



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

February 23, 2022

The Honorable Nancy Mace
U.S. House of Representatives
Washington, DC 20515

Dear Representative Mace:

Thank you for your letter of November 30, 2021, regarding the use of non-human primates in research funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). I appreciate the opportunity to respond.

Overview

NIAID is committed to funding innovative basic research, as well as the development of vaccines, diagnostics, therapeutics, and other interventions for a wide variety of infectious and immune-mediated diseases. As I noted in my response to your letter of October 21, 2021, some of this research requires the use of animal models to safely and effectively study systems and processes that would not otherwise be possible to investigate. It is important to note again that NIH, including NIAID, takes the welfare of animals used in research seriously.

NIH employs a multi-layered process to establish the highest possible standards for humane care and use of animals in NIH-funded research. NIH has developed guidance, procedures, and protocols to ensure that our intramural and extramural scientists comply with all relevant policies and regulations, including the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (the PHS Policy).¹ This includes requirements for researchers to explore alternatives to the use of animal models; prevent unnecessary use of animals by carefully determining appropriate numbers of animals necessary to answer important research questions; and ensure that pain and distress to animals are avoided or minimized as much as possible.

The NIH Office of Laboratory Animal Welfare (OLAW) provides specific guidance, instruction, and materials to institutions that must comply with the PHS Policy. One of NIH OLAW's primary functions is to advise NIH Institutes and Centers and awardee institutions concerning the implementation of and compliance with the PHS Policy. This includes communicating about regulations governing the use of animals in biomedical research, as well as establishing best practices for the critical biomedical research that requires use of animal models. These efforts represent a collaborative relationship between NIH, researchers, Institutional Animal Care and Use Committees (IACUCs), and regulatory agencies to ensure that the critical resource of animal models is utilized in a humane, responsible, and ethical manner.

¹ PHS Policy on Humane Care and Use of Laboratory Animals. <https://olaw.nih.gov/policies-laws/policy.html>

Research involving the use of non-human primates by NIH intramural researchers undergoes rigorous scientific merit review prior to review by the IACUC. NIAID intramural research is conducted in an AAALAC International-accredited² facility in accordance with the PHS Policy and the Animal Welfare Act and its implementing regulations (together, AWA).³ The principles for what is and is not allowed are described in the Guide for the Care and Use of Laboratory Animals⁴ and the AWA and are administered by NIH OLAW and the U.S. Department of Agriculture (USDA) respectively. With regard to extramural research, NIAID funding is dependent on IACUC review and approval, a decision by NIH scientific peer review that the application is highly meritorious, and acceptance of terms and conditions that require researchers to abide by all relevant animal care laws and policies.

Approximately \$658 million of NIAID funds in fiscal years 2020 and 2021 combined went to support intramural and extramural research projects that included an element utilizing non-human primates. Funded research included critical studies designed to advance the development of therapeutics and vaccines for diseases that cause significant morbidity and mortality worldwide, including COVID-19 HIV, influenza, Ebola, malaria, tuberculosis, and diseases caused by antimicrobial-resistant bacteria; investigation of medical countermeasures against chemical and radiation exposure; transplantation tolerance and xenotransplantation research; and research into the mechanisms that underlie allergic and immunologic diseases.

Contribution of Non-Human Primates from Morgan Island to NIAID Biomedical Research

The free-ranging colony of rhesus macaques on Morgan Island, South Carolina, was originally established in 1979. The island currently is owned by the South Carolina Department of Natural Resources and leased by Charles River Laboratories, Inc., as part of a contract with NIAID. The maintenance of the colony is conducted in accordance with all federal laws, regulations, and policies, and the animals on Morgan Island are provided food, water, and veterinary and other care.

Since January 1, 2020, a total of 388 non-human primates were shipped from Morgan Island to NIAID intramural or partner facilities for use in NIAID-funded research. Some non-human primates have been delivered to research facilities but have not yet entered experimental protocols. It is important to note that the Morgan Island colony also facilitates non-NIAID research, and since January 1, 2020, a total of 152 non-human primates from Morgan Island were transferred to Federal research partners.

Enclosed please find a list of all NIAID intramural research projects that utilized non-human primates from Morgan Island since January 1, 2020. These studies include important research into the testing and development of vaccines against COVID-19, HIV, tuberculosis, dengue, and West Nile, as well as projects exploring the disease mechanisms of, and biological therapeutics against, HIV, tuberculosis malaria, and viruses causing hemorrhagic fever.

² AAALAC Accreditation Program. <https://www.aaalac.org/accreditation-program/faqs/>

³ Animal Welfare Act, <https://www.govinfo.gov/content/pkg/USCODE-2015-title7/html/USCODE-2015-title7-chap54.htm> and its implementing regulations, <https://www.govinfo.gov/content/pkg/CFR-2021-title9-vol1/pdf/CFR-2021-title9-vol1-chap1-subchapA.pdf>.

