



Биологическая обстановка по особо опасным и опасным заболеваниям людей и экономически значимым заболеваниям животных

Заявление Государственного департамента США (29.08.2022)

U.S. DEPARTMENT of STATE

Home > ... > Joint Statement on the Contribution of Co...

Joint Statement on the Contribution of Cooperative Threat Reduction Partnerships to Global Health Security

MEDIA NOTE

OFFICE OF THE SPOKESPERSON

AUGUST 29, 2022

The COVID-19 pandemic has underscored the importance of strong national capacities for infectious disease surveillance, diagnosis, and response. International cooperation and assistance play a critical role in building these capacities. Our governments have partnered openly and transparently through the Biological Threat Reduction Program, which is a part of the U.S. Department of Defense

Cooperative Threat Reduction Program. These partnerships are devoted exclusively to peaceful purposes; they have nothing to do with weapons. These partnerships protect the health of humans and animals in our countries, including in the prevention, detection, and control of infectious disease outbreaks, and in enhancing laboratory biosafety and biosecurity. As partners in this program, we each have firsthand knowledge of its relevance to our shared goal of cooperating to strengthen global health security and reduce the impacts of infectious diseases on our societies. Our governments strongly affirm the common view that such cooperation should not be undermined, but rather promoted and reinforced. Pursuant to Article X, we encourage all Biological Weapons Convention States Parties to work together, including at the forthcoming Review Conference, in support of this goal.

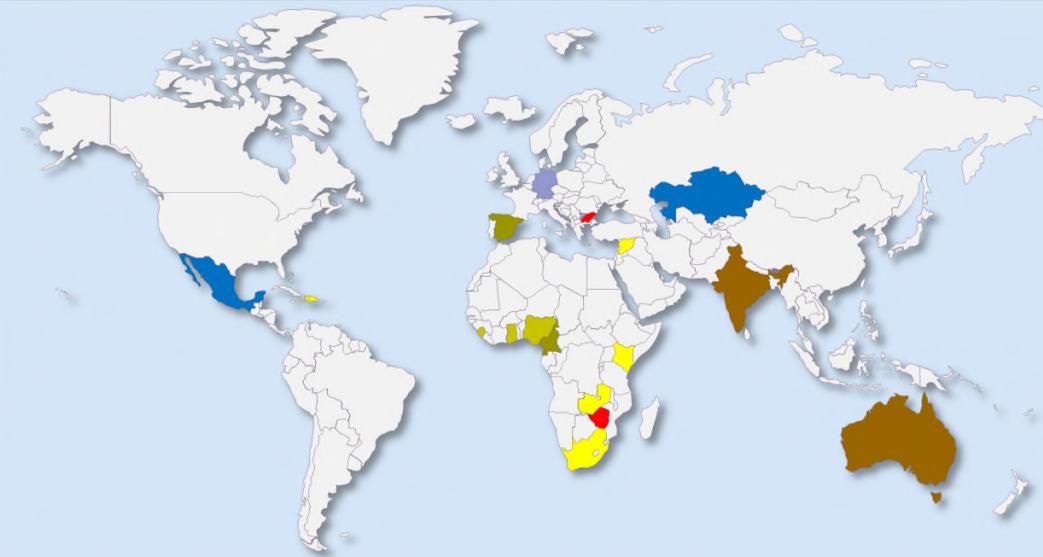
The text of the following statement was released by the Governments of the United States of America, Armenia, Georgia, Iraq, Jordan, Liberia, Philippines, Sierra Leone, Uganda, and Ukraine

«...Эти партнерские отношения преследуют исключительно мирные цели; они не имеют никакого отношения к оружию. Эти партнерские отношения защищают здоровье человека и животных в наших странах, в том числе в области профилактики, выявления и контроля вспышек инфекционных заболеваний...»

Вспышка лихорадки Эбола (2022 год)



Эпидемическая ситуация по особо опасным и опасным заболеваниям людей (2022-2023 годы)



Количество случаев заболеваний:

Лихорадка Марбург:	Испания (1), Камерун (2), Экваториальная Гвинея (25)
Лихорадка Ласса:	Гана (14), Нигерия (116), Сьерра-Леоне (15)
Ку-лихорадка:	Болгария (7), Германия (2)
Сибирская язва:	Болгария (1), Зимбабве (61)
Бруцеллез:	Казахстан (283), Мексика (5)
Японский энцефалит:	Индия (1331), Австралия (45)
Холера:	Сирия (84607), Замбия (42), Кения (16), ЮАР (2), Гаити (28901), Доминиканская Республика (47)

Эпизоотическая ситуация по экономически значимым заболеваниям животных (2023 год)



Количество очагов:

Африканская чума свиней:	Венгрия (35), Германия (2), Греция (2), Италия (51), Латвия (35), Молдова (4), Польша (168), Россия (2), Румыния (72), Сербия (15), С.Македония (1), Чехия (2), Бутан (1), ЮАР (4)
Высокопатогенный грипп птиц:	Австрия (48), Бельгия (29), Великобритания (26), Венгрия (7), Германия (7), Дания (17), Ирландия (1), Испания (1), Италия (3), Люксембург (1), Молдова (1), Нидерланды (3), Польша (49), Россия (3), Румыния (11), Сербия (1), Словакия (1), Словения (1), Франция (73), Чехия (13), Швейцария (2), Швеция (7), Израиль (3), Япония (12), ЮАР (1), Боливия (2), Гондурас (1), Канада (1), Коста-Рика (1), Мексика (1), Панама (1), США (14), Эквадор (7)



Проведение «Биг Фармой» исследований «направленной эволюции»

Запрос членов Сената США по поводу проводимых Pfizer исследований «направленной эволюции»

Congress of the United States
Washington, DC 20510

February 13, 2023

Mr. Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Robert M. Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Lawrence A. Tabak, D.D.S., Ph.D.
Acting Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20892

Dear Secretary Becerra, Commissioner Califf, and Acting Director Tabak,

We write to express grave concern regarding a recent video in which a Pfizer employee made troubling claims about the company's research practices and interactions with the Food and Drug Administration (FDA). Project Veritas identified the employee as Dr. Jordan Tritton Walker, Pfizer's Director of Research and Development, Strategic Operations - mRNA Scientific Planner. Pfizer did not dispute that Dr. Walker held that position when responding to the video.¹

