



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

September 29, 2021

(b) (6)

The Office of Policy for Extramural Research (OPERA) in conjunction with the Office of Laboratory Animal Welfare (OLAW) has completed its investigation regarding the concern you submitted on May 11, 2021 on behalf of the People for the Ethical Treatment of Animals which involved NIH supported studies conducted on owls at Johns Hopkins University. Your letter alleges that the Principal Investigator did not have the required Maryland Department of Natural Resources (DNR) permit to cover research activities and possession of live owls from 2015 to 2018 and that this may have also constituted noncompliance with the NIH Grants Policy Statement. The matter was thoroughly investigated by OPERA, OLAW, and the JHU Institutional Animal Care and Use Committee (IACUC) and the following determinations were made:

All required state and federal permits were in place to possess the owls upon initial arrival at JHU. The initial DNR permit was issued in 2013 and covered the original transport to JHU and housing of owls born and raised in captivity. Due to an administrative oversight, the permit was not renewed to cover possession of the owls between January 2015 and December 2018. No annual renewal reminders had been sent by DNR for this activity although reminders had been sent to another JHU investigator who had a wildlife permit. A renewal permit application was submitted in December 2018 and the permit was issued. DNR was made aware of the research activities and the circumstances related to the lapse and no enforcement actions were taken or citations issued. Since then, annual renewals have been appropriately submitted and approved.

No US Department of the Interior Fish and Wildlife permit is required for this research.

Policies and procedures are in place to ensure that investigators working with free roaming or captive wildlife have the appropriate permits in place before conducting animal activities. The IACUC protocol form solicits information from PIs regarding the acquisition of required permits. The IACUC and Attending Veterinarian ensure that appropriate housing is available for all species being studied, assess transportation, and evaluate health status.

JHU ensures that NIH funded investigators are compliant with the NIH Grants Policy Statement and the animal requirements. The owl study has been conducted under an IACUC approved protocol and no significant deficiencies have been identified during semiannual inspections and reviews. The Grants Policy Statement indicates that it does not supersede applicable State or local laws or regulations that impose more stringent standards for the care and use of animals in research and the DNR permit does not impose any more stringent requirements on the protocol activities.

The IACUC will ensure that wildlife permits are in place where required, all permits are currently in place, a calendar reminder process has been implemented to ensure prompt renewal of permits, and the IACUC will maintain copies of permits.

Additional measures have been implemented to ensure that required permits are in place, the owl study has been conducted under an approved IACUC protocol, and no animal welfare concerns have occurred on this study.

JHU is in compliance with the provisions of the NIH Grants Policy Statement and the Public Health Policy on Humane Care and Use of Laboratory Animals and no further actions will be taken on this matter.

Sincerely,

Patricia A. Brown - Digitally signed by Patricia A.
Brown -S
S Date: 2021.09.29 11:05:46 -04'00'

Patricia Brown, VMD, MS, DACLAM (she/her)
Director, Office of Laboratory Animal Welfare,
Office of Extramural Research,
Office of the Director, NIH

cc: Michelle Bulls
Axel Wolff



DEPARTMENT OF HEALTH & HUMAN SERVICES

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July 12, 2021

Re: Animal Welfare Assurance
#A3272-01 (OLAW Case 2L)

Dr. Denis Wirtz
Vice Provost for Research
Johns Hopkins University
3400 N. Charles Street
Baltimore, MD 21218

Dear Dr. Wirtz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 15, 2021 letter responding to my May 14, 2021 request for information regarding whether wildlife permits were in place to cover owls used in a study at Johns Hopkins University (JHU). Specifically, the Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research, NIH had received a concern from the People for the Ethical Treatment of Animals (PETA) stating that a JHU Principal Investigator (PI) did not have the necessary Maryland Department of Natural Resources (DNR) permit to cover research activities and possession of live owls from 2015 to 2018. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) investigated the matter and determined the following:

- 1) All required state and federal permits were in place to possess the owls upon initial arrival at JHU. The initial DNR permit was issued in 2013 and covered original transport to JHU and housing of owls born and raised in captivity. Due to an administrative oversight, the permit was not renewed to cover possession of the owls between January 2015 and December 2018. No annual renewal reminders had been sent by DNR for this activity although reminders had been sent to another JHU investigator who had a wildlife permit. A renewal permit application was submitted in December 2018 and the permit was issued. DNR was made aware of the research activities and the circumstances related to the lapse and no enforcement actions were taken or citations issued. Since then, annual renewals have been appropriately submitted and approved.

No US Department of the Interior Fish and Wildlife permit is required for this research.

- 2) The DNR was apprised by the PI on the status and research use of the owls and permits were issued annually since January 1, 2019.
- 3) Policies and procedures are in place to ensure that investigators working with free roaming or captive wildlife have the appropriate permits in place before conducting animal activities. The IACUC protocol form solicits information from PIs regarding the acquisition of required permits. The IACUC and Attending Veterinarian ensure that appropriate housing is available for all species being studied, assess transportation, and evaluate health status.
- 4) JHU ensures that NIH funded investigators are compliant with the NIH Grants Policy Statement and the animal requirements. The owl study has been conducted under an IACUC approved protocol and no significant deficiencies have been identified during semiannual inspections and reviews. The Grants Policy Statement indicates that it does not supersede applicable State or local laws or regulations that impose more stringent standards for the care and use of animals in research and the DNR permit does not impose any more stringent requirements on the protocol activities.

