



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

April 5, 2017

Re: Animal Welfare Assurance
A3668-01 [OLAW Case 1P]

Dr. James P. Thompson
Dean and Institutional Official for Animal Care
The University of Tennessee
2407 River Drive, Room # Teaching Hospital
Knoxville, TN 37996-4550

Dear Dr. Thompson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 7, 2017 letter responding to my request for further information. It is understood that your institution has updated the program information regarding VVC as explained in your Assurance. We also understand that the involved animal activity was not PHS-funded.

OLAW appreciates your consideration of this matter. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate and correct the issue, and to prevent recurrence. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



Tuesday March 07, 2017

Re: Animal Welfare Assurance D16-00397 (A3668-01)
[OLAW Case 1P]

Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Dear Dr. Morse,

Thank you for your review of our report regarding a noncompliance issue at the University of Tennessee, Knoxville. Below please find the response to your comments and/or questions in your letter dated February 15, 2017.

The UT IACUC fully agrees with OLAW's suggestion that a probationary period of increased IACUC oversight is appropriate for the involved protocol (2455-0616; Evaluation of the Utility of Vasopressors in Hemorrhagic Shock Using a Porcine Model) when animal work is again active. In fact, one of the corrective actions determined at the December 2016 IACUC meeting, although not delineated in my previous January 23, 2017 letter to OLAW, was a requirement for enhanced oversight by our Director of Animal Compliance and select IACUC members. This information was included in the letter sent to the principal investigator and his research team members which states in part *"The observations will continue for a duration of time to be determined following review of the IACUC member's observations, which will be discussed at upcoming IACUC meetings."*

The action of our Acting UAV, where a protocol exception for a non-animal welfare health-related issue was approved, was perhaps wrong. We both ultimately agree her action was based on good intention, but not on a medical necessity to improve animal welfare. Animal records and interviews with the Acting UAV indicated the animal was stable while under anesthesia and no signs or indications of animal pain or distress existed. The failed data acquisition for this fourth animal and the previous euthanasia of three pigs created an indirect animal welfare issue. The critical thought process at that moment was the consideration of lost animal life without possible collection of essential biomedical research data; euthanasia at that moment defeats the welfare concept of reducing animal use. I standby the decision made by the Acting UAV, at that particular moment, not for an immediate animal welfare issue but for the full picture of three versus four animals providing their lives for research with no appreciable data. I appreciate that many, many things should have been done prior to and following that event to negate having the situation present itself.

Institutional Animal Care & Use Committee
336 Ellington Plant Sciences / Knoxville, TN 37996-4564
865-974-3631 865-974-5587 fax iacuc.utk.edu

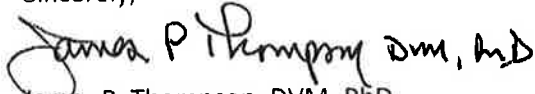
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Flagship Campus of the University of Tennessee
Obtained by Rise for Animals. Uploaded 07/08/2020

The amendment delineating the inclusion of hypoxic cardiac arrest in the animal use protocol underwent full IACUC review. We completely agree that this type of change would not fall under any bulleted points defined in our animal welfare assurance Veterinary Verification and Consultation (VVC) process. The purpose of the first listed bullet, *"Changes which have been approved by the AV or his/her designee as necessary to promote animal welfare or to relieve animal suffering,"* was created to address proposed changes to benefit animal welfare issues applicable to all study animals, not just individual animals. We are, however, comfortable in removing the first bulleted point from our VVC policy and will request this modification on our conditionally approved animal welfare assurance, which requires an update by the end of this month.

The protocol was not supported through a PHS/NSF funded project. The word "suspension" was not used during voting by the quorum of committee members during the two IACUC meetings where lengthy discussions of this protocol noncompliance occurred. Likewise, the word "suspension" was also not used in the letters to the principal investigator or to OLAW. However, halting the research until the corrective actions/sanctions were completed by the PI and research team, and forbidding the UAV from any further research animal oversight responsibility clearly implies protocol suspension.

Sincerely,

A handwritten signature in black ink that reads "James P. Thompson DVM, PhD". The signature is fluid and cursive.