Dr. Walker made two alarming claims. First, he claimed that Pfizer is conducting "directed evolution" research to improve the efficacy of its COVID-19 vaccine. Dr. Walker's description of directed evolution resembles gain-of-function (GOF) research, which has been the subject of much controversy—with good reason. HHS defines GOF as "research that improves the ability of a pathogen to cause disease [and] help define the fundamental nature of human-pathogen interactions."² In other words, GOF research is designed to make scientists study their effects and proactively develop countermeasures. Since 2011, such research has been the subject of intense scrutiny by scientists and ethicists.³ In fact, the NIH placed a moratorium on GOF research funding from 2014 to 2017 after a series of breaches in safety protocol at the NIH and CDC.⁴

Multiple sources suspect that the COVID-19 pandemic began when an enhanced virus leaked from the Wuhan Institute of Virology, where GOF research was being conducted.⁵ A few weeks ago, two scientists who previously authored UN reports on COVID-19⁶ origins wrote an op-ed in which they stated, "on

...Pfizer рассматривает возможность проведения исследования «направленной эволюции» для повышения эффективности своей вакцины...
Описание направленной эволюции, предложенное доктором Уокером, напоминает исследование усиления функции вирусов (GOF)...
...NIH ввело мораторий на финансирование исследований GOF с 2014 по 2017 год после серии нарушений протокола безопасности в NIH и CDC»

virus's potency and rapid spread. Given the possibility that GOF research may have ignited the global pandemic, it is worrying that Pfizer is engaging in research that appears similar in nature.

Dr. Walker's second troubling claim is that the relationship between major pharmaceutical companies and the FDA is a "revolving door." Below are two quotes in which Dr. Walker expands on this conflict of interest:

"So, in the pharma industry, all the people who review our drugs... eventually most of them will come work for pharma companies... It's pretty good for the industry to be honest. It's bad for everybody else in America."⁷

The undercover interviewer then asks, "Why is it bad?" Jordan continues:

"Because when the regulators reviewing our drugs know that once they stop regulating, they are going to work for the company, they are not going to be as hard towards the company that's going to give them a job."⁸

Dr. Walker's description of Pfizer's relationship with the FDA sounds like regulatory capture, in which regulators seek to advance commercial interests rather than the public's interest. If true, regulatory capture of the FDA is troubling for two primary reasons. First, it subordinates public safety to personal gain. If Dr. Walker is correct, some regulators may be sacrificing current safety standards for future employment opportunities.

Second, regulatory capture is fundamentally unfair to smaller companies without the clout to affect agency decisions. Many large pharmaceutical firms seek to shield their products from the competition by advocating for greater regulation or special exceptions. This shielding increases prices and can limit patient access to new treatments. Dr. Walker's comments help explain why smaller pharmaceutical firms report feeling ignored by the agency. Such a system is patently unfair and is antithetical to the equal enforcement of the law.

In collaboration with the FDA and NIH, we ask that you respond to the following questions:

1. Dr. Walker asked if Pfizer is conducting "directed evolution" research. One of the reasons we're exploring this is why don't we just mutate it ourselves so we could preemptively develop new vaccines? "Dr. Walker explains that so-called "directed evolution" research is distinct from gain-of-function research because directed evolution involves doing "selected structure mutations to try to see if we can make [viruses] more potent."⁹ Do subject matter experts at the FDA or NIH consider Pfizer "mutating" [SARS-CoV-2] ourselves so we could preemptively develop new vaccines to be gain-of-function research? If not, please explain the distinction.

2. The U.S. Office of Government Ethics (OGE) principles states, "Employees shall act impartially and not

directed evolution research for its COMIRNATY® (COVID-19) vaccine is legally distinct from its Pfizer-BioNTech COVID-19 vaccine?

Chip Roy
Member of Congress

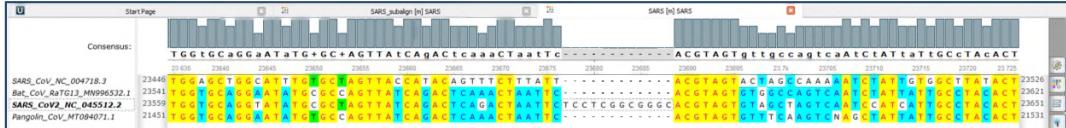
Andy Biggs
Member of Congress

W. Gregory Steube
Member of Congress

Bill Posey
Member of Congress

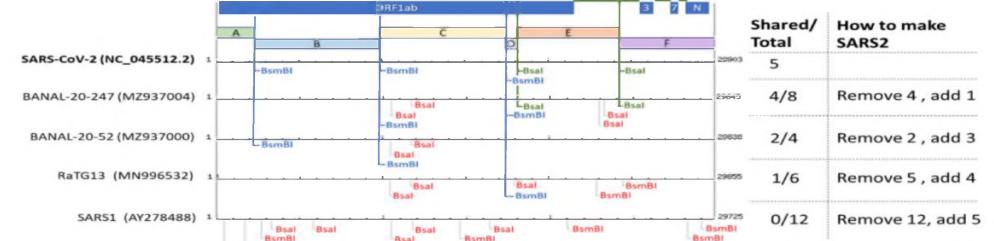
Lauren Boebert
Member of Congress

Внесение изменений в геном SARS-CoV-2 методами синтетической биологии

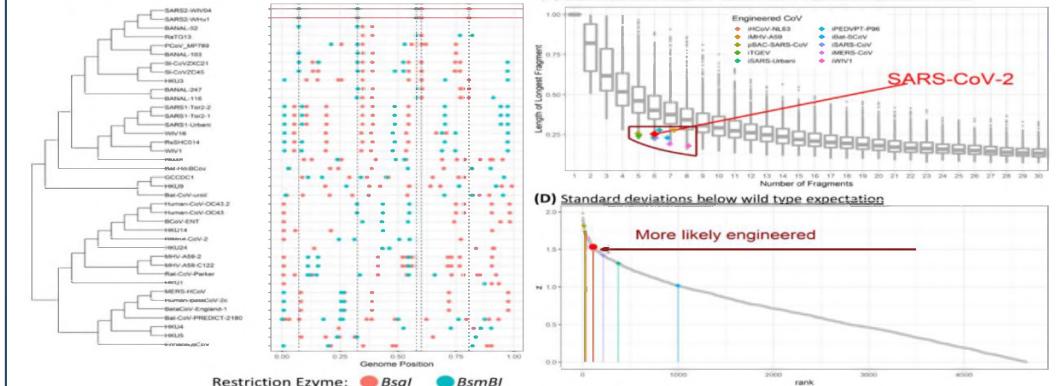


Результаты выравнивания генов коронавирусов млекопитающих (SARS-CoV, Bat-CoV, SARS-CoV-2, Pangolin-CoV)