- 5) The IACUC will ensure that wildlife permits are in place where required, all permits are currently in place, a calendar reminder process has been implemented to ensure prompt renewal of permits, and the IACUC will maintain copies of permits.

Based on its assessment of this explanation, OLAW understands that due to an administrative error, a lapse occurred in DNR permit coverage of the owls but an initial permit and current ones have been in place. Measures have been implemented to ensure that required permits are in place, the owl study has been conducted under an approved IACUC protocol, and no animal welfare concerns have occurred on this study. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals and NIH will inform PETA of this assessment. Thank you for your thorough response to this concern.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC contact
Michelle Bulls, Director, OPERA



June 15, 2021

Via Electronic Mail and US Mail

Axel Wolff, M.S., D.V.M.
Deputy Director, Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

RE: Animal Welfare Assurance #A3272-01 (OLAW Case 2L)

Dear Dr. Wolff,

Please accept this letter as the Johns Hopkins University ("JHU") response to your inquiry dated May 14, 2021, regarding alleged noncompliance by JHU with the requirements of the NIH Grants Policy Statement for work funded by the National Eye Institute Grant R01EY027718 (the "Grant"). An allegation was made to OLAW that a lapse in a wildlife possession permit¹ from the Maryland Department of Natural Resources ("DNR"), of which the DNR was aware since December 2018, constituted a failure to comply with the provisions of the NIH Grants Policy Statement. The ACUC investigated this matter and their determinations are outlined below. JHU takes compliance with animal welfare requirements and grant terms seriously, and in accordance with your request, this matter was considered by the convened meeting of the JHU Animal Care and Use Committee ("ACUC") on May 20, 2021. Following careful investigation and review of the facts, the ACUC unanimously determined that the temporary administrative lapse in the DNR possession permit ***did not constitute a significant deficiency*** from the standards of the Guide for the Care and Use of Laboratory Animals (the "Guide"), PHS Policy, or the Animal Welfare Act or its regulations. JHU has concluded that this administrative lapse was not a violation of the NIH Grants Guide, as the research was conducted at all times under an ACUC approved protocol, in species appropriate housing under an appropriate program of animal care, and in material compliance with all grant terms. More details about our investigation, the underlying circumstances, and the ACUC's determination are provided below. In response to the specific questions in your letter, the ACUC determined the following:

1. ***Were all required wildlife permits in place to cover the owls while in captivity? This also includes any federal permits.***

All of the required state and federal wildlife permits were in place to possess the owls when they arrived at JHU. JHU currently has all state and federal permits required for possession of the owls used under the Grant.

The experiments involving owls are described in a protocol written by Dr. Shreesh Mysore and approved by the ACUC. Maryland law requires that researchers obtain a

¹ While DNR uses a single form for permit applications for collection or possession of certain species, the owls were not collected from the wild, and the permit from the DNR was solely for the possession of the owls.



permit to possess certain specific species of wildlife birds for research purposes. *See* Md. Code Regs. 08.03.09.06(B). The first of multiple DNR permits obtained by JHU for possession of the barn owls used in Dr. Mysore's research was issued by the DNR in December of 2013 (b) (4) This permit was secured prior to the transport and housing of owls born and raised in captivity in the lab of Dr. Mysore's postdoctoral fellowship mentor at Stanford.

Although an expiration date after one year was indicated on the DNR permit, the DNR document provided did not explicitly instruct Dr. Mysore that a renewal of the permit would be required annually after transport of owls from California. Additionally, no correspondence either by e-mail or regular mail from DNR provided guidance near the one-year anniversary of the DNR permit issuance of the need to renew. Consequently, due to an administrative oversight, there was no active DNR permit to cover possession of the owls between January 2015 through December 2018. It is relevant, we believe, that DNR reminders are provided annually to the only other JHU faculty member holding a collection permit with DNR. In December 2018, when Dr. Mysore became aware that DNR had not sent him a renewal application, he worked with the Attending Veterinarian to contact the correct person within the DNR to request and complete the renewal application. The DNR instructed Dr. Mysore to file for a renewal application and sent him the necessary paperwork.

The renewal application submitted to the DNR included a cumulative statement of the research uses of the owls from January 1, 2015 through December 31, 2018. DNR was expressly aware of all the facts and circumstances surrounding the permit, and did not cite JHU or Dr. Mysore, but proceeded to issue the renewal permit (DNR Permit # 55025). DNR has continued to approve annual renewals of this permit, including most recently for the current year. Of note, this most recent renewal was issued by DNR *after* DNR had received a complaint from a third party regarding the 2015-2018 period. While DNR subsequently sent Dr. Mysore a letter reminding him of the need to maintain current possession permits, see Exhibit 1, DNR has not cited JHU or Dr. Mysore for this administrative lapse of which DNR has been aware of almost three and a half years.² As stated above, Dr. Mysore's work with barn owls is currently in compliance with state and federal permitting guidelines.

With respect to federal law, in general permits are required under the Migratory Bird Treaty Act for possession of certain bird species including barn owls. In this case, no federal permits were required for JHU to possess the barn owls used in this research. JHU is exempt from permitting requirements as a "public scientific or educational institution" under the Migratory Bird Treaty Act's regulatory exemptions at 50 CFR 21.12(b). The United States Department of the Interior Fish and Wildlife Service confirmed this exemption to Dr. Mysore by letter dated November 12, 2013, a copy of which is attached for your convenience as Exhibit 2. Further, there was no requirement

² The Maryland regulations authorize DNR to "suspend or revoke a permit if the permittee fails to comply with the terms of the permit or submit the annual report." Md. Code Regs. 08.03.09.06(F). At no time has DNR acted to revoke the issued permits, or to claim that JHU/Dr. Mysore failed to comply with the permit terms. The DNR letter to Dr. Mysore supports the ACUC conclusion that this was an administrative oversight. Of note, the DNR permit application is captioned as a "collecting" permit, even when only possession is sought.



to obtain a federal permit pursuant to the Animal Welfare Act as barn owls are excluded from coverage under that Act.

