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

August 11, 2023

Re: Animal Welfare Assurance
#A3012-01 [OLAW Case 1K]

David Mu, Ph.D.
Associate Dean for Research Administration
Eastern Virginia Medical School
735 Fairfax Avenue
EVMS Waitzer Hall, (b) (4)
Norfolk, VA 23507

Dear Dr. Mu,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 30, 2023 email correspondence in response to the letter dated May 31, 2023 sent from this office. The letter included a request for additional information regarding allegations of noncompliance OLAW received from People for the Ethical Treatment of Animals (PETA) regarding the USDA APHIS Inspection Report dated January 12, 2023.

OLAW requested additional information regarding a study that was extended beyond the initial 22-week period as approved in the protocol, which utilized chinchillas. Your correspondence reiterates Covid restrictions limited the investigator's ability to complete their study, resulting in experimental procedures extending beyond 22 week. It is understood a formal request to extend the 22-week timeline was not submitted to or approved by the IACUC. It is further stated the PI and the IACUC believed the extension was allowable without express IACUC approval since the protocol was approved for a total of 3yrs, and all activities described in the protocol were completed within the 3-year period.

It is stated the initiation of treatment for the chinchillas was based on veterinary directives. The chinchillas were treated at the direction of the Attending Veterinarian based on observations made by the investigative staff during planned procedures and/or observations made by the CompMed/veterinary staff during routine husbandry and monitoring procedures.

It was confirmed that unapproved animal activities did occur on this study, and OLAW requested clarification regarding the corrective actions taken to prevent future recurrence, and how information is communicated to the research community. It is stated the Post-approval Monitoring (PAM) program has been enhanced as of February 2023. The program now includes increased number of PAM professionals conducting audits and expansion of the logistics of the auditing process. It is understood all active protocols are audited at least annually, but more frequent audits may be conducted at the IACUC's discretion. It is stated during PAM records review, the auditor will discuss the requirement of an amendment to a protocol to be approved by the IACUC prior to its implementation. Auditors will also notify the staff that failure to comply constitutes a noncompliance that will be reportable to the appropriate entities. Furthermore, a written report will be sent to the PI following the PAM audit that will include a statement regarding the consequences of failure to comply with this requirement.

Regarding communication with the research community, it is stated researchers were notified of the enhanced PAM program. On May 18, 2023 a town hall was held to address various animal care and use topics, including protocol approval and amendments to approved protocols. It is stated all required users were present. It is stated moving forward, the IACUC will provide written information/reminders to the community regarding appropriate management of approved protocols. It is noted the IACUC is considering hosting semiannual town halls to provide updates on regulations, institutional policies/procedures, etc.

Regarding corrective actions taken to address inadequate recordkeeping, it is reiterated that the enhanced PAM program now includes review of records. These reviews will apply to both study and clinical records, and any deficiencies identified will be discussed with the investigative staff and the auditors will work with staff to update records and/or revise forms, as applicable. It is also stated that inadequate recordkeeping may be addressed by ensuring that forms are sufficiently designed to document approved activities, as appropriate.

Another corrective measure to address recordkeeping is the purchase of a new electronic medical recordkeeping system that allows for standardization and enhanced oversight of clinical records. This system will capture and catalogue anesthesia, treatment, diagnostic testing, clinical observation, and related medical records. It is understood the institution's goal is to implement use of the software within the next few months.

OLAW requested additional details regarding the inadequate recordkeeping of clinical care for an animal described in the USDA APHIS Inspection Report. The IACUC acknowledges that the clinical record was missing information and omitted documentation at specific timepoints. This finding is attributed to inadequate oversight and/or lack of training. To address this matter, the new Attending Veterinarian and the CompMed program manager conducted a refresher training session with the CompMed staff to review appropriate recordkeeping requirements. It is also stated from an investigative staff/study procedures perspective, proper recordkeeping was addressed during the May 18, 2023 town hall.

Thank you for the detailed responses to the follow up questions. Your correspondence states the PI and IACUC believed that extension of the study timeline without IACUC review, and approval is permitted. Please note, if the protocol defined a specific length of time for the study, and that timeline was not adhered to, that is a protocol noncompliance. Again, OLAW acknowledges that these events were related to a study that was not supported by federal funds.

We appreciate your cooperation and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs -S

Digitally signed by Jacquelyn T. Tubbs -S
Date: 2023.08.11 15:34:40 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

(b) (6)

A3012-1K

McCoy, Devora (NIH/OD) [E]

From: [redacted] (b) (6)
Sent: Friday, June 30, 2023 4:18 PM
To: Tubbs, Jai (NIH/OD) [E]
Cc: McCoy, Devora (NIH/OD) [E]; Mu, David; [redacted] (b) (6) Hosseini, Alireza; [redacted] (b) (6) (b) (6) Reilly, Tara S.; [redacted] (b) (6) (b) (6)
Subject: [EXTERNAL] FW: OLAW Case A3012-1K - ***ADDITIONAL INFORMATION REQUESTED BY JUNE 30, 2023***
Attachments: A3012-1K- interim report.pdf

Importance: High

Follow Up Flag: Follow up
Flag Status: Flagged

Sent on behalf of David Mu, Ph.D., Associate Dean for Research Administration and Institutional Official

Dear Dr. Tubbs:

RE: Eastern Virginia Medical School (EVMS), Norfolk, Virginia
Animal Welfare Assurance #A3012-01 [OLAW Case 1K]

On April 28, 2023, EVMS submitted a formal response to OLAW's inquiry dated March 31, 2023 regarding allegations of noncompliance with PHS Policy submitted to your agency by People for the Ethical Treatment of Animals (PETA). Specifically, PETA's allegations are in reference to EVMS's USDA APHIS Routine Inspection Report dated January 12, 2023. Your response to our April 2023 submission (*attached*) requests additional information regarding the following concerns:

CHINCHILLA PROTOCOL:

1. **Summary**: The project was conducted at EVMS by an area biotech company. Chinchillas remained on study after exceeding humane endpoints described in the protocol. Several weeks into the study, COVID restrictions were implemented by EVMS that limited access to the animal facility and hindered the investigator's ability to conduct research. The study was extended beyond the initial 22-week period approved in the protocol. Despite clinical intervention, one animal died and 3 others required euthanasia due to lack of response to treatment. COVID restrictions were lifted in phases and the investigator was able to complete the study. The protocol was closed and archived in December 2022.

OLAW Follow-up: It is understood this study was not supported by federal funding, but please provide additional information for clarification. Regarding the study extension, was this extension approved by the IACUC as an amendment to the protocol? Regarding the animals that required treatment, was treatment initiated based on clinical presentation of the animals? It is unclear what prompted treatment of the animals.

EVMS Response:

Regarding the study extension: As stated in EVMS's PHS Assurance on file with OLAW, IACUC approval of a protocol is granted for a period of three years; however, continuation of the project beyond the one-year and two-year anniversary dates requires IACUC approval of an annual progress report. The required report is submitted to the IACUC by the principal investigator (PI). The chinchilla protocol was approved by the IACUC on August 19, 2019 with a 3-year expiration date of August 18, 2022. Annual progress reports were submitted by the PI and approved by the IACUC in

August 2020 and August 2021, as required by IACUC policy. The approved research design stated that the experiments would be conducted over a 22-week period, although all aspects of the protocol were approved for a 3-year period. As previously explained, COVID restrictions hampered the investigator's ability to complete the study as originally planned; consequently, experimental procedures extended beyond 22 weeks. A formal request to extend the 22-week timeline was not submitted to or approved by the IACUC; however, due to COVID-19 limitations and circumstances beyond the institution's control, the PI and the IACUC believed that the extension was allowable without express IACUC approval, since the protocol was approved for a total of three years. All activities outlined in the protocol were completed within the 3-year approval period.

Regarding the animals that required treatment: As previously explained, in response to the global COVID-19 pandemic, EVMS implemented restrictions that limited access to the animal facility. Those restrictions began in March 2020 and were lifted in phases over a 9-month period. During that time, the institution was intentional about ensuring that all animals housed in the Division of Comparative Medicine (CompMed) animal facility were regularly monitored and assessed for overall well-being. While housed in the CompMed animal facility, the chinchillas were treated by direction of the Attending Veterinarian (AV) based upon observations noted by the investigative staff during planned procedures and/or observations made by the CompMed/veterinary staff during routine husbandry and monitoring procedures.