James P. Thompson, DVM, PhD

Dean and Institutional Official for Animal Care

cc: Dr. Lori Cole, Acting/Interim University Attending Veterinarian

Dr. Melinda Hauser, IACUC Chair

Secondary individual IACUC Coordinator



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February 15, 2017

Re: Animal Welfare Assurance
A3668-01 [OLAW Case 1P]

Dr. James P. Thompson
Dean and Institutional Official for Animal Care
The University of Tennessee
2407 River Drive, A102 Teaching Hospital
Knoxville, TN 37996-4550

Dear Dr. Thompson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 23, 2017 letter reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the University of Tennessee - Knoxville. It is understood that your institution has determined that there had been an unapproved significant change to a hemorrhagic shock protocol using a porcine model. Specifically, several animals were subjected to hypoxic cardiac arrest under anesthesia instead of the approved hemorrhagic shock procedure to create the cardiac arrest. There were no animal welfare concerns, but the specific concerns were that the significant change was implemented without IACUC review and approval and that none of the study members, including the University Attending Veterinarian (UAV) and the clinical assistant laboratory animal veterinarian, reported the ongoing noncompliance that involved seven pigs over a two-week period. It was not stated if this animal activity was PHS-funded.

Corrective actions included retraining of the non-veterinary research staff and "inactivation" of the protocol. [REDACTED]

Privacy

OLAW believes that the corrective measures by the University of Tennessee - Knoxville are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring, self-correction, and self-reporting as far as they go. OLAW suggests that a probationary period of increased IACUC oversight is appropriate for the involved protocol when animal work is again active.

Please also note that, although we do not disagree with your conclusion that the clinical assistant laboratory animal veterinarian acted with good intentions by allowing the significant change to occur, we disagree that she "had the authority to grant a temporary protocol exception". Her authority to intervene in a clinical medical emergency is undisputed, but her making significant changes to the research procedures can only be done under authority of the Veterinary Verification and Consultation (VVC) process. This process was apparently not used in this incident and, regardless, adding a new procedure (hypoxia) would not be appropriate for VVC.

On page 8 of your OLAW Animal Welfare Assurance document the first bulleted example for VVC states “Changes which have been approved by the AV or his/her designee as necessary to promote animal welfare or to relieve animal suffering.” This statement is too broad for VVC and as stated above, is already authorized for the veterinarian under clinical emergency situations. OLAW requests that you update your program information removing this bullet. Please also clarify if this is a PHS/NSF funded project and whether the IACUC officially suspended the protocol.

We appreciate being informed of this matter and request you **respond to this office before March 10, 2017**. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Brent C. Morse". The signature is fluid and cursive, with a long horizontal stroke at the end.

Brent C. Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



THE UNIVERSITY OF
TENNESSEE
KNOXVILLE

A3668-1P

Monday, January 23, 2017

Animal Welfare Assurance # D16-00397

Axel V. Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 1050, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Facsimile (301) 451-5672

Dear Dr. Wolff,

The University of Tennessee, Institutional Animal Care and Use Committee (IACUC) discovered a series of non-compliance events associated with an approved animal care and use protocol (2455-0616; Evaluation of the Utility of Vasopressors in Hemorrhagic Shock Using a Porcine Model) during an IACUC review of a submitted protocol amendment.

On October 25, 2016, a protocol amendment was submitted to the IACUC by a University of Tennessee Medical Center principal investigator. The amendment requested permission to use a paralytic agent (vecuronium bromide) in anesthetized pigs. The pigs were previously approved to undergo hemorrhagic shock to assess the utility of vasopressors in cardiac resuscitation. The submitted amendment was distributed to the IACUC for discussion at the November 1, 2016 meeting. The amendment reviewer and another committee member questioned a phrase written in the amendment to justify the use of the paralytic agent; the phrase was, "capping the endotracheal tube." The paralytic agent was requested as an alternative to physically occluding the endotracheal tube to allow the pigs to achieve cardiac arrest and pulseless electrical activity. The committee noted that the creation of hypoxic cardiac arrest was not an approved procedure in the original protocol and the submitted amendment implied the investigators had performed hypoxic cardiac arrest by occluding the endotracheal tube. The committee voted at the November 1, 2016 meeting to investigate the procedures performed to date. No further protocol activity was permitted until the investigation concluded and corrective action, if needed, was completed.

The investigation was lengthy and covered a time period from November 1, 2016 through January 10, 2017. Three physicians, the University Attending Veterinarian (UAV), a clinical assistant laboratory animal veterinarian, and two laboratory animal veterinary technologists directly participated in the research experiments; one principal investigator was not present for any of the experimental procedures. In addition to the subcommittee interview of these research participants, the investigation also included a separate IACUC interview of the UAV and the clinical assistant laboratory animal veterinarian.