2. *If permits were not in place, what steps have been taken with DNR to rectify the matter?*

Please see the response to question 1, above. As expected with these renewals, Dr. Mysore provided a full report to the DNR on the status and research use of the animals in the possession of JHU prior to his renewal permit applications in December of 2018 and each year thereafter to date. DNR has renewed the possession permits without question each year since January 1, 2019. JHU is currently in compliance with the DNR permitting regulations. Additional steps taken by JHU to further ensure compliance with all state regulations are described in response to question 5.

3. *Are policies and procedures in place to ensure that all investigators working with free roaming or captive wildlife have the appropriate permits in place before conducting animal activities?*

Yes. JHU has well-established policies and procedures, as described herein, to ensure that all investigators, including investigators working with free roaming or captive wildlife, have the appropriate permits in place before conducting animal activities. JHU is an AAALAC accredited institution, has held without interruption both Class A and Class R USDA licenses for many years, and abides by the OLAW assurances that we reaffirm annually.

At the investigator level, assurances that appropriate permits are in place are provided by the signatures of both the Principal Investigator and the ACUC Chair under a series of statements on our protocol review form, including the following: "I assume responsibility for compliance with all state and federal policies and regulations, and the policies and guidelines of the Johns Hopkins University, for work carried out under this protocol." No experiments on live animals can be performed without prior application for and ACUC approval of a protocol. This process was followed and a DNR permit was in place before commencement of the research with the owls at JHU.

Upon submission, protocols are given a protocol number that clearly identifies the class of animals studied or species to be studied (e.g. mouse (MO), bird (AV), bat (BA)) and their source. This information is used by the ACUC to select the most appropriate (based on expertise) committee member to be assigned primary review and also prompts work within the ACUC office to confirm that suitable housing and permits are in place for the animals, to make note of the source of the animals, and to evaluate the location where the work will be conducted. Once the protocol is approved, import or purchase of animals requires approval by purchasing administrators who will also evaluate the supplier, and by the attending veterinarians and staff who will evaluate and, if necessary, establish suitable housing and transportation arrangements and plans to evaluate the health status of all acquired animals upon arrival.

These policies and procedures have been highly effective in ensuring that needed permits for specific species are identified, and that permits are obtained and maintained. It is of



note in this case, that over the past 4 years, just 3 (out of 2425) approved protocols at JHU involved work with free roaming or captive wildlife, one of which required no DNR permits and only 2, including Dr. Mysore's protocol, remaining active. State DNR permits are up to date for these ACUC approved protocols. Copies of these permits are maintained in the ACUC office.

4. *Are policies and procedures in place to ensure that NIH funded investigators are compliant with the provisions of the NIH Grants Policy Statement?*

Yes. Johns Hopkins ensures that all NIH funded investigators are compliant with the NIH Grants Policy Statement Section 4.1.1, which addresses Animal Welfare Requirements. As required by the NIH Grants Policy Statement provision, JHU maintains a current Animal Welfare Assurance with OLAW. With an accompanying annual report, JHU renews each year our Animal Welfare Assurances with OLAW. Johns Hopkins University Policy GEN001, *Animal Care and Use Program*, a copy of which is attached as Exhibit 3, establishes the authority of the ACUC and makes explicit the requirement that all educational or research use of animals (as defined in that policy) receive prospective approval and comply with the Guide. While Section 4.1.1 of the NIH Grants Policy Statement provides that it does not "supersede applicable State or local laws or regulations that impose more stringent standards for the care and use of animals in research," the DNR permit does not impose any more stringent requirements than those contained in Dr. Mysore's animal protocol that has been reviewed and approved by the JHU ACUC without lapse since 2013. Multiple semi-annual inspections have been performed in the associated housing and lab facilities for these owls with no major deficiencies noted. Animal health checks are performed at least daily and clinical services are available 24/ 7 if needed.

5. *Provide any additional relevant information on this topic.*

As noted above, this inquiry prompted our ACUC to review the underlying circumstances for a determination of whether the circumstances in this case constituted a significant deficiency as defined by the PHS Guide. The committee voted unanimously at its May 20, 2021 meeting that this event did not rise to the level of a significant deficiency. Looking more globally at the types of animals proposed for use in research at JHU, as a quality assurance exercise, the ACUC reviewed its database of every protocol approved over the past 4 years and identified only 2 protocols requiring DNR permits. Both of these protocols are currently up to date with all required state and federal permits. As outlined above, the ACUC will continue to flag applications involving wild-caught animals or captive wildlife, and the ACUC has added a calendar reminder process for investigators to initiate permit renewal applications. The ACUC office will ensure that copies of permits are maintained in their office, and that renewals are filed regularly as required. The JHU ACUC considers this matter to be closed.

In summary, since Dr. Mysore's research work with barn owls began at JHU, the Grant has been carried out under an approved protocol under the oversight of the ACUC, and the ACUC has determined that the barn owls have been housed and treated consistent with the approved protocol and the provisions of the Guide. At no time has DNR indicated that the possession of



the owls by JHU was inconsistent with the conditions of a DNR permit, and DNR has renewed the possession permit three times after full awareness of the facts and circumstances of the continuous possession of the owls by JHU.