NONHUMAN PRIMATE (NHP) PROTOCOL

1. **Summary:** The protocol was approved for 12-23 year old rhesus macaques weighing 8-22 kg. Male macaques were requested and approved by the IACUC, since they are more likely than females to develop type 2 diabetes (T2D). Due to the COVID-19 related shortage of NHPs, metabolically abnormal rhesus macaques were not available for purchase; therefore, with IACUC approval, the PI purchased 2 metabolically normal (MN) animals and used a high-sugar diet to induce T2D. The amendment to allow the purchase of the MN animals did not take into consideration their ages. Additionally, the PI amended the protocol to add female rhesus macaques; however, the weights of the animals were not taken into consideration by the PI and that information was not provided to the IACUC via the amendment process. Lastly, 2 NHPs were given an increased amount of sweetened beverage to induce diabetes as outlined in the protocol; however, the amendment to add the beverage did not explicitly state that the total volume would increase to 1000 mL/day if the animal consumed all of the water provided. The primates referenced in the USDA inspection report were provided sweetened beverage for 1.5 months longer than the 6-month period stated in the protocol because T2D development had not been confirmed at the end of 3-6 months. The IACUC acknowledges that the extended period had not been reviewed and approved by the IACUC. The PI terminated the protocol and it was archived by the IACUC in January 2023.

OLAW Follow-up: Regarding the conduct of unapproved animal activities, what action has the IACUC taken to prevent recurrence of this type of incident? Regarding communication with the research community, has the IACUC taken any action to ensure investigators, research technicians, etc. understand the conduct of animal activities without prior IACUC approval is prohibited?

EVMS Response:

Regarding the conduct of unapproved animal activities: As of February 2023, the institution's formal post-approval monitoring (PAM) program has been enhanced by broadening the scope of the audits, increasing the number of PAM professionals conducting the audits, and expanding the logistics of the auditing process. All active protocols are audited at least one a year, although more frequent audits may be conducted at the discretion of the IACUC, the AV, the PAM auditor who acts on behalf of the IACUC, and/or the Institutional Official (IO). During the PAM records review, the auditor verbally discusses with the investigative staff the requirement for an amendment to a protocol to be approved by the IACUC prior to implementation of the amended activity. Additionally, the auditor informs the staff that failure to comply with this requirement constitutes noncompliance that will be reported to OLAW, the USDA, and/or the protocol funding agency, as applicable. Additionally, the written report sent to the PI following the PAM audit includes a statement informing the investigator of the same.

Regarding communication with the research community: Researchers have been informed of the enhanced PAM program, which now includes procedural and records reviews. Also, on May 18, 2023, the IACUC and CompMed hosted a 2-hour Town Hall which addressed a number of animal care and use topics, including federal and institutional requirements for protocol approval and amendments to approved protocols. All authorized animal users were invited to attend; however, attendance was mandatory for users authorized to work with USDA-regulated species, to include the CompMed staff. The Town Hall was well attended and all required users were present. Going forward, the IACUC and CompMed will continue to provide written information/reminders to the research community regarding proper management of IACUC-approved protocols. Additionally, the IACUC has discussed hosting semi-annual Town Halls to keep investigators abreast of federal regulations and updated guidance, current institutional policies and procedures, adequate recordkeeping, industry trends and best practices, and other related/relevant topics.

Lastly, at its July 6, 2023 meeting, the IACUC will discuss the AV's recommendation for a pre-implementation meeting (PIM) with the AV, the CompMed program manager, PAM personnel, the investigative staff, and/or IACUC Office staff. The current proposal is for a PIM prior to the start of a research protocol that is new to the EVMS animal care and use program or within 30 days of approval of a de novo renewal of an existing research project. PIM may also be extended to recently approved amendments to an approved protocol. The intent of the PIM is to ensure that all involved parties are clear on the details of the protocol, to discuss documentation requirements, to ensure that required forms, such as a post-operative monitoring form, are sufficient to document the proposed activities, and to discuss other questions/concerns raised by an attendee. The desired goals are to increase effective communication between the research community, the IACUC, and the CompMed staff and to obviate the potential for noncompliance related to off-protocol activities. If endorsed by the IACUC, investigators will be informed of the PIM. The IACUC Office will assist the AV/CompMed staff with scheduling the meetings.

2. **Summary:** On September 22, 2022, six macaques underwent an insulin administration procedure. During recovery, the animals were administered dextrose as a rescue measure and were subjected to repeated blood draws, although the procedures were not reviewed by the IACUC. The animals were under the care and management of the AV and veterinary staff and the medical interventions were documented in the animal records. On June 22, 2022, a rhesus macaque experienced an adverse evert while receiving intravenous (IV) insulin; however, the animal did not receive medical intervention more than 7 hours after the procedure ended. That animal was euthanized due to lack of improvement of its medical condition. The current AV and the CompMed program manager were not able to provide additional information regarding the provision of care for the animal. All animals were monitored and managed during the procedure, a veterinarian was consulted, and medical intervention was provided as directed by that vet when blood sugar levels were low and recovery times were extended. The previous AV stated that clinical care was provided to animal "DA9J" following an adverse event; however, those measures were not documented. Additionally, on June 23, 2022, activity was not recorded in the clinical record for several hours, although multiple notes regarding a possible treatment plan, drug administration, and clinical interventions are documented between June 23-28, 2022. The previous AV was unavailable to provide additional details regarding the case. The new AV and the current CompMed program manager could not provide details aside from information included in the medical record. The IACUC acknowledges that the anesthesia and clinical records were not properly/fully annotated.

OLAW Follow-up: What action has the IACUC taken to address inadequate recordkeeping and prevent future recurrence of this type of event? Please explain or clarify why recordkeeping of clinical care of the animal did not occur?

EVMS Response:

Action taken by the IACUC to address inadequate recordkeeping and prevent a future recurrence: As previously stated, the IACUC has enhanced its formal PAM process to include records reviews. Those reviews apply to both study and clinical records. Any deficiencies identified by the PAM auditors are immediately discussed with the investigative staff and the auditors work with the staff to update records and/or revise documentation forms, as applicable. Also, if implemented, the PIM will address inadequate recordkeeping by ensuring that forms are sufficiently designed to document the approved activities, as appropriate.

Additionally, EVMS has purchased a new electronic medical recordkeeping system that will allow for standardization and enhanced oversight of clinical records and will, in turn, promote consistency and compliance within the animal care and use program. The Species360 Zoological Information Management System (ZIMS) is designed for day-to-day and ongoing management of individual animals and animal groups within a veterinary care setting. In particular, ZIMS for Medical is the cloud-based platform within the Species360 ZIMS that captures and catalogues anesthesia, treatment, diagnostic testing, clinical observation, and related medical records. It may also be used to search and retrieve clinical data and to integrate medical and drug regulatory compliance records, all of which will help to improve and enhance communication among the veterinary staff. ZIMS for Medical may be used as a stand-alone resource or it may be integrated with other ZIMS platforms, such as ZIMS for Husbandry, to create a more comprehensive records management resource. The institution hopes to receive and implement use of ZIMS for Medical within the next few months.

Explain/clarify why recordkeeping of clinical care did not occur for "DA9J": As stated in the summary, the IACUC acknowledges that the clinical records were not properly/fully annotated due to missing information and omitted documentation at specified time points and can only attribute the inadequacy to oversight and/or lack of training. The new AV and the CompMed program manager conducted a refresher training session with the CompMed staff to review appropriate recordkeeping requirements. The current CompMed standard operating procedure (SOP) on recordkeeping was one of the resources reviewed during the training. From an investigative staff/study procedures perspective, appropriate recordkeeping was addressed during the May 18, 2023 Town Hall.

I trust that the information provided herewith addresses your questions and concerns. Please do not hesitate to contact Dr. Mu and/ (b) (6) if additional information is required.

Contact Information: **David Mu, Ph.D.**
Associate Dean for Research Administration and Institutional Official
Eastern Virginia Medical School
735 Fairfax Avenue
EVMS Waitzer Hall, (b) (4)
Norfolk, Virginia 23507
Email: MuD@evms.edu
(b) (6)

(b) (6)

Kindest regards,

(b) (6)

From: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>
Sent: Wednesday, May 31, 2023 4:48 PM
To: Mu, David <MuD@EVMS.EDU>

McCoy, Devora (NIH/OD) [E]

From: Tubbs, Jai (NIH/OD) [E]
Sent: Wednesday, July 5, 2023 10:02 AM
To: (b) (6)
Cc: McCoy, Devora (NIH/OD) [E]; Mu, David; (b) (6) Hosseini, Alireza; (b) (6) (b) (6) Reilly, Tara S.; (b) (6) (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Case A3012-1K - ***ADDITIONAL INFORMATION REQUESTED BY JUNE 30, 2023***

Good morning,

Thank you for the additional information. I will be in contact with any additional questions/comments following review.

