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February 28, 2019

Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
670b Rockledge Drive, Suite 2500, MSC6910  
Bethesda, MD 20892

Dr. Morse or Dr. Wolff:

The University of Tennessee Health Science Center (UTHSC), in accordance with Assurance A3325-01 and PHS Policy IV.F.3, reports noncompliance for participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f. The narrative below describes the findings and actions taken in this matter.

On January 30, 2019 the Institutional Animal Care and Use Committee (IACUC) was made aware that members of a research group on campus were using Avertin as an anesthetic agent. Avertin was not included in their approved. Further investigation revealed that research staff unilaterally (i.e., without the PI's knowledge) made the decision to use Avertin based on difficulties associated with their approved use of Isoflurane (specifically, several animals failed to recover from anesthesia).

A quorum of the IACUC examined these findings, during its regular meeting on February 12, 2019. During its deliberations of the incident, the IACUC considered the PI's proactive response to the protocol noncompliance, requiring all members of the research group to re-read the animal use protocol.

Following discussion, the IACUC unanimously voted:

- Require additional training on interactions with the IACUC. It is required that research staff complete the "Refresher: Working with the IACUC" course found in the AALAS Learning Library within 30 days.
- Since the noncompliance was a result of difficulties associated with the use of Isoflurane, research staff are required to complete hands-on training in the proper use of anesthetics provided by the UTHSC Veterinary staff.

These have been completed.

The PI was reminded that any future failure to comply with an approved animal protocol, IACUC procedures, or Lab Animal Care Unit procedures, no matter how minor, could be grounds for immediate suspension of their animal research program.

The protocol associated with the report of non-compliance was PHS funded, USPHS Grant AR-064354-05.

Sincerely,

A handwritten signature in black ink, appearing to read 'S. Goodman', written over a horizontal line.

Steven R. Goodman PhD  
Vice Chancellor for Research

Copied:





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910 Madison Avenue, Suite 608  
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Memphis  
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January 30, 2019

Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
670b Rockledge Drive, Suite 2500, MSC6910  
Bethesda, MD 20892

Dr. Morse or Dr. Wolff:

The University of Tennessee Health Science Center (UTHSC), in accordance with Assurance A3325-01 and PHS Policy IV.F.3, reports noncompliance for participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.f. The narrative below describes the findings and actions taken in this matter.

On Friday December 7, 2018 the Institutional Animal Care and Use Committee (IACUC) was made aware that, a Visiting Scholar, working with an on-campus research group, had gone to the UTHSC Occupational Health Office because of a mouse bite he suffered in the Cancer Research Building mouse imaging facility. An investigation revealed that this individual had not been through the Occupational Health screening, and was not associated with an IACUC approved protocol. This incident of non-compliance violated both institutional and IACUC procedures, regarding entry into the vivarium facility and working with live animals.

A quorum of the IACUC examined these findings, during its regular meeting on January 8, 2019. During its deliberations of an appropriate response to this incident, the IACUC took into account the fact that the PI cooperated with the investigation, and immediately took responsibility for this incident upon notification.

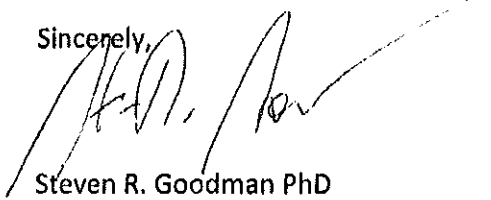
Following discussion, the IACUC unanimously voted:

It was determined that the PI and his staff complete the "Refresher: Working with the IACUC" course found in the AALAS Learning Library within 30 days.

This has been completed.

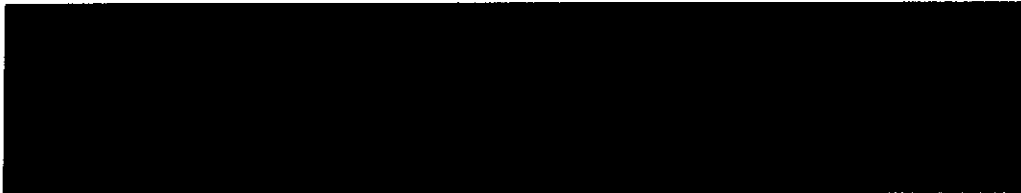
The PI was reminded that any future failure to comply with approved animal protocol, IACUC procedures, or Lab Animal Care Unit procedures, no matter how minor, could be grounds for immediate suspension of their animal research program.

Sincerely,

A handwritten signature in black ink, appearing to read 'S.R. Goodman', written over the word 'Sincerely,'.