Please do not hesitate to contact me if you have additional questions.

Sincerely,

(b) (6)

Denis Wirtz, PhD

Vice Dean for Research and Institutional Official

Attachments

cc: Brendan Canning, Chair, ACUC (w/attachments)

Dr. Eric Hutchinson, Attending Veterinarian (w/attachments)

(b) (6)

Exhibit 1



Larry Hogan, Governor
Boyd Rutherford, Lt. Governor
Jeannie Haddaway-Riccio, Secretary

March 4, 2021

Dr. Shreesh Mysore
Johns Hopkins University
3400 N. Charles Street (b) (4)
Baltimore MD 21218

Dear Dr. Mysore:

Your original permit expired on 12/31/2014. You did not respond to the request to renew so we presumed there was no longer a need for the continued use of the permit for the original research project.

We understand that you are continuing your research under a renewed permit but need to remind you that operating under an inactive permit is a violation and subject to potential enforcement action and foreclosure of the research project.

Please maintain timely records and renewals as required.

Thank you,

(b) (6)

Paul A. Peditto
Director,
Wildlife and Heritage Service

cc: (b) (6)

Exhibit 2



United States Department of the Interior

FISH AND WILDLIFE SERVICE
Post Office Box 779
Hadley, MA 01035-0779



In Reply Refer To:
FWS/Region 5/MB21504B

November 12, 2013



Thank you for your application on behalf of Johns Hopkins University for a Scientific Collecting permit, received on November 8, 2013. Your application requested authority to acquire captive bred Barn Owls from similar public educational institutions. For the reasons listed below, your application is denied.

Scientific Collecting permits are issued for the purpose of authorizing take of migratory birds from the wild. Your application indicates your source of Barn Owls is similar public educational institutions.

In accordance with 50 CFR § 21.12(b) public scientific or educational institutions may possess lawfully acquired migratory bird specimens without a Federal permit.

We welcome you to review our website regarding our laws, Treaties and Regulations page at <http://www.fws.gov/permits/ltr/ltr.html>.

Having processed your application, we cannot return the \$100.00 non-refundable processing fee.

(b) (6)

November 12, 2013

As provided in Title 50 CFR § 13.29, you may request reconsideration of your application. Such request must be submitted in writing to this office within 45 calendar days of the date of this letter and state the reason(s) for the reconsideration, including presentation of any new information pertinent to the issues raised in this letter. Your request for reconsideration must also contain certification in substantially the same form as provided by Title 50 CFR § 13.12(a)(5).

Sincerely

(b) (6)

Exhibit 3

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Policy Statement

As an institution committed to the creation of new knowledge through research, The Johns Hopkins University ("University" or "JHU") believes that excellence in research and teaching requires excellence in our animal care and use program. Animals that are used in research and teaching at the University are covered by the Johns Hopkins University Animal Care and Use Program ("Program"), and oversight of the Program with respect to compliance with applicable laws, regulations and agency guidance is the responsibility of the Johns Hopkins University Animal Care and Use Committee ("ACUC" or "Committee").

The Program is the ultimate responsibility of the President of the University, who has delegated responsibility for the Program to the Vice Provost for Research. The primary oversight responsibilities in the Program rest with the Institutional Official (IO), the Attending Veterinarian ("AV"), and ACUC. Their roles fit in a defined organizational structure where the reporting relationships, authorities, and responsibilities of each are clearly defined and transparent. Together they establish policies and procedures, ensure regulatory compliance, monitor Program performance, and support high-quality science and humane animal use.

JHU is able to receive Department of Health and Human Services (HHS) funding for animal research (e.g., from National Institutes of Health) by virtue of its approved Assurance of compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, renewed every 4 years. JHU is registered as a research facility as required by the Animal Welfare Act Regulations, which are enforced by the U.S. Department of Agriculture via at least annual unannounced inspections. JHU also maintains voluntary accreditation of its animal care and use program by the private organization AAALAC International, which conducts site visits every 3 years. JHU's ability to receive funding for animal research from federal agencies other than HHS and from private organizations also typically is dependent on proof of the PHS Assurance and is enhanced by continued accreditation from AAALAC International.

Who Is Governed By This Policy

All units of the University including The Johns Hopkins University Applied Physics Laboratory. All faculty, staff and students of the University, regardless of physical location, are subject to this Policy.

GEN001 Animal Care and Use Program

Responsible Executive: Provost & Vice President for Academic Affairs

Responsible Office: Office of the Provost

Approved by: Senior Planning Group

Effective: 01/01/2019

Last Revised: N/A

Definitions

Institutional Official	The Institutional Official (IO) is a representative of senior administration who bears ultimate responsibility for the Program and is responsible for resource planning and ensuring alignment of Program goals with the institution's mission. The Institutional Official is authorized to legally commit on behalf of the University that federal requirements will be met.
Animal	Under PHS Policy, animal means any live, vertebrate animal that is used or is intended for use in research, teaching, testing, experimentation, or related purposes at the University. The Animal Welfare Act Regulations cover all warm-blooded animals used for the same purposes but exclude birds, rats of the genus <i>Rattus</i> , and mice of the genus <i>Mus</i> , bred for use in research. As used in this Policy, the PHS definition applies.
Attending Veterinarian	The Attending Veterinarian is the veterinarian appointed by the IO who is responsible for the health and well-being of all laboratory animals used at the University. The Attending Veterinarian shall meet all credentialing requirements to fulfill his/her role. The Attending Veterinarian has direct authority for activities involving animals at the University, which he/she may delegate under this Policy.