Kind Regards,

J. Tubbs

From: (b) (6)
Sent: Friday, June 30, 2023 4:18 PM
To: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>
Cc: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>; Mu, David <MuD@EVMS.EDU>; (b) (6) (b) (6) Hosseini, Alireza <HosseiA@EVMS.EDU>; (b) (6) Reilly, Tara S. <ReillyTS@EVMS.EDU>; (b) (6) (b) (6)
Subject: [EXTERNAL] FW: OLAW Case A3012-1K - ***ADDITIONAL INFORMATION REQUESTED BY JUNE 30, 2023***
Importance: High

Sent on behalf of David Mu, Ph.D., Associate Dean for Research Administration and Institutional Official

Dear Dr. Tubbs:

RE: Eastern Virginia Medical School (EVMS), Norfolk, Virginia
Animal Welfare Assurance #A3012-01 [OLAW Case 1K]

On April 28, 2023, EVMS submitted a formal response to OLAW's inquiry dated March 31, 2023 regarding allegations of noncompliance with PHS Policy submitted to your agency by People for the Ethical Treatment of Animals (PETA). Specifically, PETA's allegations are in reference to EVMS's USDA APHIS Routine Inspection Report dated January 12, 2023. Your response to our April 2023 submission (*attached*) requests additional information regarding the following concerns:

CHINCHILLA PROTOCOL:

1. **Summary:** The project was conducted at EVMS by an area biotech company. Chinchillas remained on study after exceeding humane endpoints described in the protocol. Several weeks into the study, COVID restrictions were implemented by EVMS that limited access to the animal facility and hindered the investigator's ability to conduct research. The study was extended beyond the initial 22-week period approved in the protocol. Despite clinical

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

May 31, 2023

Re: Animal Welfare Assurance
#A3012-01 [OLAW Case 1K]

David Mu, Ph.D.
Associate Dean for Research Administration
Eastern Virginia Medical School
735 Fairfax Avenue
EVMS Waitzer Hall, (b) (4)
Norfolk, VA 23507

Dear Dr. Mu,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 28, 2023 letter in response to allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Eastern Virginia Medical School (EVMS). These allegations were received from People for the Ethical Treatment of Animals (PETA) regarding the USDA APHIS Inspection Report dated January 12, 2023.

It is described how daily health checks are performed at the institution. All animals receive daily health checks by the Division of Comparative Medicine (CompMed), which includes observations by both husbandry and veterinary staff. Animals are observed once a day by husbandry staff and once a day by the veterinary staff, including weekends and holidays. It is stated, when possible, animals are observed twice daily by husbandry staff. Some of the clinical observations noted during health checks include ambulatory status, food/water consumption, fecal/urine output, and stereotypical behaviors. These observations are documented in the hold room status log, and the veterinarian and/or supervisor are notified of any abnormalities observed. A clinical care report is generated for a sick/injured animal that has been identified and emergencies are immediately reported to a veterinarian and/or supervisor (including the investigator). It is stated a veterinarian evaluates the emergency and determines clinical treatment or if humane euthanasia is necessary. The Attending Veterinarian (AV) or relief veterinarian, if applicable, has the authority to act to protect the health and well-being of animals based on their medical expertise and judgement.

In summary, the USDA Inspection Report described how chinchillas remained on study after exceeding humane endpoints described in the protocol. The letter states these animals were assigned to a research project conducted at EVMS by an area biotech company. A total of 40 chinchillas were placed on the study and several weeks into the study, COVID restrictions were implemented and began on March 23, 2020. As a result, there was limited access to the animal facility which hindered the investigator's ability to conduct research, including weekly weighing of the animals. It is stated the study was extended beyond the initial 22-week period approved in the protocol. Due to COVID restrictions, the AV and veterinary staff continued to monitor the animals and assess their overall well-being. Per the letter, animal health records indicated weight fluctuations when the animals were assigned to the study without direct experimental manipulation. It is stated despite clinical intervention, one animal died, and 3 others required euthanasia due to a lack of response to treatment. COVID restrictions were lifted in phases for live animal users and the investigator was able to

complete their study. The letter states "… *EVMS chose not to euthanize the chinchillas, which in the institution's opinion, would have resulted in a significant number of healthy/useful animals being euthanized without just cause. Instead, concessions were made to care for the animals and to comply with the 3Rs to the extent possible, while, at the same time, keeping researchers and animal care staff safe during the pandemic until the study could resume.*" The protocol was closed and archived on December 1, 2022.

OLAW Follow-up: It is understood this study was not supported by federal funding, but please provide additional information for clarification. Regarding the study extension, was this extension approved by the IACUC as an amendment to the protocol? Regarding the animals that required treatment, was treatment initiated based on clinical presentation of the animals? It is unclear what prompted treatment of the animals.

The USDA Inspection Report described a protocol involving changes made to animal selection, procedures, and care of rhesus macaques without IACUC review and approval and/or appropriate handling and documentation of administrative changes. The letter states the original protocol was approved for 12-23yr old rhesus macaques weighing 8-22kg. It is understood male macaques were requested and approved by the IACUC since they are more likely than females to develop type 2 diabetes (T2D). However, due to the COVID-19 related shortage of nonhuman primates, metabolically abnormal rhesus macaques were not available for purchase. With IACUC approval, the investigator purchased 2 metabolically normal animals and used a high-sugar diet to induce T2D. While the investigator amended the protocol to include these animals, they did not consider their age and that information was not provided to the IACUC. Per the letter, the investigator was eventually able to secure 12 healthy surplus macaques and received IACUC approval to add females to the protocol. However, the weights of the females were not provided to the IACUC, nor did the investigator take into consideration the body weights of the female macaques. It is understood the investigator terminated this protocol and it was archived on January 5, 2023.

The USDA Inspection Report described an increase in the amount of sweetened beverage provided to animals without IACUC approval, involving two primates. The letter states the two primates were the only animals that underwent the diabetes induction portion of the study as approved by the amendment. It is stated the AV was concerned that 500ml of liquid per day was not sufficient for the size of the animals, and in response the daily amount of water provided to animals was increased. It is further stated while the amendment described how the sweetened beverage would be the only water source for the animals, the IACUC acknowledges the amendment did not explicitly state the amount of the beverage would increase to 1000ml/day if the animals consumed all the water provided. The primates referenced in the inspection report were provided the beverage for 1.5 months longer than the 6-month period stated in the protocol because T2D development had not been confirmed at the end of the 3-6-month period. The IACUC acknowledges the extended period had not been reviewed and approved by the IACUC.

OLAW Follow-up: Regarding the conduct of unapproved animal activities, what action has the IACUC taken to prevent recurrence of this type of incident? Regarding communication with the research community, has the IACUC taken any action to ensure investigators, research technicians, etc. understand the conduct of animal activities without prior IACUC approval is prohibited?

The inspection report described an incident that occurred on September 22, 2022. It involved six macaques that underwent an insulin administration procedure, and during recovery these animals received dextrose injections and repeated blood draws. Per the inspection report these procedures were not submitted to or reviewed by the IACUC. The letter states these 6 animals received dextrose

as a rescue measure by the AV due to undetectable glucose levels by a handheld glucometer. At that time the animals were under the care and management of the AV and veterinary staff, and these medical interventions were documented in the animal records.

The inspection report described failure of the facility to utilize appropriate methods to prevent, control, and diagnose medical issues that arose from the administration of insulin IV, ultimately leading to the death of an animal and hours of unresolved, low blood glucose levels in others. An incident in June 2022 involved a rhesus macaque that experienced an adverse event while receiving insulin IV. The inspection report stated the animal did not receive medical intervention more than 7h after the procedure had ended and was euthanized due to lack of improvement in their condition. The report also stated the current Attending Veterinarian and program manager were unable to provide any additional information regarding the provision of care for this animal. The response to OLAW states all animals subjected to IV insulin administration related to this protocol were monitored and managed during the procedure. Per the letter, a veterinarian was consulted, and medical intervention was provided by that veterinarian or based on their directives regarding cases where blood sugar levels were low and recovery times were extended.

The letter states regarding the case of the animal ("DA9J") that experienced the adverse event, the institution maintains the animal was regularly monitored daily by a veterinarian and/or veterinary staff as indicated in the clinical record from June 23-28, 2022. The previous AV stated clinical care was provided during the real-time event and the following days, but those measures were not documented. CompMed staff confirmed no activity was recorded for several hours on June 23rd. However, it's stated between June 24-28, 2022, the record includes multiple notes regarding a possible treatment plan, drug administration and clinical interventions. The IACUC acknowledges that the anesthesia and clinical records were not properly/fully annotated.

It is further stated that at the time of the USDA inspection, the previous AV was unavailable to provide additional details regarding this case, and the new AV and current program manager could not provide details aside from the information included in the medical record.

OLAW follow-up: What action has the IACUC taken to address inadequate recordkeeping and prevent future recurrence of this type of event? Please explain or clarify why recordkeeping of clinical care of the animal did not occur?

The USDA Inspection Report notes an additional 11 rhesus macaques underwent the same procedure and lacked blood glucose monitoring or medical interventions for hypoglycemia, including prolonged recovery from anesthesia. The letter reiterates that in cases of hypoglycemia and prolonged recovery, a veterinarian was consulted, and medical intervention was provided by the veterinarian and/or their directive and under their supervision. The response to OLAW states the IACUC was not able to address the 11 animals described in the report since the identities of the animals were not specified.

The USDA Inspection report stated in September 2022, records revealed that 6 animals had glucose levels undetectable by a handheld glucometer. The response to OLAW notes that this portion of the report is referring to the 6 animals that were administered dextrose by the AV as a rescue measure.