Steven R. Goodman PhD  
Vice Chancellor for Research

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**Institutional Animal Care & Use Committee**

910 Madison Avenue, Suite 650

Memphis, TN 38163

Phone: (901) 448-3904

Fax: (901) 448-5222

May 2, 2019

Elizabeth Goldentyer, DVM  
Regional Director – Animal Care  
USDA/APHIS, Eastern Region  
920 Main Campus Drive, Suite 200  
Raleigh, NC 27606-5210

Dear Dr. Goldentyer,

The University of Tennessee Health Science Center (UTHSC), in accordance with Assurance A3325-01, and PHS and USDA policy, reports non-compliance and concerns for animal welfare that resulted in the suspension (pending correction) of [REDACTED] IACUC protocol #18-021. This protocol utilizes a pre-term pig model (105 days gestation) to study the impact of varied neonatal diets on pre-term development. The work is not supported by any federal funding.

On April 16<sup>th</sup> 2019, the UTHSC veterinary staff reported to the IACUC Chair a number of animal welfare concerns, regarding an experiment, under #18-021, that began on April 12<sup>th</sup> with the cesarean delivery of greater than a dozen piglets. The Concerns were as follows:

1. At least three procedures were performed on piglets that were not included in the approved protocol, namely: (1) the use of isoflurane anesthesia, in order to replace an orogastric feeding tube, (2) administering sodium bicarbonate treatment, and (3) administering blood transfusions.
2. While euthanasia endpoints are listed in protocol #18-021, the PI's records indicated that the clinical criteria for establishing when an endpoint is reached were not consistently tracked. For example, heart rate was not included in any of the records, despite the approved protocol indicating a heart rate below 100 bpm, for 10 minutes, was a criteria for euthanasia.
3. On at least one occasion, an animal was not euthanized, despite having reached one of the humane endpoints described in the protocol (i.e. poor skin color). Further, on another occasion, the PI did not adhere to a UTHSC veterinarian's recommendation to euthanize an animal.
4. A major concern identified by the veterinarians was the general inadequacy of the 24/7 monitoring, and the training of the research team doing so.

The IACUC met for a regularly scheduled meeting on April 23, 2019, at which time the committee discussed the concerns outlined, above. The discussion included the unapproved use of: (1) anesthesia procedures, and (2) the delivery of blood transfusions and/or sodium bicarbonate as clinical interventions. As well, the committee discussed the inconsistent recording of clinical parameters described in the protocol including: (1) visual observations, and (2) measures of respiration, heart rate and pulse-oximetry. The failure to collect these data was

concerning to the IACUC, as was the fact that some animals that had reached a humane endpoint, but were not euthanized, either on the basis of clinical observations, or as instructed by a UTHSC veterinarian. Finally, the committee expressed significant concerns, regarding the insufficient number of staff charged with monitoring the piglets, at any one time, and the adequacy of their training.

Based on the discussion, the IACUC approved the following conditions and requirements that must be met by the PI, before the use of the pre-term pig research model may continue:

1. In coordination with UTHSC veterinary staff, the IACUC required that a new set of clearly defined clinical parameters and guidelines be established that define when a humane endpoint has been reached. These parameters and guidelines must include, but are not limited to: clinical variables to be monitored, when monitoring is initiated, frequency of monitoring, method of recording and a clear clinical decision tree. Final documents will require veterinary approval, and the IACUC, via the protocol amendment process and Full Committee Review.
2. In conjunction with the UTHSC veterinary staff, the PI must establish how many pre-term piglets a single individual can adequately monitor to ensure each animal is receiving appropriate care and monitoring. Research staff tasked with monitoring the animals must also be adequately trained (as determined by the veterinary staff) to assess the established clinical monitoring variables, and follow the guidelines (as defined in item one, above), in order to recognize when a piglet requires veterinary care and/or has reached a humane endpoint.
3. The IACUC determined that following approval of the modifications to protocol #18-021, the PI will be permitted to perform only **one** experiment, after which the committee has required a report on the outcomes of that experiment, including a review of all medical records.
4. The committee has also required that the PI and his research staff complete the *Working with the IACUC Refresher* course through the AALAS Learning Library.
5. The PI was reminded that any future failure to comply with an approved animal protocol, IACUC procedures, or Lab Animal Care Unit procedures, no matter how minor, could be grounds for termination of his animal research program.

These corrective actions are currently in progress.

Sincerely,



Steven R. Goodman, PhD  
Vice Chancellor for Research  
Institutional Official

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