The National Research Council's Guide for the Care and Use of Laboratory Animals serves as the primary source for standards for the JHU Animal Care and Use Program.

The definitions used herein are adapted from the [Animal Welfare Act Regulations](#) found in [the Code of Federal Regulations, Title 9, Chapter 1, Subchapter A, Part 1](#) (7 U.S.C. 2131-2159; 7 CFR 2.22, 2.80, and 371.7), Public Health Service Policy on Humane Care and Use of Laboratory Animals, and the Guide for the Care and Use of Laboratory Animals.

Policy**I. Animal Care and Use Program****A. Administrative Structure****1. Institutional Official ("IO")**

The Vice Provost for Research serves as IO, a position defined by federal law and PHS Policy. The IO coordinates policy regarding the Program with the Deans of the Schools of the University and the Director of Health Safety and Environment or their designees. The Chair of the ACUC and the Associate Provost for Animal Research and Resources each have university-wide responsibilities in the Program and report directly to the IO.

2. Research Animal Resources ("RAR")

- a. **Associate Provost for Animal Research and Resources.** The Associate Provost reports directly to the IO and serves as the Attending Veterinarian for the Johns Hopkins Animal Care and Use Program. The Associate Provost serves as the Director of Research Animal Resources and thus is responsible for arranging and overseeing the Program of Animal Husbandry and the Program of Veterinary Medical care for all animals at the University at all locations, or at any location that is a part of the Johns Hopkins Health System. The Associate Provost shall be responsible for reviewing and approving the suitability (with respect to the program of veterinary care and animal welfare) of any proposed renovation, expansion, or new construction of facilities in which animals may be housed or used.

GEN001 Animal Care and Use Program

Responsible Executive: Provost & Vice President for Academic Affairs

Responsible Office: Office of the Provost

Approved by: Senior Planning Group

Effective: 01/01/2019

Last Revised: N/A

- b. Associate Director of RAR -Director of Laboratory Animal Medicine. The Associate Director of RAR reports to the Director of RAR and assists in arranging and directing the Program of Animal Husbandry. As Director of Laboratory Animal Medicine, he/she oversees the veterinary medical care of animals at the University through a 24-hour, 7-day/week on-call service staffed by clinical veterinarians trained, or in training, in laboratory animal care. The clinical veterinarians make rounds regularly and are available for consultation in the preparation of proposals for animal research or teaching.

II. The Role of the Johns Hopkins University Animal Care and Use Committee**A. Responsibilities**

The ACUC is responsible for oversight of the Program and its components as described in the Public Health Service (PHS) [Policy on Humane Care and Use of Laboratory Animals](#), the [Guide for the Care and Use of Laboratory Animals](#), and in the Animal Welfare Act Regulations, where applicable.

The responsibility of the ACUC is to oversee and routinely evaluate the Program. The University provides suitable orientation, background materials, access to appropriate resources, and specific training to assist ACUC members in understanding their roles and responsibilities and evaluating issues brought before the Committee.

ACUC responsibilities and authority include:

1. Review, at least semiannually, the Program for the humane care and use of Animals;
2. Inspect, at least once every 6 months, the University's animal facilities, which includes all areas in which animals are housed or used in research (including satellite facilities);
3. Prepare reports to the IO of ACUC evaluations;
4. Review and respond to any concerns involving the care and use of animals at the University;
5. Make recommendations to the IO on any aspect of the Program, facilities, or personnel training;
6. Review and approve, require modifications in (to secure approval), or withhold approval of protocols for research, testing, or teaching activities involving the use of Animals and any proposed significant changes to those activities.
7. Review and approve ACUC policies as needed to guide investigators in the humane use of Animals;
8. Suspend an activity with Animals that it previously approved if the activity is not being conducted in accordance with applicable federal regulations/policies.

B. Authority of the ACUC

All research and teaching procedures to be carried out using Animals must be approved prospectively by the ACUC. The ACUC is authorized to suspend any activity it previously approved as indicated above. The ACUC has the authority to investigate suspected violations of this Policy, any ACUC policies, and any applicable federal regulations and policies, and may take actions as a result of such investigations. The ACUC shall have the authority to make, through the IO, all reports to government agencies or accrediting bodies as may be required by law, regulation or policy.

GEN001 Animal Care and Use Program

Responsible Executive: Provost & Vice President for Academic Affairs

Responsible Office: Office of the Provost

Approved by: Senior Planning Group

Effective: 01/01/2019

Last Revised: N/A

C. Oversight Functions

Oversight of the Program with respect to compliance with laws and policy in the responsibility of the ACUC. The ACUC chair is appointed by the IO and reports directly to the IO.

D. Committee Membership

The ACUC membership consists of at least 5 members, appointed by the IO, and includes at least:

1. A Doctor of Veterinary Medicine with training and experience in laboratory animal science and medicine, who has direct or delegated Program authority and responsibility for activities requiring animals at the institution,
2. at least one practicing scientist experienced in research involving animals,
3. at least one member from a nonscientific background, drawn from inside or outside the University, and
4. at least one member who is not affiliated with the institution in any way to represent general community interests in the proper care and use of animals.

The ACUC meets as often as necessary to fulfill its responsibilities, and records of committee meetings and results of deliberations are maintained in accordance with the [Records Retention and Destruction Policy](#).