(A) SARS-CoV-2 BsaI/BsmBI restriction map



(B) SARS CoV BsaI/BsmBI Restriction maps



Расположение сайтов рестрикции у SARS-CoV-2

(Bruttel M. Endonuclease fingerprint indicates a synthetic origin of SARS-CoV-2 / Bruttel M., Washburne A. // bioRxiv. – 2022. – P. 1-17)

По мнению ряда исследователей, SARS-CoV-2 может являться продуктом направленной эволюции, так как имеет набор уникальных сайтов рестрикции, характерных для синтетических вирусов



Pfizer Executive: 'Mutate' COVID via 'Directed Evolution' for Company to Continue Profiting Off of Vaccines ... 'COVID is Going to be a Cash Cow for Us' ... 'That is Not What We Say to the Public' ... 'People Won't Like That' ... 'Don't Tell Anyone'



18 U.S. Code § 175 – Prohibitions with respect to biological weapons

IN GENERAL.— whoever knowingly develops, produces, stockpiles, transfers, acquires, or possesses any biological agent, toxin, or delivery system as a weapon, or knowingly assists a foreign state or any organization to do so, or attempts, threatens, or conspires to do the same to be done under this title or imprisoned for life or any term or, but there is extraterritorial Federal jurisdiction over an offense under this section committed by or against a national of the United States.

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Подходы США к установлению глобального контроля в области биобезопасности

The stated goals of the biological program of the USA Заявленные цели биологических программ США

1. Monitoring of the biological situation
2. Assistance to developing countries
3. Development of means and methods of biological protection

«1. Мониторинг биологической обстановки;
2. Оказание помощи развивающимся странам;
3. Разработка средств и методов биологической защиты...»

«1. Строительство военных лабораторий вокруг границ геополитических противников;
2. Сбор штаммов особо опасных микроорганизмов, эндемичных для определенных территорий;
3. Участие военного ведомства в финансировании научно-исследовательских проектов;
...
6. Испытания на людях токсичных препаратов...»

Signs of the USA conducting research bypassing the obligations under the BTWC Признаки проведения США исследований в обход требований КБТО

INDIRECT КОСВЕННЫЕ

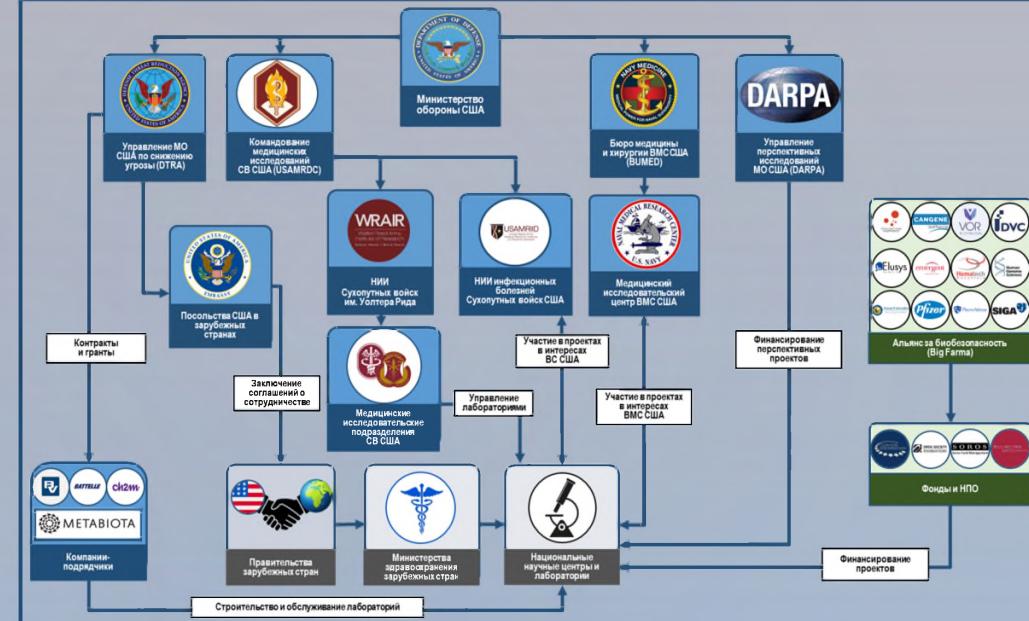
1. Construction of military laboratories around the borders of geopolitical opponents
2. Collection of strains of particularly dangerous microorganisms endemic to certain territories
3. Increasing the number of works on the artificial creation of dangerous microorganisms with specified properties
4. Participation of the military department in the financing of research projects
5. Increased funding of biological programs (including in the field of synthetic biology, paleogenomics, etc.)
6. Human testing of toxic drugs
7. Collection of biological material of "mono-ethnoses"

«...2. Непринятие на национальном уровне необходимых мер по запрещению и предотвращению разработки, производства, накопления, приобретения или сохранения биологического оружия;
3. Заключение соглашений, допускающих проведение работ в нарушение I статьи КБТО;
4. Сохранение в национальном законодательстве мер, позволяющих осуществлять разработку биологического оружия;
5. Патентование технических средств доставки и применения биологического оружия»

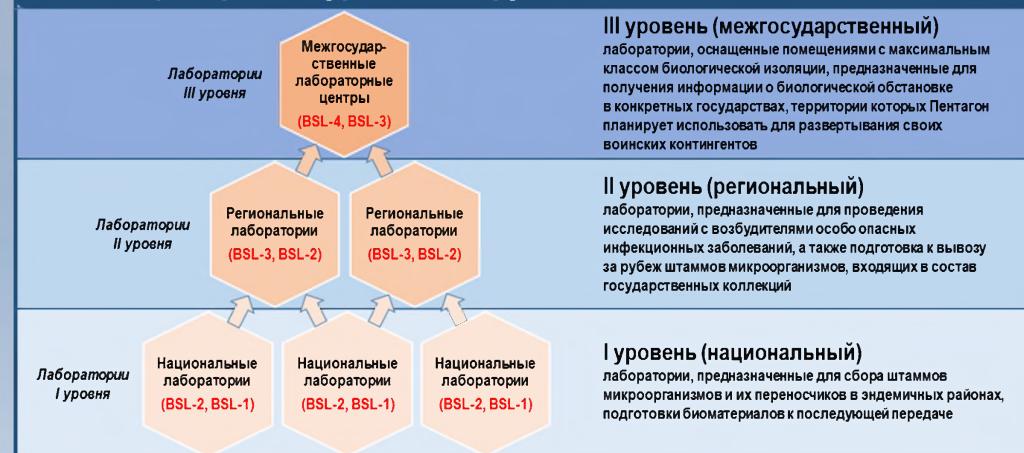
DIRECT (IN VIOLATION OF THE BTWC) ПРЯМЫЕ (в нарушение КБТО)

