

June 13, 2023

Alfred Abuhamad, MD
President and Provost
Dean of the School of Medicine

The Honorable J. Chapman Petersen
Chair, Senate Committee on Agriculture, Conservation, and Natural Resources

The Honorable David W. Marsden
Chair, Senate Subcommittee on Companion Animals

Dear Senators Petersen and Marsden:

My sincerest apologies for the delay in this response. With regard to your inquiry dated February 1, 2023, I include the following information concerning AWA violations and the measures taken by EVMS to ensure compliance with all applicable laws governing animal research. EVMS has maintained an AAALAC-accredited laboratory animal medicine program directed by veterinarians over the past 22 years and is committed to maintaining a compliant animal care and use program.

A detailed explanation for the cause of the AWA violations for which EVMS was cited by the USDA for the years 2021-2023.

The September 14, 2021 USDA routine inspection report of the EVMS animal care and use program contained two critical citations. The first violation cited that three animals underwent multiple major operative procedures on more than one IACUC-approved protocol without prior approval from the APHIS Administrator. The protocols involved were a continuation of the same study with identical study objectives, but were assigned unique identifiers during the triennial de novo reviews required by NIH Office of Laboratory Animal Welfare (OLAW) to administratively document and track each newly reviewed and IACUC-approved version of the same project. The protocols included that animals will undergo multiple major survival surgeries, the surgical procedures and the number of surgeries each animal will undergo while assigned to the project, the animals that have undergone prior surgeries under a previous unique numerical identifier, and the need to use the same animals in the current surgical protocol (i.e., under the current unique identifier).

The original version of this research project began at EVMS in the mid-1980s and has continued since then as a federally funded project. EVMS had followed its historical practice of using unique identifiers during triennial reviews and the guidance provided from three former USDA Veterinary Medical Officers regarding EVMS' Multiple Major Survival Surgery Policy (MMSS Policy), approved by the USDA, that prior approval by the APHIS Administrator is not required each time a multiple major survival surgery is performed in this context. EVMS has now modified its practice and application of the MMSS Policy to ensure compliance with the AWA. No animal welfare issues were reported following the surgeries performed under the protocols.

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The second violation cited was that one animal was injured by a plastic hut (an enrichment device) used in the primary enclosure. In keeping with the AWA, environmental enrichment is provided to research animals to improve their well-being and physical enrichment devices, such as chew toys, wooden blocks/platforms, and plastic huts, are used routinely. Per institutional policy, enrichment devices are checked regularly by the research/veterinary care staff to assess their integrity and ensure their safety. Additionally, research animals at EVMS are subject to wellness checks twice a day, at a minimum, including weekends and holidays. The incident that led to a citation stemmed from March 2020 protocol records that indicated that an animal caught a toe in the enrichment hut. The records indicated that the animal was observed on the same day, was treated in accordance with the protocol, and referred immediately to the veterinary staff for evaluation and treatment. The animal was diagnosed with a dislocated and/or fractured toe and ultimately lost part of the digit. Following the incident, the facility changed the type of huts used to an alternate style. There have been no additional occurrences since that time.

Information detailing if and how individuals responsible for these violations were disciplined and/or held accountable for their failures.

Upon receipt of the USDA inspection report, EVMS carefully considered both citations with respect to institutional policies, procedures, and practices. The institution determined that the incidents were not caused by the direct actions or failures of an individual person or persons and, therefore, targeted disciplinary action was not warranted.

Information detailing whether these violations were associated with protocols for which EVMS received public monies, and if so, the source of monies.

The cited protocols were supported by funding from the National Institutes of Health (NIH).

Information detailing if the PI or designee reported these violations to the entities funding the research associated with these violations.

The USDA citations were reported to the federal and private funding sources.

Information detailing any action taken by EVMS to address the publishing of data from the protocols associated with these violations.

EVMS actions include following regulatory guidelines on publications from OLAW regarding protocol violations, alerting and speaking with the investigators, and monitoring publications using PUBMED. No publications have utilized data from the violations.