It is understood the items cited by the USDA Veterinary Medical officer (VMO) during the inspection were brought to the attention of the IACUC. These items were not reported to OLAW because both protocols were closed and neither protocol was PHS, or NSF funded and the VMO stated verbally that no corrective action plan was required. The IACUC acknowledges its responsibility to ensure that all significant changes to an IACUC-approved protocol are reviewed and approved by the committee prior to implementation. The committee discussed the findings from the

USDA inspection and enhanced the post-approval monitoring (PAM) program in response. Such improvements include broadening the scope of the components of the EVMS animal care and use program that are audited, the number of PAM professionals conducting the audits, and the logistics of the auditing process.

It is noted additional PAM measures were implemented in February 2023 and are summarized as the following:

- Additional staff to assist the current PAM auditor.
- Additional audits to occur. All active protocols will be audited once a year, at a minimum. The expectation is protocols involving USDA-regulated species are to be audited more frequently, depending upon experimental activity. All IACUC-approved amendments to a protocol will be subject to review, along with the parent protocol/original protocol form.
- The PAM auditor will continue to submit a written report to the investigator following the audit. Additionally, all concerns noted during the audit will be discussed with the laboratory representative(s) at the end of the visit, and all major concerns will be brought to the attention of the IACUC in a timely manner.
- Additional activities may be added by the PAM auditor and may include:
    - A monthly walkthrough of the CompMed animal facility to determine which protocols have animals assigned to them and to observe any random compliance concerns, questions, and/or points of discussion. Generally, the walkthrough will be conducted prior to the scheduled monthly IACUC meeting.
    - A monthly meeting with the CompMed staff to discuss any concerns they may have observed and/or questions they may have regarding procedures performed in the animal facility.

The IACUC will assess these enhancements to the PAM program in February 2024 and interim assessment may be conducted as directed by the IACUC committee, IACUC Chair and/or Vice Chair, the Institutional Official, the Vice Dean for Research, and/or the EVMS President and Provost, Dean of the School of Medicine.

The letter states the IACUC is also working with the Office of Research IT team to create a real-time morbidity and/or mortality (M&M) reporting mechanism. This mechanism will allow the IACUC, and the Comp Med staff to have more effective oversight and management of the animal care and use program. In the interim, an Outlook mailbox is available for animal users to submit M&M reports. The PAM Auditor, the CompMed Program Manager, and the IACUC Office staff have access to the mailbox and will screen the reports to determine the next course of action (e.g., immediately send to the Attending Veterinarian and/or the IACUC; report to the IACUC at the next scheduled meeting; etc.).

Thank you for the detailed responses to each of OLAW's concerns. Please provide the additional requested information to this office by **June 30, 2023**.

Sincerely,
Jacquelyn T. Tubbs -S
Digitally signed by Jacquelyn T. Tubbs -S
Date: 2023.05.31 09:36:32 -04'00'
Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3012-1K

EVMS
Eastern Virginia Medical School

April 28, 2023

Jacquelyn T. Tubbs, D.V.M., DACLAM
Senior Animal Welfare Program Specialist
National Institutes of Health (NIH) Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
jacquelyn.tubbs@nih.gov

Dear Dr. Tubbs:

RE: Allegations of Noncompliance with PHS Policy
OLAW Case A3012-1K
Eastern Virginia Medical School (EVMS)
Animal Welfare Assurance #D16-00007 (formerly A3012-01)

This letter is in response to your March 31, 2023 request for information regarding allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals lodged by People for the Ethical Treatment of Animals (PETA), Eastern Virginia Medical School (EVMS).

EVMS is committed to providing animal care in accordance with federal regulations and the standards for the care and use of animals required for accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACi). All animals involved in the EVMS animal care and use program receive daily health checks by the Division of Comparative Medicine (CompMed), including observations by both husbandry and veterinary staff. At a minimum, animals are observed once a day by the husbandry staff and once a day by the veterinary staff, to include weekends and holidays. When possible, the husbandry staff observes the animals twice daily. Observations include, but are not limited to, the following: ambulatory status; food and water consumption; feces and urine output; normal posture/movements; and stereotypical behaviors. Observations are documented on the holding room status log, and abnormalities are brought to the attention of a veterinarian and/or supervisor. If a sick or injured animal is identified, a clinical care report is generated as outlined in the related EVMS CompMed animal facility standard operating procedure (SOP). Emergencies are reported immediately to a veterinarian and/or supervisor, and the principal investigator is also informed. The veterinarian assesses the emergency and determines how best to proceed with respect to clinical treatment or humane euthanasia. While the IACUC, in partnership with CompMed, is responsible for implementing the EVMS animal care and use program, the

Research
735 FAIRFAX AVENUE, WAITZER HALL - SUITE 1112
NORFOLK, VA 23507
tel 757.446.8480
www.evms.edu

Attending Veterinarian (AV) (or relief veterinarian, as applicable), has the authority to act to protect the health and well-being of animals based on their medical expertise and judgment.

Responses to OLAW's specific concerns are as follows:

1. OLAW Concern: Chinchillas remained on study after exceeding humane endpoints described in the protocol. The study continued beyond the 22-week timeline described in the protocol. Four female chinchillas were not removed from the protocol after exceeding the humane endpoint regarding loss of body weight. Per the protocol, "Any animal that experiences more than 20% weight loss will also be removed from the study." It is understood all the animals exceeded 20% loss of body weight. It is noted that three animals were euthanized, and one animal died despite veterinary care. A review of medical and study records revealed the animals were not consistently weighed on a weekly basis. Also, a review of records and discussion with the program manager revealed animals remained on the protocol for longer than 22wk.

Response: The chinchillas referenced in the USDA inspection report were assigned to a research project conducted at EVMS by an area biotech company whose research aim is to modernize procedures for ENT surgeons, specifically via use of a nonsurgical eardrum repair treatment that replaces traditional tympanoplasty with a clinic-based procedure. A total of 40 chinchillas arrived at EVMS on February 19, 2020. Per institutional policy, all new arrivals to the EVMS central animal facility undergo a standard acclimation period to ensure they are healthy and suitable to begin the prescribed research regimen. Following the acclimation period, the chinchillas were placed on study. Several weeks into the study period, EVMS implemented COVID restrictions in response to the global COVID-19 pandemic. Those restrictions, which began on March 23, 2020, limited access to the animal facility and hampered the investigator's ability to conduct the research as described in the approved protocol, to include weekly weighing of the animals. Because of the COVID restrictions, the study was extended beyond the initial 22-week period stated in the protocol; however, the EVMS Division of Comparative Medicine (CompMed) Attending Veterinarian (AV) and veterinary staff continued to monitor the animals and assess their overall well-being. Animal health records indicate that weights fluctuated when the animals were assigned to the study without direct experimental manipulation. Despite clinical intervention, one animal died, and three others were euthanized in consultation with the investigator and the AV to minimize pain and distress due to lack of response to treatment. Over a 9-month period, COVID restrictions were lifted in phases for live animal users, and the investigator was eventually able to complete the study.

EVMS is aware that some institutions opted to euthanize many, if not all, of their research animals during the height of the COVID pandemic when physical distancing was encouraged to mitigate spread of the disease. However, in keeping with the Russell and Burch 3Rs (i.e., replacement, reduction, and refinement), EVMS chose not to euthanize the chinchillas, which in the institution's opinion, would have resulted in a significant number of healthy/useful animals being euthanized without just case. Instead, concessions were made to care for the animals and to comply with the 3Rs to the extent possible, while, at the same time, keeping researchers and animal care staff safe during the pandemic until the study could resume.

The protocol expired on August 18, 2022. Per institutional policy, the investigator has up to 90 days after the 3-year expiration date to submit an IACUC Closure Form for review/approval by the IACUC. The protocol was officially closed and archived by the IACUC on December 1, 2022. The investigator has no plans to continue the study.

2. OLAW Concern: A separate protocol involved changes made to animal selection, procedures, and care of rhesus macaques without IACUC review and approval and/or appropriate handling and documentation of administrative changes. The age of animals on study was changed without IACUC approval, resulting in the use of two male macaques older than the maximum age of 23yr for the study. Also, animal weights were changed without IACUC approval, resulting in 5 female macaques being placed on study and their weights were below the minimum weight requirement.

Response: The protocol objective was to determine the effects of CSF1R inhibition on metabolic profiles in middle-aged and older prediabetic macaques. The original protocol was approved for 12-23 year-old male rhesus macaques weighing 8 to 22 kg. Male macaques were requested by the investigator and approved by the IACUC, since they are more likely than females to develop type 2 diabetes (T2D). When the investigator was ready to begin the study, metabolically abnormal rhesus macaques were not available for purchase due to the COVID-19-related nationwide shortage of nonhuman primates (NHPs). Instead, the investigator was able to purchase two metabolically normal animals and the IACUC approved use of a high-sugar (fructose) diet for 3-6 months to induce T2D. Although the investigator amended the protocol to include metabolically normal males, he failed to consider the age of the animals; therefore, that information was not provided to the IACUC.