1. Violation of article IV of the BTWC
2. Failure to take the necessary measures at the national level to prohibit and prevent the development, production, accumulation, acquisition or preservation of biological weapons
3. Conclusion of agreements allowing the work to be carried out in violation of Article I of the BTWC
4. Preservation of measures in national legislation that allow the development of biological weapons
5. Patenting of technical means of delivery and use of biological weapons

Глобальная архитектура предупреждения, реагирования и нейтрализации биоугроз в интересах США



Разделение строящихся и реконструируемых американских лабораторий на уровни по функциональным возможностям





Отчет Управления генерального инспектора Министерства здравоохранения США

Department of Health and Human Services OFFICE OF INSPECTOR GENERAL

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

Inquiries about this report may be addressed to the Office of Public Affairs at
Public.Affairs@oig.hhs.gov.

Christi A. Grimm
Inspector General

January 2023
A-05-21-00025

Отчет Управления генерального инспектора Министерства здравоохранения США об аудите деятельности Национальных институтов здравоохранения и EcoHealth Alliance (январь 2023 г.)

Report in Brief

Date: January 2023
Report No. A-05-21-00025

Why OIG Did This Audit
OIG initiated this audit because of concerns regarding the National Institutes of Health's (NIH's) grant awards to EcoHealth Alliance (EcoHealth), NIH's monitoring of EcoHealth, and EcoHealth's use of grant funds, including its monitoring of subawards to a foreign entity.

Our objectives were to determine whether NIH monitored grants to EcoHealth in accordance with Federal requirements, and whether EcoHealth used and managed its NIH grant funds in accordance with Federal requirements.

How OIG Did This Audit
We obtained a list of all NIH awards to EcoHealth and all subawards made by EcoHealth during Federal fiscal years 2014 through 2021 (audit period). Our audit covered three NIH awards to EcoHealth totaling approximately \$8.0 million, which included \$1.8 million of EcoHealth's subawards to eight subrecipients, including the Wuhan Institute of Virology (WIV).

Our audit methodology was designed to address NIH and EcoHealth's policies, procedures, and internal controls in place to monitor, manage, and use grant funds. We selected and reviewed 150 EcoHealth transactions totaling \$2,578.65 across the 3 NIH awards comprised of different types of cost categories for allowability.

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

What OIG Found

Despite identifying potential risks associated with research being performed under the EcoHealth awards, we found that NIH did not effectively monitor or take timely action to address EcoHealth's compliance with some requirements. Although NIH and EcoHealth had established monitoring procedures, we found deficiencies in complying with those procedures limited NIH and EcoHealth's ability to effectively monitor Federal grant awards and subawards to understand the nature of the research conducted, identify potential problem areas, and take corrective action. Using its discretion, NIH did not refer the research to HHS for an outside review for enhanced potential pandemic pathogens (ePPPs) because it determined the research did not involve and was not reasonably anticipated to create, use, or transfer an ePPP. However, NIH added a special term and condition in EcoHealth's awards and provided limited guidance on how EcoHealth should comply with that requirement. We found that NIH was only able to conclude that research resulted in virus growth that met specified benchmarks based on a late progress report from EcoHealth that NIH failed to follow up on until nearly 2 years after its due date. Based on these findings, we conclude that NIH missed opportunities to more effectively monitor research. With improved oversight, NIH may have been able to take more timely corrective actions to mitigate the inherent risks associated with this type of research.

We identified several other deficiencies in the oversight of the awards. Some of these deficiencies include: NIH's improper termination of a grant; EcoHealth's inability to obtain scientific documentation from WIV; and EcoHealth's improper use of grant funds, resulting in \$89,171 in unallowable costs.

OIG oversight work has continually demonstrated that grant-awarding agencies' oversight of subrecipients, whether domestic or foreign, is challenging. The shortcomings we identified related to NIH's oversight of EcoHealth demonstrate continued problems. Compounding these longstanding challenges are risks that may limit effective oversight of foreign subrecipients, which often depends on cooperation between the recipient and subrecipient, and the countries in which the research is performed. Although WIV cooperated with EcoHealth's monitoring for several years, WIV's lack of cooperation following the COVID-19 outbreak limited EcoHealth's ability to monitor its subrecipient. NIH should assess how it can best mitigate these issues and ensure that it can oversee the use of NIH funds by foreign recipients and subrecipients.

The full report can be found at <https://oig.hhs.gov/oas/reports/region5/52100025.asp>.

«...надзорные органы не осуществляли эффективного мониторинга и не принимали своевременных мер для обеспечения соответствия деятельности EcoHealth требованиям к проводимым исследований, связанных с созданием, транспортировкой или использованием модифицированных пандемических патогенов...»

Office of Inspector General

<http://oig.hhs.gov>

The mission of the Office of Inspector General (OIG), as mandated by Public Law 99-435, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a variety of activities, including audits, investigations, and inspections conducted by the following operating components:

Office of Audit Services

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audits with done by others. Audits examine the performance of HHS programs and/or its grants and contracts in carrying out their respective responsibilities and are used to evaluate the quality of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy, efficiency, and effectiveness throughout HHS.

Office of Evaluation and Inspections

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of HHS programs. Through OEI's evaluations, HHS can identify areas for improvement and take corrective action. OEI also presents practical recommendations for improving program operations.

Office of Investigation

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI uses its resources by actively coordinating with the Department of Justice (DOJ), the Federal Bureau of Investigation (FBI), and the U.S. Attorneys' Offices, as well as other Federal agencies. The Office of OI often leads to civil convictions, administrative sanctions, and/or civil monetary penalties.

Office of Counsel to the Inspector General

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, civil monetary penalties, and administrative law proceedings. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG handles other inquiries, issues compliance program guidance, publishes fraud alerts, and provides other products to the health care industry concerning the anti-kickback statute and other HHS enforcement authorities.