Institutional Animal Care & Use Committee
336 Ellington Plant Sciences / Knoxville, TN 37996-1564
865-974-3631 865-974-5587 fax iacuc@utk.edu

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Findings from the investigation revealed ten pigs had undergone experimental study on the approved protocol. The experiments occurred on October 5 (2 pigs), October 12 (2 pigs), October 19 (3 pigs), and October 26 (3 pigs). On October 5, no evidence of approved protocol deviation was identified by the IACUC investigation subcommittee. However, on October 12 clear evidence existed that a new experimental procedure (hypoxic cardiac arrest) was introduced on one pig which was not authorized in the approved protocol. The investigation subcommittee also found the 3 pigs on October 19 and the 3 pigs on October 26 also underwent unapproved hypoxic cardiac arrest. The investigation subcommittee and the IACUC membership carefully evaluated whether evidence existed that any animal suffered in the absence of inhalation anesthesia from the time of endotracheal tube occlusion through the onset of cardiac arrest, subsequent cardiac resuscitation, and euthanasia. The committees could find no evidence of animal suffering and concluded the approved concurrent use of non-inhalant anesthesia in the experimental protocol had prevented any animal welfare concern.

Despite the absence of an animal welfare concern, clear noncompliance was evident. As was stated earlier, the approved protocol granted permission to study the effect of vasopressors in a hemorrhagic shock model. The pigs were to have a femoral artery catheter placed to allow controlled blood loss to the point of cardiac arrest and pulseless electrical activity. The research group, which included the UAV and staff members of the Office of Laboratory Animal Care, had extreme difficulty achieving femoral artery catheterization in the first 3 pigs and, as a result, neither hemorrhagic shock nor any meaningful scientific data collection were achieved. During experimental study of the fourth pig (October 12), a request for permission to occlude the endotracheal tube to induce cardiac arrest was made to the clinical assistant laboratory animal veterinarian who was serving as Acting UAV (the UAV was on vacation). The Acting UAV granted permission in an effort to avoid yet another failed experiment without data collection and the pending loss of another research animal life. The researchers were able to successfully induce cardiac arrest and pulseless electrical activity, and were able to collect essential preliminary data verifying their ability to successfully perform cardiac resuscitation in anticipation of fulfilling later aspects of the experimental design investigating the utility of vasopressors in cardiac resuscitation. Given the immediate experimental presentation, I concluded the Acting UAV had the authority to grant a temporary protocol exception based on (1) a clear absence of an existing animal welfare violation within the ongoing experiment and (2) a reasonable attempt to avoid a pending animal death without the collection of essential scientific data. However, the Acting UAV had an absolute responsibility to ensure no further unapproved experimental procedures were performed on this research project until such time as an amendment request to add new procedures was considered by the IACUC. The Acting UAV also had the absolute responsibility to inform the UAV and the IACUC that an unapproved procedure was authorized in an effort to prevent possible unnecessary loss of animal life without the benefit of securing essential research data. None of these essential responsibilities were fulfilled. It is important to note that the Acting UAV, soon after October 12 and before the return of the UAV from vacation, was away from the University on annual personal leave for two weeks.

The University Attending Veterinarian, who was a co-principal investigator and full member of the research team, participated fully in all experiments performed on October 19 (3 pigs) and October 26 (3 pigs). Despite questioning whether the hypoxic cardiac arrest observed on the fifth pig (October 19) was approved, the UAV allowed the experiments to proceed through the tenth pig on October 26. As a co-principal investigator and full member of the research team, the UAV had an obligation to understand fully the approved protocol and its associated animal use procedures. It is clear the UAV did not have the working knowledge needed to ensure adherence to the approved IACUC protocol. Specifically, the UAV (1) failed to prevent 6 animals from undergoing unapproved experimentation and (2) even though the UAV reported only becoming aware of unapproved animal research activity after the tenth pig, the UAV failed to report the non-compliance events to the IACUC office as required by an attending laboratory animal veterinarian. Both failures were considered egregious.

While the investigation was ongoing, at the December 6, 2016 IACUC meeting, the membership voted on immediate corrective measures for the non-veterinary members of the research team for their role in the non-

compliance events. These requirements were completing IACUC on-line training modules available at the AALAS Learning Library "Working with the UT Knoxville IACUC" and "Common Compliance Issues." An IACUC vote was secured which held the protocol inactive and prevented ordering research animals until such time as verified training had occurred and the protocol amendment was considered and approved by the IACUC. The UAV, the clinical assistant laboratory animal veterinarian, and the two laboratory animal veterinary technicians, were ruled ineligible to participate further in the research, until the roles of each individual in the noncompliance issue were resolved.

At the January 10, 2017 IACUC meeting, the IACUC determined that the laboratory animal veterinarians played central roles in perpetuating the non-compliance and that they failed to report the non-compliance to the IACUC.