Later during the study, the investigator was able to secure 12 healthy surplus macaques from another institution (i.e., five males and seven females). The investigator received IACUC approval to add female animals to the protocol; however, the weights of the females were not provided to the IACUC, nor did the investigator or the IACUC take into consideration that female macaques would likely weigh considerably less than their male counterparts. As indicated in the USDA inspection report, five female animals ranged in weight from 4.9 – 7.3 kg.

The protocol was terminated by the investigator and archived by the IACUC on January 5, 2023. The investigator has no plans to continue the study at EVMS.

3. OLAW Concern: Another finding noted was an increase in the amount of sweetened beverage provided to animals without IACUC approval. Two primates received 1000mL of sweetened beverage for numerous days, while 500mL is approved for use. It is stated the duration of time that monkeys were provided a sweetened beverage was lengthened without IACUC review or approval.

Response: Metabolically abnormal rhesus macaques were not available for purchase due to the COVID-19-related nationwide shortage of nonhuman primates (NHPs). Instead, the

investigator was able to purchase metabolically normal animals and the IACUC approved use of a high-sugar (fructose) diet for 3-6 months to induce type 2 diabetes (T2D). The approved amendment stated that 500 mL/day of a fruit-flavored, 15% fructose-sweetened beverage would be administered, along with the normal monkey chow that was provided ad libitum. The two rhesus macaques referenced in the USDA inspection report were the only animals subjected to the diabetes induction portion of the study as approved by the amendment. The AV was concerned that 500 mL of liquid per day was not sufficient for the size of the animals; therefore, the daily amount of water provided to the animals was increased. In follow-up to the AV change, the investigator submitted a subsequent amendment to clarify the protocol, which was approved by the IACUC. The clarification stated that, once the high-fructose diet began, the sole source of water provided to the animals would be the fructose-supplemented beverage to ensure development of the desired metabolic disturbance, while also providing sufficient liquid consumption for the animals. Although the clarifying amendment stated that the sweetened beverage would be the only water source for the animals, the IACUC acknowledges that it did not explicitly state that the amount of beverage would increase from 500 mL/day to 1000 mL/day if the animals consumed all of the water provided.

Additionally, the information provided to the IACUC by the investigator regarding the high-fructose regimen stated that it is well established in the field that fructose-fed adult rhesus macaques typically develop hypertriglyceridemia and insulin resistance between 3-6 months. The animals referenced in the USDA inspection report received the sweetened beverage for 1.5 months longer than the 6-month maximum period stated in the protocol, since T2D development was not confirmed at the end of the 3–6-month period. The IACUC acknowledges that the extended period was not reviewed and approved by the IACUC.

The protocol was terminated by the investigator and archived by the IACUC on January 5, 2023. The investigator has no plans to continue the study at EVMS.

4. OLAW Concern: Additionally, as part of recovering from an anesthetic event on study, animals were subjected to additional monitoring procedures which were not documented in the approved protocol. On September 22, 2022, six macaques underwent an insulin administration procedure, and during recovery these animals received dextrose injections and repeated blood draws. These procedures were not submitted to or reviewed by the IACUC.

Response: The IACUC-approved protocol stated that study animals would be subjected to multiple blood draws, an IVGTT, ITTs conducted and/or supervised by the AV, and a carotid ultrasound as outlined in the research design to allow for comparison of baseline data with data gathered after the high-fructose diet and CSF1R antibody treatment. The six animals referenced in the USDA report were administered dextrose by the AV as a rescue measure, since their blood glucose levels were undetectable by a handheld glucometer following insulin administration. Blood was collected during the rescue period for sequential real-time monitoring of glucose levels. The animals were under the care and management of the AV and the veterinary staff and the intervention measures were documented in the animal records. The dextrose administration and blood glucose monitoring were not submitted to the IACUC for review because they were used as

rescue measures at the discretion on the AV to address the real-time health and welfare concerns of the animals in question.

The protocol was terminated by the investigator and archived by the IACUC on January 5, 2023. The investigator has no plans to continue the study at EVMS.

5. OLAW Concern: Per the inspection report, the facility failed to utilize appropriate methods to prevent, control, and diagnose medical issues that arose from the administration of insulin IV, ultimately leading to the death of an animal and hours of unresolved, low blood glucose levels in others. Medical records revealed multiple rhesus macaques experienced severe low blood sugar and prolonged anesthesia recovery times following a procedure involving administration of insulin IV under anesthesia. An incident in June 2022 involved a rhesus macaque that experienced an adverse event while receiving insulin IV. Per anesthesia monitoring records, the animal remained in unconscious or semi-conscious (as defined by the facility) for >4h until recordings ceased. During this time, no medical care was provided, and blood glucose monitoring did not occur, despite being hypoglycemic at the end of the 30-minute study. Per medical records, the animal did not receive medical intervention more than 7h after the procedure had ended. Ultimately, the animal was euthanized due to lack of improvement in their condition. Additionally, the current Attending Veterinarian and program manager were unable to provide any additional information regarding the provision of care for this animal.

Response: All animals subjected to intravenous (IV) insulin administration under the protocol in question were monitored and managed during the procedure. In cases where blood sugar levels were considerably low and/or recovery times were extended, a veterinarian was consulted, and medical intervention was given by that veterinarian and/or according to their directive and under their supervision.

In the case of "DA9J," the animal experienced an adverse event following IV insulin administration; however, the institution respectfully maintains that it was regularly monitored each day by a veterinarian and/or veterinary staff (to include weekends), as indicated in the clinical record dated June 23-28, 2022. Additionally, the previous AV stated that clinical care was provided during the real-time event and for several days following the initial onset; however, those measures are not documented. Upon review of the anesthesia record, the CompMed staff confirmed that, on June 23, 2022, which was the first day of the experimental period for "DA9J," no activities were recorded between 2:45 p.m. when the post-procedural stage of the animal was noted (Stage 3 of sedation) and 7:00 p.m. when a note was entered stating that the animal did not fully recover from the procedure at 4 hours post-ketamine administration. CompMed further confirmed that interventions were not documented in the clinical record for ~7 hours post-procedure. However, thereafter and for several days following (June 24-28, 2022), the record includes multiple notes regarding a possible treatment plan, drug administrations, and clinical interventions. During the 6-day experimental period, "DA9J" occasionally showed slight improvements in response to medical intervention; however, the improvements were temporary and, ultimately, the AV humanely euthanized the animal on June 28, 2022.

In the event of emergency clinical care, the institution relies upon the medical expertise of the AV (or relief veterinarian, if applicable) to assess each case and determine the best course of action in their professional opinion. In the case of "DA9J" and all animals assigned to the protocol, the AV cared for the animals as deemed suitable with respect to their overall well-being and the research objective. When warranted, animals were humanely euthanized. However, the IACUC acknowledges that the anesthesia and clinical records were not properly/fully annotated as required by the related EVMS CompMed animal facility SOP.

At the time of the USDA inspection, the former AV was not available to give a detailed explanation or provide further information regarding "DA9J's" treatment following the IV insulin event, and the new AV and current program manager were not able to provide information outside of what is included in the written record.

The protocol was terminated by the investigator and archived by the IACUC on January 5, 2023. The investigator has no plans to continue the study at EVMS.

6. OLAW Concern: **The inspection report notes an additional 11 rhesus macaques underwent the same procedure and lacked blood glucose monitoring or medical interventions for hypoglycemia even when levels were too low to be detected by the handheld glucometer at the end of the procedure. Prolonged recovery from anesthesia also occurred in these animals.**

Response: All animals subjected to intravenous (IV) insulin administration under the protocol in question were monitored and managed during the procedure. In cases where blood sugar levels were considerably low and/or recovery times were extended, a veterinarian was consulted, and medical intervention was given by that veterinarian and/or according to their directive and under their supervision

The IACUC is not able to specifically address the 11 rhesus macaques referenced in the USDA inspection report, since more than 11 animals were involved in the study and the identities of the animals cited in the report are not provided. However, upon review of the clinical records, the CompMed staff confirmed that, early during the experimental period (June 2022), glucose monitoring was not documented for all animals assigned to the experimental protocol. As the experimental regimen proceeded, however, and later during the experimental period, which ended in September 2022, glucose monitoring was documented for all animals subjected to IV insulin administration. Other clinical notes indicate that some animals recovered from anesthesia in the anticipated timeframe, while others took longer to recover.

In the event of emergency clinical care, the institution relies upon the medical expertise of the AV (or relief veterinarian, if applicable) to assess each case and determine the best course of action in their professional opinion. However, the IACUC acknowledges that the anesthesia and clinical records were not properly/fully annotated as required by the related EVMS CompMed animal facility SOP.

The protocol was terminated by the investigator and archived by the IACUC on January 5, 2023. The investigator has no plans to continue the study at EVMS.

