from naturally occurring bat coronaviruses circulating in China was capable of binding to the human ACE2 receptor in a mouse model. In the WIV experiment, mice infected with the genetically enhanced “chimeric” bat coronavirus, SHC014WIV1, became sicker than those infected with only the naturally occurring WIV1 bat coronavirus strain.

¹¹See NIAID, *An Analysis: Evolutionary Distance of SARS-CoV-2 and Bat Coronaviruses Studied Under the NIH-Supported Research Grant to EcoHealth Alliance* at <https://www.niaid.nih.gov/diseases-conditions/coronavirus-bat-research>.

non-compliance with its request to turn over unpublished data, among other reasons.

Actions taken by EcoHealth Alliance. Representatives from EcoHealth Alliance told us they had informed NIH of the results showing that laboratory mice became sicker from one of the bat coronaviruses under experiment at WIV compared to a control cohort of mice in an annual progress report they submitted to the agency in April 2018, earlier than the August 2021 date asserted by the NIH Principal Deputy Director.¹² EcoHealth Alliance also stated their organization did not receive a response from NIH about the experimental results after submitting the progress report to the agency.

Further, EcoHealth Alliance representatives told us they disagreed that the experimental results showed clear evidence of increased viral growth. For example, they stated that while the humanized mice infected with the genetically altered bat coronavirus became sicker than those infected only with the naturally occurring WIV1 bat coronavirus, the difference was not statistically significant. The progress report provided to us by EcoHealth Alliance, however, did not include information on the statistical significance of the experimental results in question.

At the same time, the EcoHealth Alliance representatives told us that the WIV researchers did not use a reliable measure of viral growth. Specifically, rather than measuring "viral titer," which is an established measure of growth of an active virus, the WIV researchers measured the number of genome copies per gram of virus material. According to the EcoHealth Alliance representatives, this method does not equate to viral titer because it may contain inactivated, incomplete, or dead viruses, in addition to active virus. As noted earlier, the NIH award condition required EcoHealth Alliance to report an increase in viral growth. To do so,

¹²EcoHealth Alliance representatives said they first disclosed the mouse experiment in a prior progress report for the June 2017 through May 2018 grant period (year 4 of the NIH grant) which they had submitted to NIH in April 2018, before the end of the year 4 grant period. GAO examined the year 4 and year 5 progress reports but could not determine whether the progress reports described the same experiment. EcoHealth Alliance provided us other documents, including a screenshot of the progress-reporting tab of NIH's eRA Commons system, indicating that EcoHealth Alliance had transmitted a document to NIH on April 13, 2018. EcoHealth Alliance also provided us a copy of an e-mail, sent later that month to an NIAID official, in which the president of EcoHealth Alliance transmitted the year 4 progress report.

EcoHealth Alliance and WIV would need to be in a position to detect and clearly measure such growth.¹³

HHS Office of Inspector General's (HHS-OIG) assessment. In a January 2023 report, the HHS-OIG stated that it had reviewed NIH's and EcoHealth Alliance's actions under this award and found that EcoHealth Alliance had failed to make immediate notification of research that exceeded the threshold, specified in the award conditions, of viral growth greater than 1 log.¹⁴ The OIG stated that, while reporting such a result in a progress report did not constitute immediate notification, NIH did not clearly define a process for providing proper notification. The OIG made several recommendations, including that NIH implement enhanced monitoring, documentation, and reporting requirements for award recipients with foreign subrecipients. NIH generally concurred with the recommendation.

¹³EcoHealth Alliance representatives told us in January 2023 that, while they did not disagree that WIV should have used viral titer, the point is moot, because the experiment did not demonstrate real enhanced growth given the small number of mice used and the lack of statistical significance.

¹⁴HHS-OIG, *The National Institutes of Health and EcoHealth Alliance Did Not Effectively Monitor Awards and Subawards, Resulting in Missed Opportunities to Oversee Research and Other Deficiencies*. A-05-21-00025. (Jan. 2023).

Appendix III: Comments from the Department of Health and Human Services

Appendix III: Comments from the Department
of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

May 16, 2023

Candice N. Wright
Director, Science Technology
Assessment, and Analytics
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Wright:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "**FEDERAL RESEARCH: NIH Could Take Additional Actions to Manage Risk Involving Foreign Subrecipients**" (GAO-23-106119).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FEDERAL RESEARCH: NIH COULD TAKE ADDITIONAL ACTIONS TO MANAGE RISK INVOLVING FOREIGN SUBRECIPIENTS (GAO-23-106119)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation 1

The Secretary of Health and Human Services ensure that NIH timely assesses and, as appropriate, implement actions – such as changes to its internal processes – that would allow NIH to more quickly improve its oversight of awards involving foreign subrecipients.

HHS Response

HHS concurs with GAO's recommendation.

In coordination with the HHS Office of Grants, NIH is evaluating how best to consider the GAO recommendation within the framework of 2 C.F.R. §§ 200.331 - 200.333, Subrecipient Monitoring and Management (Uniform Administrative Regulations). NIH will also need to consider 2 CFR 200.100(c), which states that, "The Federal awarding agency may adjust requirements to a class of Federal awards or non-Federal entities when approved by the Office of Management and Budget..." While NIH evaluates whether the agency needs additional authority to implement the recommendation, NIH will also assess potential opportunities for enhancing existing internal processes.