E. Committee Staff

Certain functions to support the ACUC are performed by ACUC staff, who carry out the below roles:

1. Process protocols, amendments, and various university standard operating procedures and policies for review by the ACUC.
2. Organize the ACUC semi-annual facility inspections, distribute notices of deficiencies and follow up on corrections, including via announced or unannounced visits.
3. Investigate, on behalf of the ACUC, all animal welfare concerns reported to the ACUC and/or the ACUC office.
4. Inspect, an area proposed for satellite housing to determine its suitability for this purpose in relation to ACUC policies, and make a recommendation regarding its approval.
5. Arrange, coordinate, and/or teach workshops and group or individual training sessions on a variety of procedures needed in research with animals at the University.

F. Facilities Management

Facilities Management is a critical element of the Program. The ACUC, through the semi-annual inspection and Program review process, or RAR coordinate needs for facility evaluation (e.g., heating and ventilation), repair, and pest control with each unit of the University. Deficiencies related to facilities management issues that are identified in ACUC semi-annual inspections are reported to the appropriate facilities management director as well as to the investigator.

III. Investigating and responding to Noncompliance

Allegations of noncompliance with ACUC policies or applicable federal regulations/policies may be received from observations during semi-annual inspections, reports to the ACUC or its staff, through the Compliance Hotline, through reports to the IO, as well as by reports to the several individuals listed on an Animal Welfare Concerns document posted in all areas in which animals are housed or used in covered activities. All concerns

GEN001 Animal Care and Use Program

Responsible Executive: Provost & Vice President for Academic Affairs

Responsible Office: Office of the Provost

Approved by: Senior Planning Group

Effective: 01/01/2019

Last Revised: N/A

are reported to the ACUC and reviewed at its meetings. If warranted, an ACUC Compliance subcommittee is convened to evaluate the information collected and to determine a corrective action plan. Individual violations may result in suspension of access to the animal facility pending investigation and necessary retraining.

Serious or continuing deviations from PHS policy and protocol suspensions related to PHS-funded activities are reported through the IO to the Office of Laboratory Animal Welfare along with a corrective action plan; and protocol suspensions involving animals covered under the Animal Welfare Act are reported to the Animal and Plant Health Inspection Service, Eastern Regional Office. Reports are simultaneously reported to the private accrediting agency AAALAC International along with the corrective action plan. In accordance with federal regulations and University policies, persons who report suspected noncompliance in good faith shall not be subject to retaliation in their employment.

Exceptions/Exclusions

This Policy does not apply to allegations or complaints that do not fall within the definition of animal care and use as set forth in this document or to matters that fall exclusively under other policies, including violations of the University Research Integrity Policy, conflict of interest policies, or violations of fiscal or other University policies, which shall be directed to the offices responsible for such matters. Where an allegation includes matters that may be partly within the scope of this Policy and also within the scope of another policy, the Institutional Officer shall coordinate as necessary with other offices.

Policy Enforcement

Enforcement	The Institutional Official and ACUC (as defined in the Policy) are responsible for the conduct of investigations. Disciplinary actions may be taken as outlined in the Policy.
Reporting Violations	All members of the University community have an obligation to report good faith concerns regarding violations of ACUC protocols or policies within the scope of this Policy. Violations may be reported as set forth in Section III of the Policy, or through the Compliance Hotline.

Related Resources

University Policies and Documents
Johns Hopkins University Animal Care and Use Program
Records Retention and Destruction Policy
University Forms and Systems
Animal Care and Use Program Forms
Animal Care and Use Program Policies and Guidelines
Animal Care and Use Program FAQs

GEN001 Animal Care and Use Program

Responsible Executive: Provost & Vice President for Academic Affairs

Responsible Office: Office of the Provost

Approved by: Senior Planning Group

Effective: 01/01/2019

Last Revised: N/A

Contacts

Subject Matter	Office Name	Telephone Number	E-mail/Web Address
Policy Clarification and Interpretation	Office of the Animal Care and Use	(b) (6)	acuc@jhmi.edu www.jhu.edu/animalcare
Anonymous Reporting/ EthicsLine	Johns Hopkins University and Health System Compliance Line		https://johnshopkinsspeak2us.tnwreports.com/
Reporting violations of civil or criminal law	Office of the Vice President and General Counsel		http://web.jhu.edu/administration/general_counsel/
Reporting allegations of research misconduct	Research Integrity Officer		http://web.jhu.edu/administration/provost/bios/links

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, June 16, 2021 7:51 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Response to Office of Laboratory Animal Welfare (OLAW)

Thank you for this detailed report, (b) (6) I will first need to confer with another NIH oversight office before preparing the response.

Axel Wolff

From: (b) (6)
Sent: Tuesday, June 15, 2021 12:32 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: Brendan Canning <bjc@jhmi.edu>; Eric Hutchinson <ehutchi8@jhmi.edu>; (b) (6)
Subject: Response to Office of Laboratory Animal Welfare (OLAW)

Good day Dr. Wolff,

Please see attached for the response from Johns Hopkins University regarding your inquiry.