Category	Amount	Count
Current Audit	\$664,442	11
Completed Audit	630,465	11
Open Audit	611,090	11
Open Investigation	597,112	11
Completed Investigation	581,646	16
Open Fraud Case	733,750	8
Open Civil Case	71,170	2
Open Criminal Case	349,819	2
Open FOIA Case	369,819	7
Open Other Case	3,748,715	17
Open Total	8,673	33
Open Total	1,155,842	15
Open Total	550,858	15
Open Total	574,984	17
Open Total	1,246,744	0
Open Total	1,505,568	1
Open Total	3,952,312	1
Open Total	7,755,860	6

APPENDIX I: NATIONAL INSTITUTES OF HEALTH COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES
National Institute of Health
Bethesda, Maryland 20892
www.nih.gov

DATE: December 20, 2022
TO: Audit T. Hudgins
Principal Deputy Inspector General
FROM: Acting Principal Deputy Director, National Institute of Health
SUBJECT: NIH Comments on Draft Report, "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)

Attached are the National Institutes of Health's (NIH) comments on the draft Office of Inspector General (OIG) report, "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).

NIH appreciates the review conducted by OIG and the opportunity to provide the clarifications on this draft report. If you have questions or concerns, please contact Marilene Stine in the Office of Management Assessment at 301-435-5402.

Yours truly,
Tina A. Schwartz, PhD
Attachments

APPENDIX J: ECOHEALTH COMMENTS
EcoHealth Alliance
22 December 2022

Shari L. Fischer
Regional Inspector General for Audit Services
Office of Inspector General, Region V
203 North Michigan, Suite 1360
Chicago, IL 60601

Re: Report Number: A-05-21-00025

Dear Ms. Fischer,
Thank you for providing draft of the report entitled "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). These comments are in response to the review of the draft report. The comments are intended to provide the OIG with the information necessary to make the final report as accurate as possible. The comments are contained in the attached Appendix J.

This OIG audit report covers National Institute of Health (NIH) and EcoHealth Alliance (EHA) compliance with Federal requirements to ensure proper monitoring and use of grant funds. The audit period covered by this report is January 1, 2014, through December 31, 2021. The OIG audit objectives were to determine whether NIH and EcoHealth Alliance (EHA) monitored grants and subawards to EcoHealth Alliance (EHA) and its subrecipients in accordance with Federal requirements, including the terms and conditions of the grants and subawards, and whether NIH and EcoHealth Alliance (EHA) used grant funds in accordance with Federal requirements.

We note that the draft did not find significant issues with NIH's grant oversight and compliance, summarizing its findings as follows: "EcoHealth has steps in place to conduct risk assessments and monitor its grants and subawards. The OIG audit found that NIH's monitoring of its subrecipients' EHA accepts OIG's recommendations on how to ensure that subawards are compliant with Federal requirements, how to ensure compliance with the terms and conditions of grants and subawards, and how to ensure that subrecipients disclose requirements associated with reporting subcontract funding. In fact, EHA had already corrected several of the findings identified in the draft report. NIH has also taken steps to correct the identified issues, and corrected them once we were notified of a finding by the OIG audit team."

We note the additional OIG audit team finding that EHA "did not always use its grant funds in accordance with Federal requirements, resulting in \$89,171 in unallowable costs." This

and EcoHealth Did Not Effectively Monitor Awards and Subawards (A-05-21-00025)

52 NIH and EcoHealth Did Not Effectively Monitor Awards and Subawards (A-05-21-00025)



Анализ эффективности американских мероприятий в сфере биобезопасности

6

National Science Advisory Board for Biosecurity (NSABB)

Национальный научно-консультативный совет по биозащите является федеральным консультативным комитетом, который по просьбе правительства США рассматривает вопросы, связанные с исследованиями в области биозащиты и двойного назначения



Джеральд В. Паркер

председатель Национального научно-консультативного совета по биозащите

Заместитель декана программы Global One Health в Колледже ветеринарной медицины и биомедицинских наук, директор кампуса Global One Health в Техасском университете A&M, директор программы политики в области пандемии и биозащиты в Институте международных отношений Скоукофта при Школе государственного управления и государственной службы им. Буша, является членом нескольких консультативных советов.

Более 26 лет службы в ведущих военно-медицинских научно-исследовательских программах и организациях. Бывший командир Медицинского научно-исследовательского института инфекционных заболеваний армии США. Занимал руководящие должности в Министерстве внутренней безопасности, Министерстве здравоохранения и социальных служб (HHS) и Министерстве обороны (DOD), включая должность первого заместителя помощника госсекретаря по вопросам готовности и реагирования в HHS и заместителя помощника министра обороны по химической и биологической защите в DOD.

PROPOSED BIOSECURITY OVERSIGHT FRAMEWORK FOR THE FUTURE OF SCIENCE

January 2023

Доклад Национального научно-консультативного совета по биозащите (27 января 2023 г.)



Executive Summary
Life sciences research involving pathogens serves a critical role in pandemic preparedness and in ensuring that the United States and the global community are prepared to detect, respond to, and respond to emerging threats. Periodic assessment of dual-use and biodefense oversight frameworks helps to ensure that they effectively address existing and emerging safety and security concerns while continuing to support scientific progress and innovation. To help inform such efforts, in February 2022 the U.S. Government charged the NSABB with evaluating and providing recommendations on the effectiveness of the existing oversight framework for life sciences dual-use and biodefense.

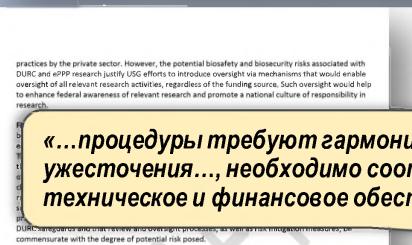
- Research with enhanced potential pandemic pathogens (ePPPs), including the White House Office of Science and Technology Policy (OSTP) Departmental Development of Review Mechanisms for Potential Pandemic Pathogen Care and Oversight (P3CO), and the Department of Health and Human Services (HHS) Framework for Guiding Decision Making about Proposed Research Involving Enhanced Potential Pandemic Pathogens.
- Dual Use of Research of Concern (DURC), including the USG Policy for Oversight of Life Sciences DURC.

In developing findings and recommendations presented in this report, the NSABB Working Group took into account the P3CO and DURC oversight frameworks and considered relevant policies and guidance, and consulted with subject matter experts in pathogen research, research administration and oversight, biosafety and biodefense, biodefense, and national security, among others, from the USG, federal funding agencies, academic institutions, and scientific and professional societies. The Working Group also considered public comment.