Guide for the Care and Use of Laboratory Animals. <https://olaw.nih.gov/sites/default/files/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf>

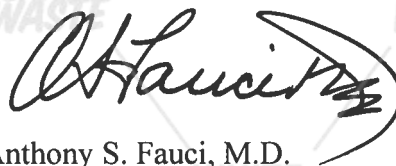
The AWA requires that IACUCs responsible for overseeing research conducted using dogs, cats, primates, and other mammals, but excluding birds, rats and mice, report annually to the USDA Animal and Plant Health Inspection Service on the number of animals used for this research. For each animal used, a USDA Pain Category also must be reported. Category C experiments involve no pain, distress, or use of pain-relieving drugs. In Category D experiments, interventions such as anesthetics or analgesics are used to relieve pain or distress. However, it must be noted that the results of some critical studies would be compromised with such interventions. For example, research to study important infectious disease processes might require that an infection run its course. Such protocols would generally fall under Category E with the earliest experimental endpoint used to minimize the likelihood of pain or distress occurring. These procedures are conducted under the highest level of scrutiny, must be reported to the USDA, and require additional written scientific justifications as to why the research objectives cannot be achieved in an alternative manner.

NI Investment in Non-Animal Alternatives for Research

As I described in my previous response, NIH has made significant investments into the development of non-animal alternatives that could limit the use of animals in research. This includes continued support for efforts to develop new technologies to mimic disease or predict how drugs will work in humans. NIH collaborates with partners in the private and public sectors, including the Defense Advanced Research Projects Agency, the Environmental Protection Agency, and the U.S. Food and Drug Administration, on these advancements. Additionally, many studies examining the fundamental biology of viruses, previously able to be assessed only in animals, are now conducted using cell culture systems instead where the technology exists that allows this possibility. When scientifically possible, these non-animal studies can be used to identify therapeutic candidates with the most promise before moving to animal studies as needed for further development of these products. Such an approach can greatly reduce the number of animals that may be needed for this important research. Despite recent advances in non-animal alternatives, research on many critical physiologic and immune processes still requires animal models. NIH and NIAID are committed to continuing to pursue research to develop non-animal alternatives.

Thank you for your interest in NIAID's research program. I hope this information is helpful to you. Best regards.

Sincerely,



Anthony S. Fauci, M.D.
Director
National Institute of Allergy
and Infectious Diseases

Enclosure:

List of NIAID projects utilizing non-human primates from Morgan Island

**List of NIAID projects utilizing non-human primates from Morgan Island
(January 1, 2020 - December 13, 2021)**

Please Note: Abstracts from these projects are publicly available by searching the ZI numbers listed below at the following website: <https://reporter.nih.gov>.

Project name (project number[s])	Location	Cost	# of animals	USDA pain category
Malaria Pathogenesis in young children and vaccine discovery (FY20: ZIA AI001134-11 FY21: ZIA AI001134-12) Pregnancy Malaria Vaccine development (FY20: ZIA AI001176-09 FY21: ZIA AI001176-10)	NIAID (Bethesda, MD)	\$311,920	68	D – 68
The Biology of HIV Infections (FY20: ZIA AI001213-05 FY21: ZIA AI001213-06)	NIAID (Bethesda, MD)	\$98,240	12	D – 12
Viral Hemorrhagic Fevers: Disease Modeling and Transmission (FY20: ZIA AI001089-12)	NIAID (Hamilton, MT)	\$36,719	6	C – 5 E – 1
Virus Ecology Unit (FY20: ZIA AI001179-08)	NIAID (Hamilton, MT)	\$85,678	14	C – 14
Emerging respiratory viruses - pathogenesis and countermeasures (FY20: ZIA AI001259-01 FY21: ZIA AI001259-02)	NIAID (Hamilton, MT)	\$97,917	16	C – 8 E – 8
Laboratory And Preclinical Studies Of Flaviviruses (FY20: ZIA AI000891-20 FY21: ZIA AI000891-21)	NIAID (Bethesda, MD)	\$204,200	40	C – 40

Mechanisms of Immune Activation and Disease Progression in Animal Models (FY20: ZIA AI001029-13)	NIAID (Bethesda, MD)	\$51,620	6	D – 6
SARS-CoV-2 infection of non-human primates (FY21: ZIA AI001294-02)	NIAID (Bethesda, MD)	\$134,320	28	C – 28
Comparative Medicine Infectious Diseases- Bethesda (FY21: ZIG AI001047-14)	NIAID (Bethesda, MD)	\$27,200	5	C – 5
Development of Vaccines to Prevent Tuberculosis (FY21: ZIA AI005136-03)	NIAID (Bethesda, MD)	\$22,440	12	D – 12
Pre-clinical Vaccine Development for Respiratory Viruses (FY20: ZIC AI005135-02 FY21: ZIC AI005135-03) Rapid Development of Vaccines for Emerging Viruses (FY21: ZIC AI005128-06)	NIAID (Bethesda, MD) and BIOQUAL, Inc. (Rockville, MD)	\$98,416	19	D – 19
HIV/AIDS Vaccine and Antibody Development (FY21: ZIC AI005002-20)	NIAID (Bethesda, MD)	\$10,230	5	D – 5
Ebola Antibodies & Virology (FY20: ZIA AI005081-16 FY21: ZIA AI005081-17)	Boston University (Boston, MA) and USAMRIID (Frederick, MD)	\$987,179	41	E – 41
Animal Medicine Infrastructure Support - Animal Care (FY20: ZIG AI005099-08 FY21: ZIG AI005099-09)	NIAID (Bethesda, MD)	\$659,914	121	C – 121

Note: The number of non-human primates listed for these studies include those that were used in experiments within the requested time frame. Some of the animals listed in this table were delivered to the laboratories prior to the requested time frame.