Information detailing actions that EVMS has taken to prevent such violations from occurring in the future.

Regarding the first citation, on the date of the inspection, September 14, 2021, all multiple major operative procedures approved under the protocol were suspended until the APHIS

Administrator granted approval to resume the surgeries. In addition, EVMS has updated its practice to ensure that when a protocol is given a unique identifier during a triennial review, EVMS submits a written request for a USDA-granted exemption to allow animals associated with an earlier protocol number to be transferred to the new protocol number, if applicable.

Regarding the second citation, EVMS discontinued use of the specific plastic hut enrichment devices immediately following the incident in 2020 and prior to the September 2021 USDA inspection. No additional or similar occurrences have been documented since the alternate style huts have been in use. The research/veterinary care staff will continue to check all enrichment devices regularly to assess their integrity and ensure their safety. Additionally, research animals will remain subject to two wellness checks a day, at a minimum, including weekends and holidays.

Information detailing EVMS' plan to ensure ongoing and consistent compliance with federal laws and regulations about animal welfare of animals used for experimental purposes.

EVMS is committed to maintaining a compliant animal care and use program as evidenced by its continued accreditation by AAALAC, a private, nonprofit organization that promotes the humane care and use of animals in science and overall animal welfare through voluntary accreditation and assessment programs. AAALAC is recognized around the world as the gold standard of responsible animal care and use for research, teaching, and testing. Accredited institutions volunteer to participate in AAALAC's program, by complying with AAALAC International standards as set forth by the Guide for the Care and Use of Laboratory Animals (the Guide), NRC 2011. AAALAC accreditation is supplemental to maintaining compliance with local, state, and federal animal research requirements.

EVMS is one of more than 1,050 companies, universities, hospitals, government agencies, and research institutions in 50 countries/regions that has earned AAALAC accreditation. AAALAC accreditation is granted for a 3-year period. In June 2022, the institution received notification of its eighth consecutive continued full accreditation. The accreditation letter states the following: "AAALAC Council commends you [EVMS] and the staff for providing and maintaining an exemplary program of laboratory animal care and use. Especially noteworthy were the strong institutional support to the program, evidenced in part by your involvement and the allocation of resources, including a renovated and well-equipped animal facility; the active and engaged Institutional Animal Care and Use Committee (IACUC) supported by a proactive Chair and veterinarians interacting with principal investigators to provide customer support, thorough protocol review, a robust Post-approval monitoring program with regular IACUC reporting and documentation of compliance with Occupational Health program entrance requirements; the effective veterinary medical care and training programs, evidenced in part by the universal acceptance and application of aseptic technique in rodent survival surgery; and attention to the animal environment, evidenced in part by a clean facility and the comprehensive environmental enrichment program."

Knowledge of federal laws and regulations informs, encourages, and helps to ensure compliance. All persons authorized to work with live animals at EVMS are required to complete online training courses which detail federal laws/regulations, industry best practices, and institutional policies and procedures. Online training must be completed every two or three years, depending upon the subject matter, for as long as the individual uses live animals at the institution. Additional species-specific/research project-specific training opportunities are offered on-site by the veterinary care staff, as needed. Also, the institution, via the EVMS Office of Research, promotes and financially supports training and continuing education opportunities for persons involved in the animal care and use program (i.e., researchers, animal care staff, IACUC members, administrative support staff, etc.). Personnel attend regular informational and educational conferences and workshops and participate in webinars to stay updated on regulations and best practices. IACUC support staff receives information from the regulatory agencies and AAALAC, which the staff makes available to authorized animal users. Collectively, these practices are designed to ensure ongoing and consistent compliance of the animal care and use program for experimental purposes.

Please let me know if I can provide any additional information.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alfred Abuhamad', written in a cursive style.

Alfred Abuhamad, M.D.
President, Provost
Dean of the School of Medicine
Mason C Andrews Professor, Obstetrics and Gynecology and Radiology
Eastern Virginia Medical School

cc: Milton L. Brown, MD, PhD, Vice Dean for Research
Stacy R. Purcell, Vice President and General Counsel