7. OLAW Concern: In September 2022, the procedure was performed again with 6 animals. Records revealed that multiple animals had blood glucose levels that were too low to detect by the handheld glucometer (less than 20 mg/dL) for prolonged lengths of time. Per the inspection report, this led to multiple animals suffering from incredibly low blood sugar without continuous medical intervention to resolve the issue. It is understood that at the time of the USDA inspection, this protocol was closed.

Response: As stated above, the IACUC-approved protocol stated that study animals would be subjected to multiple blood draws, an IVGTT, ITTs conducted and/or supervised by the AV, and a carotid ultrasound as outlined in the research design to allow for comparison of baseline data with data gathered after the high-fructose diet and CSF1R antibody treatment. The six animals referenced in the USDA report were administered dextrose by the AV as a rescue measure, since their blood glucose levels were undetectable by a handheld glucometer following insulin administration. Blood was collected during the rescue period for sequential real-time monitoring of glucose levels. The animals were under the care and management of the AV and the veterinary staff, and the intervention measures were documented in the animal records. The dextrose administration and blood glucose monitoring were not submitted to the IACUC for review because they were used as rescue measures at the discretion on the AV to address the real-time health and welfare concerns of the animals in question.

The protocol was terminated by the investigator and archived by the IACUC on January 5, 2023. The investigator has no plans to continue the study at EVMS.

The items cited by the USDA Veterinary Medical Office (VMO) in the inspection report were brought to the attention of the IACUC via the inspection process. They were not reported to OLAW, as both protocols had been closed and archived by the IACUC at the time of the inspection, and neither investigator had study continuations pending. The USDA inspection report confirms that the protocols were closed and no longer active; consequently, the Veterinary Medical Officer (VMO) stated verbally that no corrective action plan was required by the USDA. Neither protocol was funded by PHS or NSF funds.

The IACUC acknowledges its obligations to ensure that all significant changes to an IACUC-approved protocol are reviewed and approved by the IACUC prior to implementation, in accordance with federal regulations and as detailed in the institution's current PHS Assurance. This obligation is reflected in IACUC policies, including its Guidelines for Post-approval Monitoring (PAM). A dedicated PAM program focused on procedural auditing has been in effect as a protective measure since 2009. The IACUC discussed the findings in the January 2023 USDA report at its February 2, 2023 meeting and made enhancements to the PAM program in response to the findings. This includes broadening the scope of the components of the EVMS animal care and use program that are audited, the number of PAM professionals conducting the audits, and the logistics of the auditing process.

The following specific additional PAM measures went into effect in February 2023:

- Additional staff assist the current PAM auditor. Audits will consist of the standard procedural review, along with a documents/records review (e.g., animal records; study records, to include surgical documentation; weight records; food and water consumption records; behavioral testing/enrichment records, adverse events reports; euthanasia records; etc.).

- Additional audits. As stated in the current PAM guidelines, all active protocols will be audited once a year, at a minimum; however, the expectation is for protocols involving a USDA-regulated species to be audited more frequently, depending upon experimental activity. With respect to records reviews, all IACUC-approved amendments to a protocol will be subject to review, along with the parent protocol/original protocol form.

- The PAM auditor will continue to submit a written report to the investigator following the audit. As is the current practice, a copy of the report will be sent to the IACUC Office to document the audit in the protocol management databases and to place a hard copy in the protocol file. Additionally, all concerns noted during the audit will be discussed with the laboratory representative(s) at the end of the visit, and all major concerns will be brought to the attention of the IACUC in a timely manner. A written notification of major concerns will be sent to the IACUC Office and the office personnel will be responsible for relaying that info to the IACUC. At the discretion of the IACUC personnel, the notification will be forwarded to the IACUC Chair and Vice Chair, who will instruct on how to proceed further, or the notification will be sent to the entire Committee.

- The PAM auditor may add the following activities to the PAM process:

    - A monthly walkthrough of the CompMed animal facility to determine which protocols have animals assigned to them and to observe any random compliance concerns, questions, and/or points of discussion. Generally, the walkthrough will be conducted prior to the scheduled monthly IACUC meeting.

    - A monthly meeting with the CompMed staff to discuss any concerns they may have observed and/or questions they may have regarding procedures performed in the animal facility.

The enhancements to the PAM program and their effectiveness will be formally assessed by the IACUC in February 2024. Interim assessments may be conducted as directed by the collective IACUC committee, the IACUC Chair and/or Vice Chair, the Institutional Official (IO), the Vice Dean for Research, and/or the EVMS President and Provost, Dean of the School of Medicine .

In addition to the PAM program enhancements, the IACUC is currently working with the Office of Research IT team to develop a real-time morbidity and/or mortality (M&M) reporting mechanism, so that cases and trends of high and/or unexpected M&M may be reported to the IACUC immediately. Currently, institutional policy requires investigators to report M&M in the IACUC annual report due at the end of the first, second, and third years post-IACUC approval. The real-time reporting mechanism will allow the IACUC and the CompMed staff to have more efficient and effective oversight and management of the animal care and use program. Beta

testing of the new automated system is anticipated in the coming weeks. In the interim, an Outlook mailbox, entitled "PAM_M&M Reporting" is available for animal users to submit M&M reports. The PAM Auditor, the CompMed Program Manager, and the IACUC Office staff have access to the mailbox and will screen the reports to determine the next course of action (e.g., immediately send to the Attending Veterinarian and/or the IACUC; report to the IACUC at the next scheduled meeting; etc.).

I trust that the information provided herewith addresses your questions and concerns. Please do not hesitate to contact me if additional information is required.

Sincerely,

(b) (6)

David Mu, Ph.D.
Associate Dean for Research Administration
Institutional Official

DM/cbh

cc: (b) (6)

Alireza Hosseini, M.D.
IACUC Chair

(b) (6)

Tara S. Reilly, D.V.M., cVMA
Attending Veterinarian
Division of Comparative Medicine

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Friday, April 28, 2023 3:58 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD); Tubbs, Jai (NIH/OD) [E]
Subject: RE: OLAW Investigative Case A3012-1K - ***Response from Eastern Virginia Medical School, Norfolk, VA***

Good afternoon (b) (6)

Thank you for sending us this response to OLAW investigative case A3012-1K and Dr. Tubbs will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA (pronunciation)
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Friday, April 28, 2023 3:24 PM
To: Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>
Cc: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>; Mu, David <MuD@EVMS.EDU>; (b) (6) (b) (6) Hosseini, Alireza <HosseiA@EVMS.EDU>; (b) (6) Reilly, Tara S. <ReillyTS@EVMS.EDU>; (b) (6)
Subject: [EXTERNAL] RE: OLAW Investigative Case A3012-1K - ***Response from Eastern Virginia Medical School, Norfolk, VA***
Importance: High

Dear Dr. Tubbs:

RE: Allegations of Noncompliance with PHS Policy
OLAW Case A3012-1K
Eastern Virginia Medical School (EVMS)
Animal Welfare Assurance #D16-00007 (formerly A3012-01)

The attached letter is submitted on behalf of David Mu, Ph.D., Associate Dean for Research Administration and Institutional Official, Eastern Virginia Medical School, Norfolk, VA in response to your inquiry dated March 31, 2023 (*also attached*). Please do not hesitate to contact Dr. Mu directly if additional information is required.

David Mu, Ph.D.

Associate Dean for Research Administration/Institutional Official
Eastern Virginia Medical School (EVMS)
735 Fairfax Avenue
EVMS Waitzer Hall, (b) (4)
Norfolk, VA 23507
(b) (6)
MuD@evms.edu

(b) (6)

From: Mu, David <MuD@EVMS.EDU>
Sent: Monday, April 3, 2023 9:36 AM
To: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; (b) (6)
Hosseini, Alireza <HosseiA@EVMS.EDU>
Subject: OLAW Investigative Case A3012-1K

Dear Ms. McCoy,
We will respond by April 30, 2023.
Thank you for your message.
David

David Mu, PhD, Professor
Associate Dean for Research Administration
Director of MEdical sTudent Research Opportunities (METRO)
Eastern Virginia Medical School
(b) (6) ✉ mud@evms.edu

From: McCoy, Devora (NIH/OD) [E] <devora.mccoy@nih.gov>
Sent: Monday, April 3, 2023 7:56 AM
To: Mu, David <MuD@EVMS.EDU>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; (b) (6)
(b) (6)
Subject: [EXTERNAL] OLAW Investigative Case A3012-1K

Good morning Dr. Mu,

Attached please find Dr. Tubbs' investigative report, OLAW Case A3012-1K. Please note that information is being requested to be sent to our office by April 30, 2023. If you have any questions, feel free to contact us by phone or by email.