NSABB Working Group Findings on P3CO (Phase 1) & DURC (Phase 2) Oversight Frameworks Phase 1 Report

Findings 1. The current definitions of a PPP and enhanced PPP (ePPP) are too narrow: Overemphasis on pathogens that are both likely "highly" transmissible and likely "highly" virulent

<https://www.ostp.gov/13757/documents/pdf/>
<https://www.ostp.gov/13757/documents/pdf/ostp-13757-ppp-eppp-definitions.pdf>
<https://www.ostp.gov/13757/documents/pdf/ostp-13757-ppp-eppp-definitions.pdf>
<https://www.ostp.gov/13757/documents/pdf/ostp-13757-ppp-eppp-definitions.pdf>



practices by the private sector. However, the potential biosafety and biodefense risks associated with ePPP research justify USG efforts to introduce oversight via mechanisms that would enable oversight of all relevant research activities, regardless of the funding source. Such oversight would help to enhance federal awareness of relevant research and promote a national culture of responsibility in research.

«...процедуры требуют гармонизации и ужесточения..., необходимо соответствующее техническое и финансовое обеспечение...»

Recommendation 2. Amend the USG P3CO policy to reconsider current exclusions for research activities associated with a pathogen and its products or production, which could be broadly interpreted as exclusions that are not virulent. The identification, review, and evaluation of potential ePPP research considers risks and benefits, including whether the research is critical to public health or national security, thus these exclusions are not needed.

Recommendation 3. Amend the P3CO compliance procedures to better harmonize, standardize, and simplify, and enhance the P3CO compliance procedures.

Recommendation 4. Amend the P3CO policy to clarify that federal department-level review is required for research that is reasonably anticipated to enhance the transmissibility and/or virulence of any pathogen (i.e., PPPs and non-PPPs) if the resulting pathogen is reasonably anticipated to exhibit the following characteristics that meet the definition of a PPP:

- Likely moderately or highly transmissible and likely capable of wide and uncontrollable spread in human populations; and/or
- Likely moderately or highly virulent and likely to cause significant morbidity and/or mortality in humans;

And, in addition:

- Likely to pose a severe threat to public health, the capacity of public health systems to respond, or national security.

Assessments for the identification of ePPP research must be focused on the potential for an activity or a modification to involve or produce a pathogen that meets the criteria for an ePPP and not on the specific experimental approach or method to be undertaken. However, research reasonably anticipated to involve any of the experimental categories described in Section IV.C of the current P3CO Framework must be evaluated under the P3CO framework. The P3CO policy must also provide implementing directions, instructions and guidance on how to apply the experimental categories identified in Section IV.C of the current P3CO Framework to help illustrate how modifications to a pathogen would or would not cross the threshold necessary to constitute an ePPP.

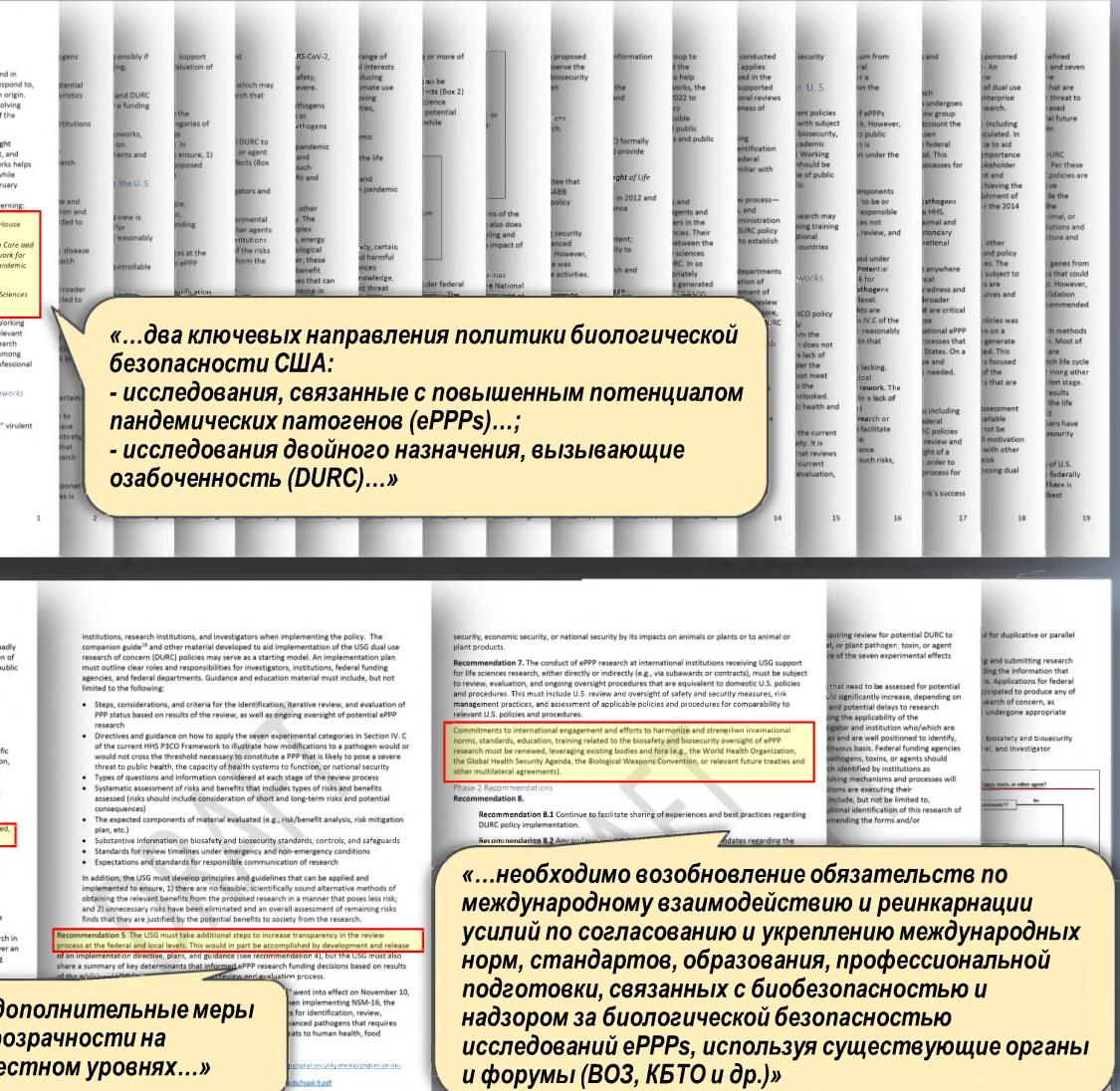
Recommendation 4. Amend Section III.C and III.D of the OSTP P3CO Policy Guidance to be consistent with the P3CO policy. The P3CO policy should be the primary mechanism for feasible, scientifically sound alternative ways of obtaining the benefits sought in the research in a manner that poses less risk. Amend Section III.C to, "Risks that are not necessary to answer an important scientific question have been eliminated and an overall assessment of remaining risks finds that they are justified by the potential benefits to society from the research."