HHS will provide an action plan to address the recommendation in our 180-day letter response to Congress.

Accessible Text for Appendix III: Comments from the Department of Health and Human Services

May 16, 2023

Candice N. Wright
Director, Science Technology Assessment, and Analytics
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

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The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: FEDERAL RESEARCH: NIH COULD TAKE ADDITIONAL ACTIONS TO MANAGE RISK INVOLVING FOREIGN SUBRECIPIENTS (GAO-23-106119)

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HHS Response

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In coordination with the HHS Office of Grants, NIH is evaluating how best to consider the GAO recommendation within the framework of 2 C.F.R. §§ 200.331 - 200.333, Subrecipient Monitoring and Management (Uniform Administrative Regulations). NIH will also need to consider 2 CFR 200.100(c), which states that, “The Federal awarding agency may adjust requirements to a class of Federal awards or non-Federal entities when approved by the Office of Management and Budget....” While NIH evaluates whether the agency needs additional authority to implement the recommendation, NIH will also assess potential opportunities for enhancing existing internal processes.

HHS will provide an action plan to address the recommendation in our 180-day letter response to Congress.

Appendix IV: Comments from the U.S. Agency for International Development

**Appendix IV: Comments from the U.S. Agency
for International Development**



May 23, 2023

Jason Bair
Managing Director
International Affairs & Trade
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20226

Re: Federal Funds to Selected Chinese Entities (GAO - 106119)

Dear Mr. Bair:

I am pleased to provide the formal response of the U.S. Agency for International Development (USAID) to the draft report produced by the U.S. Government Accountability Office (GAO) titled Federal Funds to Selected Chinese Entities, (GAO-106119).

USAID would like to thank GAO for the opportunity to respond to this draft report. USAID concurs with the content and findings of GAO report 106119. USAID previously provided funding to the University of California, Davis (UC Davis) through a prime award, and UC Davis undertook subawards in which the Wuhan Institute of Virology and Wuhan University were second-tier subawardees. The prime award to UC Davis ended on September 30, 2020. Based on USAID's own review of our project records and financial databases in connection with this audit engagement, USAID concurs with GAO's findings that no additional USAID funding has been provided to either Wuhan Institute of Virology or Wuhan University. Similarly, USAID concurs with GAO's findings regarding no USAID funding to China's Academy of Military Medical Sciences. While there were no recommendations for USAID as a result of this audit, USAID remains committed to rigorous oversight of USAID funded awards, including those with foreign subawardees.

I am transmitting this letter from USAID for inclusion in the GAO's final report. Thank you for the opportunity to respond to the draft report, and for the courtesies extended by your staff while conducting this engagement. We appreciate the opportunity to participate in the complete and thorough evaluation of our prior awards.

Sincerely,

Colleen R. Allen

Colleen Allen
Assistant Administrator
Bureau for Management

Accessible Text for Appendix IV: Comments from the U.S. Agency for International Development

May 23, 2023

Jason Bair
Managing Director
International Affairs & Trade
U.S. Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20226

Re: Federal Funds to Selected Chinese Entities (GAO - 106119)

Dear Mr. Bair:

I am pleased to provide the formal response of the U.S. Agency for International Development (USAID) to the draft report produced by the U.S. Government Accountability Office (GAO) titled Federal Funds to Selected Chinese Entities, (GAO-106119).

USAID would like to thank GAO for the opportunity to respond to this draft report. USAID concurs with the content and findings of GAO report 106119. USAID previously provided funding to the University of California, Davis (UC Davis) through a prime award, and UC Davis undertook subawards in which the Wuhan Institute of Virology and Wuhan University were second-tier subawardees. The prime award to UC Davis ended on September 30, 2020. Based on USAID's own review of our project records and financial databases in connection with this audit engagement, USAID concurs with GAO's findings that no additional USAID funding has been provided to either Wuhan Institute of Virology or Wuhan University. Similarly, USAID concurs with GAO's findings regarding no USAID funding to China's Academy of Military Medical Sciences. While there were no recommendations for USAID as a result of this audit, USAID remains committed to rigorous oversight of USAID funded awards, including those with foreign subawardees.

I am transmitting this letter from USAID for inclusion in the GAO's final report. Thank you for the opportunity to respond to the draft report, and for the courtesies extended by your staff while conducting this engagement. We appreciate the opportunity to participate in the complete and thorough evaluation of our prior awards.

Sincerely,

Colleen Allen
Assistant Administrator
Bureau for Management

Appendix V: GAO Contact and Staff Acknowledgements

GAO Contact

Candice N. Wright at (202) 512-6888 or wrightc@gao.gov.

Staff Acknowledgments

In addition to the contact named above, Farahnaaz Khakoo-Mausel (Assistant Director), Jenny Chanley, Eliot Fletcher, Ryan Han, Lena Nour, Jeff Rueckhaus, and Ashley Stewart made key contributions to this report.

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