Please note: all times offered are Eastern Daylight Time

(b) (6)





DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

May 14, 2021

Re: Animal Welfare Assurance
#A3272-01 (OLAW Case 2L)

Dr. Denis Wirtz
Vice Provost for Research
Johns Hopkins University
3400 N. Charles Street
Baltimore, MD 21218

Dear Dr. Wirtz,

On May 11, 2021, the Office of Laboratory Animal Welfare (OLAW) received a transmittal from the Office of Policy for Extramural Research Administration, Office of Extramural Research, NIH, submitted by the People for Ethical Treatment of Animals (PETA) which alleges possible noncompliance with Maryland Department of Natural Resources (DNR) requirements by a Johns Hopkins University Principal Investigator (PI). Specifically, the allegation states that PI Shreesh Mysore was conducting research on barn owls from 2015 to 2018 without the appropriate wildlife permits in place. In support of this allegation, reference was made to communication with (b) (6) who states that state law was not being followed regarding required permitting. The research work is funded by the National Eye Institute under grant #R01EY027718. Apparently the PI had a valid collecting permit in 2014 but failed to renew it despite the requirement for a permit during the conduct of scientific or educational purposes and for propagation of captive wildlife. It is possible that failure to comply with state law due to lack of permits is also a violation of the NIH Grants Policy Statement.

Please direct the Institutional Animal Care and Use Committee, avoiding any conflicts of interest, to investigate the matter and determine the following:

- 1) Were all required wildlife permits in place to cover the owls while in captivity? This also includes any federal permits.
- 2) If permits were not in place, what actions have been taken with the DNR to rectify the matter?
- 3) Are policies and procedures in place to ensure that all investigators working with free roaming or captive wildlife have the appropriate permits in place before conducting animal activities?
- 4) Are policies and procedures in place to ensure that NIH funded investigators are compliant with the provisions of the NIH Grants Policy Statement?
- 5) Provide any additional relevant information on this topic.

Please provide the requested information by **June 15, 2021**. Feel free to contact me should you have any questions.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC contact



PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

May 11, 2021

Michelle G. Bulls
Director
Office of Policy for Extramural Research Administration
National Institutes of Health
6705 Rockledge Dr.
Bethesda, MD 20817

Via e-mail: Michelle.Bulls@nih.gov

Dear Director Bulls:

I am writing on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters regarding serious concerns about a National Institutes of Health-funded grant for experiments on barn owls conducted by Johns Hopkins University's (JHU) Shreesh Mysore, an assistant professor in the Department of Psychological and Brain Sciences at Johns Hopkins University (JHU; PHS Assurance # D16-00173). Specifically, after we supplied evidence to the Maryland Department of Natural Resources (DNR) that from 2015 through 2018, Mysore failed to obtain permits needed to confine and conduct invasive brain experiments on owls in his laboratory, (b) (6)

(b) (6) confirmed to us in a letter dated May 5, 2021, that he had indeed been breaking state law for years.¹

Based on the information presented below, we ask that your office investigate this important matter and demand repayment of all disallowed taxpayer funds expended by Mysore and/or JHU during the period in which he violated Maryland state law, per the requirements of the NIH Grants Policy Statement. We also ask that you prohibit Mysore from receiving future funding from NIH and other government agencies for experiments on animals, based on his history of noncompliance with state law and the overwhelming failure of his experiments on owls to translate to human health as documented by NIH itself.

Mysore is the recipient of National Eye Institute (NEI) grant # R01EY027718 for a project involving the study of the neural correlates

(b) (6) Letter from Maryland Department of Natural Resources to PETA. May 5, 2021.

Washington, D.C.
1536 16th St. N.W.
Washington, DC 20036
202-483-PETA

Los Angeles
2154 W. Sunset Blvd.
Los Angeles, CA 90026
323-644-PETA

Norfolk
501 Front St.
Norfolk, VA 23510
757-622-PETA

Berkeley
2855 Telegraph Ave.
Ste. 301
Berkeley, CA 94705
510-763-PETA

Info@peta.org
PETA.org

Affiliates:

- PETA Asia
- PETA India
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands
- PETA Foundation (U.K.)

Obtained by Rise for Animals.

of sensory selection and stimulus prioritization in barn owls (*Tyto alba*). To this end, he keeps approximately 30 barn owls in his laboratory at JHU, performs invasive neurophysiological experiments on them and ultimately kills them. A permit is required in Maryland “to possess a protected bird or parts of a protected bird for educational or scientific purposes, or for the purpose of propagation,”² and since barn owls are a “protected bird,”³ Mysore violated the regulations implementing the state’s captive wildlife statutes while using federal funds. Evidence furnished to PETA by the Maryland Department of Natural Resources (DNR) confirmed that, from 2015 through 2018, Mysore engaged in the regulated confinement of owls for experimentation without securing the necessary permits as is required by Maryland state law.

In (b) (6) letter to PETA, (b) (6) states, “... Dr. Mysore’s original scientific collecting permit expired on December 31, 2014. A few years later, Dr. Mysore reapplied for a scientific collecting permit...” and (b) (6) notes that the DNR sent Mysore a letter on March 4, 2021, warning him “that he will need to renew the permit annually and that operating under an inactive permit is a violation and subject to potential enforcement action and foreclosure of the research project.”⁴

As you know, the NIH Grants Policy Statement is explicit in disallowing the expenditure of taxpayer funds for costs resulting from violations of state law:

Costs resulting from non-Federal entity violations of, alleged violations of, or failure to comply with, Federal, state, tribal, local or foreign laws and regulations are unallowable, except when incurred as a result of compliance with specific provisions of the Federal award, or with prior written approval of the NIH awarding IC.⁵

The Statement also includes adherence to Title 45 Section 75.441 of the Code of Federal Regulations, which states:

Costs resulting from ... violations of, ... or failure of the institution to comply with, Federal, state, ... local ... laws and regulations are unallowable except when incurred as a result of compliance with specific provisions of the Federal award, or with prior written approval of the HHS awarding agency.⁶

Mysore used federal funds to conduct experiments on owls while in violation of Maryland state law. The permitting provisions for scientific collection are not optional—they are a basic legal prerequisite to keeping these owls, who would otherwise be protected under the law, confined for use in invasive brain experiments. Mysore’s failure to satisfy the requirements of Maryland’s wildlife regulations strongly counsels against allowing

²Md. Code Regs. 08.03.09.06(B).