Amend Section V.C of the P3CO policy to require that the research proposal, including the research plan, be submitted to the relevant DURC committee for the proposed research in a manner that poses less risk; and, if applicable, the DURC committee will have the authority to evaluate the potential remaining risks that find that they are justified by the potential benefits to society from the research."

Recommendation 4. Amend the P3CO policy to include additional steps to increase transparency in the review process at the federal and local levels. This would be accomplished by development and release of an implementation directive, plan, and guidance (see recommendation 4), but the USG must also ensure that key determinants of the review process are transparent and that the results of the review process are made available to the public.

Recommendation 4.2 Amend the P3CO policy to provide for the development of educational materials, including training, for DURC personnel to develop, evaluate, and oversight

«...предпринять дополнительные меры по повышению прозрачности на федеральном и местном уровнях...»





Международная реакция на разоблачение американских военно-биологических программ

Инициатива партии «Макабаян» по расследованию деятельности США на Филиппинах

INQUIRER.NET

House urged to scrutinize US-funded lab project in PH



The Makabayan lawmakers also cited reports of other laboratories and research facilities in the Philippines funded by EcoHealth Alliance, a foreign nonprofit organization that received millions of dollars in grants from the US Agency for International Development (USAID).

There are three EcoHealth Alliance projects currently being undertaken in the Philippines, including the Predict project that aims to "identify new emerging infectious diseases that could become a threat to human health," and the Emerging Infectious Disease Repository (EIDR), which seeks to "unravel the origins of emerging infectious disease events."

"Even if the work of EcoHealth Alliance truly relates to pursuing global health, it is unmistakable that one of the overarching objectives of this USAID grant is to advance US foreign policy," they noted, adding that EcoHealth Alliance also got funding from the DTRA.

«Парламент призвал тщательнее изучить финансируемые США биолаборатории на Филиппинах»



Филиппинская партия Макабаян

philstar
GLOBAL

Investigate foreign-funded biolab – Makabayan

MANILA, Philippines – The House Makabayan bloc has expressed concerns over the reported construction of an animal disease diagnostic laboratory in Tarlac City with funding from the United States' Defense Threat Reduction Agency (US-DTRA).

In a joint resolution, Reps. France Castro of ACT Teachers, Arlene Brosas of Gabriela and Raoul Manuel of Kabataan asked House leaders to investigate foreign-funded bio-laboratory projects in the Philippines, including the US-DTRA.

The party-list lawmakers said the \$643,000-facility was turned over to the Department of Agriculture in September 2020 to "boost the country's biosecurity."

«Макабаян» требует расследования деятельности биолабораторий, финансируемых из-за рубежа»

BusinessWorld™

Embassy says US-supported biolabs fully run by DA



THE UNITED States Embassy in Manila allayed concerns raised by opposition lawmakers on US-funded biolaboratories in the Philippines, saying the American government is only providing support to the agricultural department, which operates these facilities.

John Groch, acting spokesperson of the embassy, said the US government, through the United States Defense Threat Reduction Agency (DTRA), extended funding and technical training to the Department of Agriculture (DA).

«Посольство США сообщает, что биолаборатории полностью управляются министерством сельского хозяйства»

*DTRA has built, monitor, and provide funding to the Department of Agriculture, however...

Военно-морское медицинское исследовательское подразделение № 2 (NAMRU-2)



NAMRU-2 является биомедицинской исследовательской лабораторией ВМС США, которая официально создана с целью изучения инфекционных заболеваний потенциального военного значения в Азии. Основная лаборатория и штаб-квартира NAMRU-2 находились в Джакарте с 1991 по 2010 год, когда правительство Индонезии потребовало закрыть их.

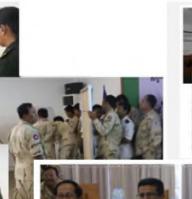
В 2002 году учрежден филиал в Пномпене (Камбоджа) (с 2010 года функционирует как основная лаборатория в регионе).

В 2007 году учрежден филиал в Сингапуре.

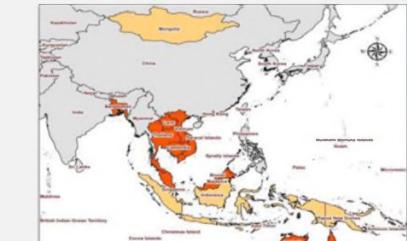


Личный состав NAMRU-2 укомплектован 4 представителями ВМС США и более 90 камбоджийскими учеными, врачами, технологами, специалистами.

NAMRU-2 собирает и характеризует более 5000 образцов в год и быстро распространяет полученную информацию среди партнеров в Камбодже и правительстве США.



NMRC-Asia HQ in Singapore. NAMRU-2's laboratory in Phnom Penh, Cambodia



18

Naval Medical Research – Asia Naval Medical Research Unit TWO



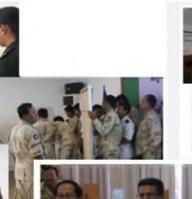
Host(s): Singapore: Ministry of Defense; Cambodia: Ministry of Health

Research Expertise in

- Biosurveillance of infectious diseases
- Pathogen characterization/bioinformatics
- Drug resistant malaria therapeutics

Recent accomplishments

- Established Middle East Respiratory Syndrome-Corona Virus (MERS-CoV) surveillance in SE Asia
- Supports Global Health Security through laboratory upgrade with Cambodia Ministry of Health and Royal Cambodian Armed Forces
- Evaluation of vector control and abatement devices in Laos
- Conducts SMS-based disease surveillance in Cambodia to provide real-time disease trend data
- Conducting Therapeutic treatment efficacy studies to reduce malaria burden in SE Asia



Completion of Lab training at NAMRU-2 for military personnel



Фигуранты военно-биологических исследований США на Украине



Кеннет Майерс
директор DTRA
(2009–2016)



Роберт Поул
директор DTRA
(2017–2020)



Риз М. Уильямс
директор DTRA
(с 2020 г.)