Privacy

Privacy

Until another University Attending Veterinarian is identified and employed by our institution, Dr. Lori Cole will serve as Acting/Interim UAV. The clinical assistant laboratory animal veterinarian and the two laboratory animal veterinary technicians will work directly under the supervision of Dr. Cole to assure adherence to acceptable research animal oversight and welfare assurance. I intend to personally meet monthly with Dr. Cole, the clinical assistant laboratory animal veterinarian, and the veterinary technicians until such time as a new UAV is hired or I am satisfied they each fully understand and are performing their laboratory animal care oversight responsibilities with due competence and professionalism.

Please feel free to contact either myself (telephone # [redacted] jthompson@utk.edu) or Dr. Lori Cole, (telephone # [redacted] lcole21@utk.edu) should you need additional information regarding any aspect of this incident or its resolution.

Sincerely yours,



James P. Thompson, DVM, PhD
IO, University of Tennessee, Knoxville

cc: Dr. Melinda Hauser, IACUC Chair
Dr. Lori Cole, Director Animal Compliance Support
[redacted] IACUC Coordinator

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Tuesday, January 24, 2017 7:51 AM
To: 'Thompson, Jim (Jim)'
Subject: RE: University of Tennessee: Animal Welfare Non-compliance Issue Report

Thank you for this report, Dr. Thompson. We will respond soon. In future please send all final reports to olawdco@od.nih.gov.

Axel Wolff

From: Thompson, Jim (Jim) [mailto:jthomp70@utk.edu]
Sent: Monday, January 23, 2017 5:30 PM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Cc: Hauser, Melinda R <mhauser@utk.edu>; Cole, Lori Scheyd <lcole21@utk.edu>; [REDACTED]@utk.edu
Subject: University of Tennessee: Animal Welfare Non-compliance Issue Report

Secondary individual

Monday, January 23, 2017

Animal Welfare Assurance # D16-00397

Axel V. Wolff, MS, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 1050, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982
Facsimile (301) 451-5672

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the procedures performed to date. No further protocol activity was permitted until the investigation concluded and corrective action, if needed, was completed.

The investigation was lengthy and covered a time period from November 1, 2016 through January 10, 2017. Three physicians, the University Attending Veterinarian (UAV), a clinical assistant laboratory animal veterinarian, and two laboratory animal veterinary technologists directly participated in the research experiments; one principal investigator was not present for any of the experimental procedures. In addition to the subcommittee interview of these research participants, the investigation also included a separate IACUC interview of the UAV and the clinical assistant laboratory animal veterinarian.

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even though the UAV reported only becoming aware of unapproved animal research activity after the tenth pig, the UAV failed to report the non-compliance events to the IACUC office as required by an attending laboratory animal veterinarian. Both failures were considered egregious.

While the investigation was ongoing, at the December 6, 2016 IACUC meeting, the membership voted on immediate corrective measures for the non-veterinary members of the research team for their role in the non-compliance events. These requirements were completing IACUC on-line training modules available at the AALAS Learning Library "Working with the UT Knoxville IACUC" and "Common Compliance Issues." An IACUC vote was secured which held the protocol inactive and prevented ordering research animals until such time as verified training had occurred and the protocol amendment was considered and approved by the IACUC. The UAV, the clinical assistant laboratory animal veterinarian, and the two laboratory animal veterinary technicians, were ruled ineligible to participate further in the research, until the roles of each individual in the noncompliance issue were resolved.

At the January 10, 2017 IACUC meeting, the IACUC determined that the laboratory animal veterinarians played central roles in perpetuating the non-compliance and that they failed to report the non-compliance to the IACUC. [REDACTED]

Privacy

another University Attending Veterinarian is identified and employed by our institution, Dr. Lori Cole will serve as Acting/Interim UAV. The clinical assistant laboratory animal veterinarian and the two laboratory animal veterinary technicians will work directly under the supervision of Dr. Cole to assure adherence to acceptable research animal oversight and welfare assurance. I intend to personally meet monthly with Dr. Cole, the clinical assistant laboratory animal veterinarian, and the veterinary technicians until such time as a new UAV is hired or I am satisfied they each fully understand and are performing their laboratory animal care oversight responsibilities with due competence and professionalism.

Please feel free to contact either myself [REDACTED] telephone # [REDACTED] jthompson@utk.edu) or Dr. Lori Cole, [REDACTED] telephone # [REDACTED] lcole21@utk.edu) should you need additional information regarding any aspect of this incident or its resolution.

Sincerely yours,

James P. Thompson, DVM, PhD
IO, University of Tennessee, Knoxville

cc: Dr. Melinda Hauser, IACUC Chair
Dr. Lori Cole, Director Animal Compliance Support
[REDACTED] Secondary individual IACUC Coordinator