Best,
Devora

Devora McCoy, BS, MBA (pronunciation)
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

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

March 31, 2023

Re: Animal Welfare Assurance
#A3012-01 [OLAW Case 1K]

David Mu, Ph.D.
Associate Dean for Research Administration
Eastern Virginia Medical School
735 Fairfax Avenue
EVMS Waitzer Hall, (b) (4)
Norfolk, VA 23507

Dear Dr. Mu,

The Office of Laboratory Animal Welfare (OLAW) has received from People for the Ethical Treatment of Animals (PETA) allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Eastern Virginia Medical School regarding the USDA APHIS Inspection Report dated January 12, 2023 (see attachment). It is possible that such occurrences should have been reported directly to our office as required by the PHS Policy and per your commitment to do so in your Animal Welfare Assurance.

We request information regarding the Inspection Report dated January 12, 2023 describing the following incidents:

- Chinchillas remained on study after exceeding humane endpoints described in the protocol. The study continued beyond the 22-week timeline described in the protocol. Four female chinchillas were not removed from the protocol after exceeding the humane endpoint regarding loss of body weight. Per the protocol, "Any animal that experiences more than 20% weight loss will also be removed from the study." It is understood all the animals exceeded 20% loss of body weight. It is noted that three animals were euthanized, and one animal died despite veterinary care. A review of medical and study records revealed the animals were not consistently weighed on a weekly basis. Also, a review of records and discussion with the program manager revealed animals remained on the protocol for longer than 22wk.

- A separate protocol involved changes made to animal selection, procedures, and care of rhesus macaques without IACUC review and approval and/or appropriate handling and documentation of administrative changes. The age of animals on study was changed without IACUC approval, resulting in the use of two male macaques older than the maximum age of 23yr for the study. Also, animal weights were changed without IACUC approval, resulting in 5 female macaques being placed on study and their weights were below the minimum weight requirement.

- Another finding noted was an increase in the amount of sweetened beverage provided to animals without IACUC approval. Two primates received 1000mL of sweetened beverage for numerous days, while 500mL is approved for use. It is stated the duration of time that monkeys were provided a sweetened beverage was lengthened without IACUC review or approval.

- Additionally, as part of recovering from an anesthetic event on study, animals were subjected to additional monitoring procedures which were not documented in the approved protocol. On September 22, 2022, six macaques underwent an insulin administration procedure and during recovery these animals received dextrose injections and repeated blood draws. These procedures were not submitted to or reviewed by the IACUC.

- Per the inspection report, the facility failed to utilize appropriate methods to prevent, control, and diagnose medical issues that arose from the administration of insulin IV, ultimately leading to the death of an animal and hours of unresolved, low blood glucose levels in others. Medical records revealed multiple rhesus macaques experienced severe low blood sugar and prolonged anesthesia recovery times following a procedure involving administration of insulin IV under anesthesia. An incident in June 2022 involved a rhesus macaque that experienced an adverse event while receiving insulin IV. Per anesthesia monitoring records, the animal remained in unconscious or semi-conscious (as defined by the facility) for >4h until recordings ceased. During this time, no medical care was provided, and blood glucose monitoring did not occur, despite being hypoglycemic at the end of the 30-minute study. Per medical records, the animal did not receive medical intervention more than 7h after the procedure had ended. Ultimately, the animal was euthanized due to lack of improvement in their condition. Additionally, the current Attending Veterinarian and program manager were unable to provide any additional information regarding the provision of care for this animal.

- The inspection report notes an additional 11 rhesus macaques underwent the same procedure and lacked blood glucose monitoring or medical interventions for hypoglycemia even when levels were too low to be detected by the handheld glucometer at the end of the procedure. Prolonged recovery from anesthesia also occurred in these animals.

- In September 2022, the procedure was performed again with 6 animals. Records revealed that multiple animals had blood glucose levels that were too low to detect by the handheld glucometer (less than 20 mg/dL) for prolonged lengths of time. Per the inspection report, this led to multiple animals suffering from incredibly low blood sugar without continuous medical intervention to resolve the issue. It is understood that at the time of the USDA inspection, this protocol was closed.

As authorized under section V. A. 4. of the PHS Policy, and as referenced in your Animal Welfare Assurance for Humane Care and Use of Laboratory Animals, OLAW is requesting that your institution provide an explanation of the circumstances surrounding the above concerns. Specifically, regarding your institution's corrective and preventive measure for the implementation of significant protocol changes without IACUC approval. This includes (but not limited to) changes to the age of animals used for study, use of animal with body weights below the minimum required, administration of dextrose to animals, and repeated blood collection in animals. Please describe how daily health checks are performed at the institution and if it involves both husbandry and veterinary staff.

Please instruct the IACUC, avoiding any conflict of interest, to investigate these allegations and if substantiated but not previously reported to OLAW, please state why not. Please also provide further information regarding the incident(s) and all corrective/preventive actions. If PHS/NSF-funded, please report the applicable grant/contract number.

We appreciate your cooperation and ask that you please provide the requested information **by April 30, 2023**. Please contact me if I can be of assistance at jacquelyn.tubbs@nih.gov.

Sincerely,

Jacquelyn T. Tubbs -S

Digitally signed by Jacquelyn T. Tubbs -S
Date: 2023.03.31 09:24:09 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3012-1K

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Friday, March 24, 2023 1:41 PM
To: McCoy, Devora (NIH/OD) [E]
Subject: FW: Concerns re treatment of animals at Eastern Virginia Medical School:

From: (b) (6)
Sent: Thursday, March 23, 2023 3:44 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: [EXTERNAL] RE: Concerns re treatment of animals at Eastern Virginia Medical School:

Hello Dr. Morse,

Thank you very much for your kind acknowledgement and also for looking into our concerns pertaining to EVMS. We very much appreciate it.

(b) (6)

From: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Sent: Thursday, March 23, 2023 3:14 PM
To: (b) (6)
Subject: RE: Concerns re treatment of animals at Eastern Virginia Medical School:

Hello (b) (6)

OLAW acknowledges receipt of your message and attachments. We will review the information and take any action as required by the PHS Policy.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: (b) (6)
Sent: Wednesday, March 15, 2023 11:07 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: [EXTERNAL] Concerns re treatment of animals at Eastern Virginia Medical School:

Dear Dr. Morse:

I hope this correspondence finds you well. Please see the attached letter from PETA, regarding critical violations of the Animal Welfare Act at Eastern Virginia Medical School. We believe these violations also represent noncompliance with federal animal welfare guidelines and ask that your office investigate the matter.

Thank you for your time and consideration.

Sincerely,

A3012-1K

AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA

PEOPLE FOR
THE ETHICAL
TREATMENT
OF ANIMALS

Washington
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

Info@peta.org
PETA.org

March 15, 2023

Brent C. Morse, D.V.M.
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Via e-mail: MorseB@mail.nih.gov

Dear Dr. Morse:

We believe that the federal Animal Welfare Act violations documented in the attached U.S. Department of Agriculture inspection report posted against Eastern Virginia Medical School (EVMS; Animal Welfare Assurance D16-00007) constitute violations of the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). Last year, EVMS received $7,365,364 from the National Institutes of Health (NIH), and according to NIH, an estimated 47% of those funds supported projects that involved experiments on animals.

In 1985, members of Congress from both sides of the aisle worked together to strengthen protections for animals in laboratories in order to address deep-seated ethical concerns held by the American public regarding the use of animals in experiments. Polling by the Pew Research Center found that more than 50% of U.S. adults oppose the use of animals in experiments, and other surveys suggest that the support of the shrinking group that continues to accept animal experimentation is contingent on the existence and enforcement of stringent regulations aimed at protecting animals.

As you know, institutions that receive funding from Public Health Service agencies—including NIH—are required to comply with PHS Policy. Failure to comply violates not only federal animal welfare guidelines and policies but also public expectations that facilities receiving tax dollars to use animals—who are capable of experiencing pain, distress, love, and companionship and value their lives just as we value ours—at the very least, comply with minimal standards aimed at ensuring some modicum of animal welfare.

We ask that your office investigate the incident outlined in the attached report.

Thank you for your time and consideration.

Sincerely,

(b) (6)

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

Inspection Report

Eastern Virginia Medical School
358 Mowbray Arch, PO Box 1980
Norfolk, VA 23501

Customer ID: **497**
Certificate: **52-R-0003**
Site: 001
EASTERN VIRGINIA MEDICAL SCHOOL

Type: ROUTINE INSPECTION
Date: 12-JAN-2023

2.31(c)(7) **Critical**

Institutional Animal Care and Use Committee (IACUC).

Significant changes were enacted in two protocols without IACUC review and approval and/or appropriate handling and documentation of administrative changes.

In the first protocol (19-015), chinchillas were kept on study despite reaching and passing humane endpoints. Animals were also kept on study far beyond the 22-week timeline described in the protocol.

***Four female chinchillas were not removed from protocol 19-015 in accordance with the protocol's humane endpoint. Protocol 19-015 states, "Any animal that experiences more than 20% weight loss will also be removed from the study." All of the animals were placed on study upon arrival at the facility, and the program manager stated that none of the animals were transferred off the study.