Джессика Уинтроп
руководитель
проектов DTRA



Стивен Л. Эдвардс
генеральный директор
Black&Veatch



Лэнс Липпенкотт
менеджер проектов
Black&Veatch



Дэвид Мустра
менеджер
Black&Veatch



Нита Мадхэз
генеральный
директор Metabiota



Мэри Гуттиери
вице-президент
Metabiota



Скотт Тхорnton
старший микробиолог
Metabiota



Анна Гибсон
ведущий научный
сотрудник Metabiota



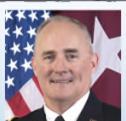
Льюис фон Таэр
президент, исполнит.
директор Battelle



Джейфри Водсворт
бывший исполнит.
директор Battelle



Дэвид Гарсия
сотрудник Центра военной
медицины Battelle



Энтони Маккуин
командование
медицинских
исследований
и разработок,
командир Форта-
Детрик



Томас Фриден
экс-глава Центров
по контролю и
профилактике
заболеваний
в США (CDC)



Френсис Коллинс
бывший директор
Национальных
институтов
здравоохранения
(NIH)



Карен Э. Сейлорс
исполнительный
директор и
соучредитель
Labyrinth Global
Health Inc.



Михаэль Дольстен
главный научный
сотрудник и
президент отдела
международных
исследований Pfizer



Колин Джонссон
ведущий
исследователь
в научном центре
Университета Теннесси



Тара О'Тул
исполнительный
вице-президент
фонда In-Q-Tel



Хантер Байден
возглавлял Rosemont
Seneca Technology
Partners, являющиеся
ведущим финансовым
спонсором Metabiota



Эшли Лукас
советник по вопросам
общественного
здравоохранения
в Loyal Source
Government Services



Эрик Борц
вирусолог,
ассоциированный
профессор Университета
Аляска Анкоридж



Риза Икранбегийн
сотрудник
лаборатории
при украинском
филиале ВОЗ



Кертис Белаяч
исполнительный
директор
Украинского научно-
технологического
центра (с 2014 г.)



Эндрю Худ
исполнительный
директор
Украинского научно-
технологического
центра (2004–2012)



Эдди Майер
председатель
правления
Украинского научно-
технологического
центра от Евросоюза



Натали Паузлс
представитель
совета директоров
Украинского научно-
технологического центра от Евросоюза



Моргун Сергей
Начальник Санитарно-
эпидемиологического
управления Командования
Медицинских сил ВСУ.
Организовывал
взаимодействие ВСУ
и DTRA в рамках военно-
биологических исследований.
Лично курировал проект
UP-8, исследования
коронавируса и других
патогенов.

Адрес проживания:
г.Киев, б-р Боровиковского,
д. [redacted] кв. [redacted]



Литовка Сергей
Начальник
Центрального санитарно-
эпидемиологического
управления ВСУ.
Осуществлял прямое
руководство проектом
UP-8. Организовывал отбор
военнослужащих для взятия
биоматериала, готовил
отчетные материалы для
DTRA. Давал указания на
допуск американских биологов
на объекты МО Украины
Адрес проживания:
г.Днепр, пер. Сечевой, д. [redacted]



Курпита Владимир
Руководитель
Центра общественного
здравоохранения Министерства
здравоохранения Украины.
Осуществлял общий
контроль и руководство за
взаимодействием украинских
специалистов и DTRA.
Участвовал в проекте
№ 68727 EN 02761868.
Контролировал вывоз 1 тыс.
образцов сыворотки крови из
разных регионов Украины.
Адрес проживания: г.Киев,
ул. Симиренка, д. [redacted] кв. [redacted]



Демчишина Ирина
Заведующая вирусологической
референс-лабораторией
Центра общественного
здравоохранения Министерства
здравоохранения Украины.
Поддерживала личные
контакты с представителями
Black&Veatch, Metabiota,
CH2M Hill, УНТЦ. Лично
организовывала передачу
биоматериалов за рубеж,
контролировала реализацию
проектов серий UP и TAP.
Адрес проживания: г.Киев,
ул. Антоновича, д. [redacted] кв. [redacted]



Музыка Денис
Заместитель директора
по международному
сотрудничеству Института
экспериментальной и
клинической ветеринарной
медицины (ИЭКВМ),
заведующий лабораторией
вирусных заболеваний
птицы в ИЭКВМ.
Выполнял основную часть
исследования в проекте UP-4,
участник проекта Р-160.
Адрес проживания:
г.Киев, ул. Ереванская,
д. [redacted] кв. [redacted]



Пекарская Лариса
Менеджер по финансам и
налогам Black and Veatch.
Работала в сфере управления
международной технической
помощью на Украине (DTRA,
USAID, Millennium Challenge
Corporation), занималась
вопросами финансирования
проектов DTRA на Украине,
а также связанными
с ними документооборотом
Black and Veatch.
Адреса проживания: г.Киев,
ул.Кикиндзе д. [redacted] кв. [redacted]; г.Киев,
ул.Бальзака, д. [redacted] кв. [redacted]



Михайловская Наталья
Менеджер в Metabiota по
исследовательским проектам
и по реализации программ
в странах бывшего СССР,
консультант в Labyrinth Global
Health, Inc. Оказывала помощь
в реализации биопрограммы
DTRA «Threat Reduction
Networks Support» TD-04-03-01.
Сотрудничала с Д.Музыкой
по реализации проектов UP-4,
UP-9, UP-10 и подготовке
итоговой отчетности.
Адрес проживания: г.Киев,
ул. Ереванская, д. [redacted] кв. [redacted]
Адрес проживания: г. Львов,
ул. Прогулочная, д. [redacted]



Лозинский Игорь
Заведующий лабораторией
природно-очаговых инфекций
НИИ эпидемиологии и гигиены
ЛНМУ. Курировал процесс
модернизации лаборатории
для проведения военно-
биологических исследований,
руководил работами по
проекту UP-8. В рамках
проекта ведущий специалист
по проведению анализа
биоматериала, участвовал
в анализе данных.



Заявление Д.Кирби о прекращении деятельности биолабораторий США на Украине



31 января, 22:49, обновлено 31 января, 23:05

В Белом доме считают необоснованными заявления РФ о работе биолабораторий США на Украине

Координатор по стратегическим коммуникациям в СНБ Белого дома Джон Кирби признал, что США действительно "проводили с украинцами некоторые исследования по предотвращению пандемии", но добавил, что все эти исследовательские центры были "покинуты и безопасно деактивированы" до начала СВО

Документ правительства Украины о порядке учета, хранения, транспортировки, уничтожения, ввоза и вывоза патогенных биологических агентов