³Md. Code Regs. 08.03.01.01.

⁴(b) (6)

⁵U.S. Department of Health and Human Services, National Institutes of Health. *NIH Grants Policy Statement*. National Institutes of Health; April 2021.

⁶45 CFR §75.300. Statutory and National Policy Requirements.

Mysore and JHU to engage in the continued possession of barn owls and other protected birds. **Furthermore, Mysore's experiments on owls do not pass a harm-benefit analysis, given that NIH itself has reported that Mysore's animal-based projects have a shockingly dismal 5% "approximate potential to translate" to human health, determined by the very low likelihood that his published papers will be cited in later clinical trials or guidelines.**⁷

It is incumbent upon your office to uphold its regulations and support sound human-relevant science by seeking repayment of relevant funds and permanently barring Mysore from receiving future NIH grant awards.

You can contact me directly via e-mail at (b) (6). Thank you for your time and consideration. I look forward to your response.

Sincerely,

(b) (6)

cc: Michael Lauer, Director, Office of Extramural Research (OER)
Patricia Brown, Director, Office of Laboratory Animal Welfare (OLAW)
Michael Chiang, Director, National Eye Institute (NEI)

⁷iCite, Hutchins BI, Santangelo G. iCite Database Snapshots (NIH Open Citation Collection) [Internet]. figshare; 2019. doi: 10.35092/yhjc.c.4586573. Search terms "mysore, shreesh, owl" were inputted and the average approximate potential to translate (APT) was determined.

Wolff, Axel (NIH/OD) [E]

From: Brown, Patricia [OLAW] (NIH/OD) [E]
Sent: Tuesday, May 11, 2021 3:12 PM
To: Wolff, Axel (NIH/OD) [E]
Subject: RE: For Director Michelle Bulls, from PETA – Request to recoup NIH grant misspent on illegal owl use at JHU lab

Yes, Brent told me he had assigned it to you because of your past involvement.
Thanks for taking on this one.
Pat

From: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Sent: Tuesday, May 11, 2021 2:59 PM
To: Brown, Patricia [OLAW] (NIH/OD) [E] <brownp@od.nih.gov>
Subject: RE: For Director Michelle Bulls, from PETA – Request to recoup NIH grant misspent on illegal owl use at JHU lab

I'll be continuing with this case.
Thanks.

From: Brown, Patricia [OLAW] (NIH/OD) [E] <brownp@od.nih.gov>
Sent: Tuesday, May 11, 2021 2:21 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Subject: FW: For Director Michelle Bulls, from PETA – Request to recoup NIH grant misspent on illegal owl use at JHU lab

FYI
Pat

From: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Sent: Tuesday, May 11, 2021 1:03 PM
To: Brown, Patricia [OLAW] (NIH/OD) [E] <brownp@od.nih.gov>
Cc: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Chiang, Michael (NIH/NEI) [E] <michael.chiang@nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: RE: For Director Michelle Bulls, from PETA – Request to recoup NIH grant misspent on illegal owl use at JHU lab

Perfect and thanks so much, Pat!!

From: Brown, Patricia [OLAW] (NIH/OD) [E] <brownp@od.nih.gov>
Sent: Tuesday, May 11, 2021 12:56 PM
To: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>
Cc: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Chiang, Michael (NIH/NEI) [E] <michael.chiang@nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: RE: For Director Michelle Bulls, from PETA – Request to recoup NIH grant misspent on illegal owl use at JHU lab

Dear Michelle,

OLAW is reviewing the allegations concerning Johns Hopkins University and will coordinate with OPERA on further actions that may be necessary.

Sincerely,
Pat

Patricia Brown, VMD, MS, DACLAM (she/her)
Director, Office of Laboratory Animal Welfare,
Office of Extramural Research, Office of the Director, NIH
301-451-4209, brownp@mail.nih.gov

From: [REDACTED] (b) (6)

Sent: Tuesday, May 11, 2021 12:15 PM

To: Bulls, Michelle G. (NIH/OD) [E] <michelle.bulls@nih.gov>

Cc: Lauer, Michael (NIH/OD) [E] <michael.lauer@nih.gov>; Chiang, Michael (NIH/NEI) [E] <michael.chiang@nih.gov>;
Brown, Patricia [OLAW] (NIH/OD) [E] <brownp@od.nih.gov>; [REDACTED] (b) (6)

Subject: For Director Michelle Bulls, from PETA – Request to recoup NIH grant misspent on illegal owl use at JHU lab

May 11, 2021

Michelle G. Bulls
Director
Office of Policy for Extramural Research Administration
National Institutes of Health
6705 Rockledge Dr.
Bethesda, MD 20817

Dear Director Bulls:

Please find enclosed a letter on behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters regarding serious concerns about a National Institutes of Health–funded grant issued to Johns Hopkins University's (JHU) Shreesh Mysore for experiments on barn owls that he conducted illegally for years, per confirmation to PETA from [REDACTED] (b) (6). Thank you for your consideration of this important issue, and we look forward to your response.

Sincerely,

[REDACTED] (b) (6)

Read PETA scientists'
revolutionary plan to phase
out animal experimentation

The 2021 Research Modernization Deal