1. Female chinchilla #2665L was received by the facility on 2/19/20 and weighed 404 grams upon intake. On July 29, 2020 the animal weighed 317 grams, a loss of 21.5% body weight. On August 6, 2020 the animal weighed 291 grams, a loss of 27.9% body weight, at which time the animal was euthanized.

2. Female chinchilla #2658R was received by the facility on 2/19/20 weighed 468 grams. On 4/30/20 the animal weighed 328 grams, a loss of 29.9% body weight. On 5/6/20 the animal weighed 324 grams, a loss of 30.7% body weight. On

Prepared By: (b) (6)
Title:

Date: 19-JAN-2023

Received by Title: IACUC Representative

Date: 19-JAN-2023

5/11/20 the animal weighed 343 grams, a loss of 26.7% body weight. The animal was euthanized on 5/13/20.

3. Female chinchilla #2668R was received by the facility on 2/19/20, and weighed 686 grams. On 1/27/21 the animal weighed 534 grams (22.1% weight loss). On 8/23/21 the animal weighed 511 grams (25.5% weight loss). The animal was euthanized on 10/18/21.

4. Female chinchilla #2667L weighed 668 grams upon intake. Study records show that on 8/31/20 the animal weighed 500 grams, a loss of 25.1% body weight. Despite veterinary care, the animal died on 9/7/20.

The procedure states that animals will be weighed weekly. However, review of medical and study records showed that animals were not consistently weighed on a weekly basis.

*** The protocol states that animals will be on study for 22 weeks, during which time they will undergo potentially painful procedures with anesthesia and analgesia provided. Review of records and discussion with the program manager show that animals were kept on this protocol for longer than 22 weeks, some animals remained on the protocol from March 2020 to November 2021 (21 months).

In the second protocol (20-018), changes were made to animal selection, procedures, and care of rhesus macaques without IACUC review and approval and/or appropriate handling and documentation of administrative changes.

***The age of animals used on study was changed without IACUC approval. According to health records, two male animals ("HHA" and "AB67") were used on study despite being older than the maximum age of 23 years described in the protocol.

***The weight of animals used on study was changed without IACUC approval. The protocol states that animals will weigh 8-22 kg. Five female animals (DN96, CX48, 6-191, 07U011, and EB74) received on March 21st, 2022 and placed on study were below the minimum weight required. The animals underwent physical exams shortly after intake and their

Inspection Report

body weights ranged from 4.9 kilograms to 7.3 kilograms.

***The amount of sweetened beverage provided to the animals was increased without IACUC approval. An amendment approved June 7, 2021 added 500 mL of a sweetened beverage to the monkey's diet. Two monkeys ("HHA" and "35R") began this procedure on September 13, 2021, and records show that they consumed 1,000 mL of sweetened beverage on many days. The Program Manager stated that the monkeys were given refills of the sweetened beverage after consuming the first 500 mLs.

***The duration of time that monkeys were given a sweetened beverage was lengthened without IACUC review or approval. Study records provided to USDA officials show that 2 animals ("HHA" and "35R") were given this sweetened beverage from September 13, 2021 until April 25th, 2022 (7.5 months), but the protocol stated that the sweetened beverage would only be provided for 3-6 months.

***As part of recovering from an anesthetic event on study, animals were subjected to additional monitoring procedures which are not documented in the approved protocol. On September 22nd, 2022, 6 macaques underwent an insulin administration procedure and during recovery all of these animals were given dextrose injections and repeated blood draws. These procedures were not submitted to or reviewed by the IACUC.

For the above changes, these were not reviewed and approved by the IACUC or documented as administrative changes. Making significant changes to protocols without IACUC review and approval deprives the IACUC of the opportunity to provide oversight of animal activities and compliance with the Animal Welfare Act.

Correct by February 16, 2023 by ensuring that animal activities are accurately and completely described so that the

Prepared By: (b) (6)
Title:
Date: 19-JAN-2023

Received by Title: IACUC Representative
Date: 19-JAN-2023

IACUC can have oversight as required by the Animal Welfare Act regulations. At the time of the inspection, these protocols were closed and no longer active.

2.33(b)(2) Critical

Attending veterinarian and adequate veterinary care.

The facility failed to utilize appropriate methods to prevent, control, and diagnose medical issues that arose from the administration of IV insulin, ultimately leading to the death of an animal and hours of unresolved, low blood glucose levels in others.

Medical records show multiple rhesus macaques experienced severe low blood sugar and prolonged anesthesia recovery times after a procedure where intravenous insulin was administered under anesthesia. After insulin administration, blood samples were taken at set intervals to monitor blood sugar for 30 minutes. Neither the protocol, nor an associated amendment, addressed low blood sugar as a potential side effect of insulin administration nor did they include any interventions to take should blood sugar fall to dangerously low levels.

In June 2022, a male rhesus macaque, "DA9J," experienced an adverse event while on protocol receiving intravenous insulin. According to his surgery/anesthesia monitoring record, he remained in "Stage 3" of anesthesia, defined by the facility as "animals are unconscious or semi-conscious," for over 4 hours until recordings cease. During this time, he received no medical care or monitoring of blood glucose, despite being hypoglycemic at the end of the 30-minute study. Based on medical records, he did not receive medical intervention until more than 7 hours after the end of the procedure, although he remained barely responsive and did not "fully recover" from the procedure. Ultimately, the animal did not improve and was euthanized on 6/28/22 with the medical note that he did not "wake up" from the procedure and was "paralyzed, tonic/clonic". The current AV and program manager were unable to provide any additional information about

the provision of care for this animal.

An additional 11 rhesus macaques underwent this same procedure and also received no monitoring of their blood glucose or medical interventions for low blood sugar despite having blood glucose levels that were so low they were undetectable by the handheld glucometer (less than 20 mg/dL) at the end of the procedure. These animals all took an excessive amount of time to recover from their anesthesia, some over 5 hours. Per medical record review, prior documented recovery times for these same animals after other anesthetic events ranged from about 45 minutes to 1 hour.

In September 2022 the procedure was performed again on 6 of the same animals. Despite the addition of a minimal and ineffective intervention (sugar (dextrose) injections) and repeated blood sugar measurements, records show multiple animals had blood glucose levels that were so low they were undetectable by the handheld glucometer (less than 20 mg/dL) for prolonged lengths of time. This led to multiple animals suffering from incredibly low blood sugar without continuous medical intervention to resolve the issue.

Animals exposed to anesthesia and insulin require special attention and care to prevent low blood sugar, low body temperature, injury, and death. Animals with very low blood sugar may experience serious consequences including brain damage, loss of consciousness, and seizures.

Correct by February 16, 2023 by ensuring that appropriate methods are used to prevent, control, diagnose, and treat medical issues in animals, including the availability of emergency, weekend, and holiday care. At the time of the inspection, this protocol was closed and no longer active.

Prepared By: (b) (6)
Title:
Date: 19-JAN-2023

Received by Title: IACUC Representative
Date: 19-JAN-2023

Inspection Report

This inspection was conducted with the CompMed Program Manager and IACUC representatives from the Office of Research.

The exit interview was conducted with the CompMed Program Manager, Director of Research Compliance, IACUC Chair, Institutional Official and IACUC representatives from the Office of Research.

Additional Inspectors:

(b) (6)

Prepared By: (b) (6)

Title:

Date: 19-JAN-2023

Received by Title: IACUC Representative

Date: 19-JAN-2023

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 497
Inspection Date: 12-Jan-2023

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
497	52-R-0003	001	EASTERN VIRGINIA MEDICAL SCHOOL	12-JAN-2023

Count	Scientific Name	Common Name
000006	*Oryctolagus cuniculus*	DOMESTIC RABBIT / EUROPEAN RABBIT
000016	*Macaca fascicularis*	CRAB-EATING MACAQUE / CYNOMOLGUS MONKEY
000009	*Macaca mulatta*	RHESUS MACAQUE
000007	*Papio anubis*	OLIVE BABOON
000000	*Chinchilla lanigera*	CHINCHILLA
000038	**Total**	

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Thursday, March 23, 2023 3:34 PM
To: McCoy, Devora (NIH/OD) [E]
Subject: FW: Concerns re treatment of animals at Eastern Virginia Medical School:

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, March 23, 2023 3:14 PM
To: (b) (6)
Subject: RE: Concerns re treatment of animals at Eastern Virginia Medical School:

Hello (b) (6)

OLAW acknowledges receipt of your message and attachments. We will review the information and take any action as required by the PHS Policy.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: (b) (6)
Sent: Wednesday, March 15, 2023 11:07 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: [EXTERNAL] Concerns re treatment of animals at Eastern Virginia Medical School:

Dear Dr. Morse:

I hope this correspondence finds you well. Please see the attached letter from PETA, regarding critical violations of the Animal Welfare Act at Eastern Virginia Medical School. We believe these violations also represent noncompliance with federal animal welfare guidelines and ask that your office investigate the matter.

Thank you for your time and consideration.

Sincerely,

(b) (6)