



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 6, 2020

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

Dr. James P. Thompson  
Dean and Institutional Official for Animal Care  
The University of Tennessee  
2407 River Drive, (b) (4) Teaching Hospital  
Knoxville, TN 37996-4550

Dear Dr. Thompson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 27, 2020 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 on March 5, 2020 your institution determined that three out of four mice receiving chemotherapeutic agents had exceeded the approved 20% weight-loss limit on a cancer protocol. The affected animals were immediately euthanized. It was stated that this animal activity was not PHS-funded.

Corrective actions required by the IACUC included the use of an online calendar for experiments to allow post-approval monitoring and veterinary oversight. Animal weight records must be available at all times for assessment. A protocol amendment must be submitted clarifying that diet gel will be made available to animals at a 13-14% loss of starting body weight. At that time, a veterinary consult must be submitted.

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. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, correct the noncompliance, and prevent recurrence. OLAW concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact



## Institutional Animal Care & Use Committee

336 Ellington Plant Sciences

Knoxville, Tn 37996

office: 865-974-5548

fax: 865-5649

iacuc.utk.edu

Monday, April 27, 2020

Animal Welfare Assurance # D16-00397

Brent Morse, DVM, DACLAM  
 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. Morse:

The University of Tennessee Knoxville, in accordance with Assurance D16-00397 and PHS Policy IV.F.3 provides this report of noncompliance regarding weight loss experienced by 3 mice in excess of the IACUC approved endpoint for study removal as described in animal-use protocol 1452 entitled "Anticancer Agents Controlling Tumorigenicity of Mutagenized Cells."

On March 5, 2020, the IACUC Office was alerted by the Office of Laboratory Animal Care (OLAC) to a non-compliance issue related to activities covered by protocol 1452. Three of four mice receiving chemotherapeutic agents were determined to have lost greater than 20% of their pre-treatment body weight. The affected mice were euthanized that same day. A review of the weight records indicated the mice remained on the study for a period of up to 3 days beyond the endpoint criterion. The IACUC discussed the incident on April 7, 2020 and determined it was necessary to report the event as an animal welfare issue.

Internal funding covered all costs associated with procurement, use, and care of these animals, thus reporting to a federal agency was not required. To ensure future investigator and laboratory actions related to animal health and welfare are conducted in accordance with the approved protocol, the following measures for enhanced oversight were documented and required by the IACUC:

1. Prior to initiating any new experiments, an on-line calendar in which study activities are scheduled at least 24 hours in advance of any procedure must be in place to provide a timeline allowing for appropriate post-approval monitoring and veterinary oversight.
2. Animal weight records must be available at all times for assessment by the IACUC or OLAC. A paper copy of data sheet or access to an online spreadsheet containing these data is acceptable. The data must include the weight of the animal when starting the study, the weight data collected every other day, as specified in the approved protocol, and the percent change in body weight at each weighing interval.
3. An amendment to the protocol must be submitted to clarify diet gel will be offered earlier as mice begin to experience 13-15% loss of starting body weight. The amendment must specify a veterinary consult will be requested at the time diet gel is offered.

Typically, this investigator engages in no more than 4 experiments annually. The IACUC is requiring that the reporting systems described in items 1 and 2 are in place for the duration of the next two experiments. The IACUC will receive periodic updates from the Compliance Coordinator. Upon completion of these experiments, the IACUC will re-assess protocol compliance to determine if continued oversight is required.

The PI agreed to comply with the corrective measures and indicated personnel engaged in animal research would perform all future studies with adherence to the protocol.

The University of Tennessee has a strong commitment to protecting animal welfare in all animal-use research and teaching protocols. The assistance and guidance provided by OLAW to support this effort is appreciated. Please contact Dr. Melinda Hauser, IACUC Director and Chair (email: [mhauser@utk.edu](mailto:mhauser@utk.edu); phone: (b) (6) should you have any questions regarding this final report.

Sincerely yours,

(b) (6)

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

cc: Dr. Melinda Hauser, IACUC Director and Chair  
Dr. Lori Cole, University Attending Veterinarian

(b) (6)

**From:** Morse, Brent (NIH/OD) [E]  
**To:** Thompson, Jim (Jim)  
**Cc:** Hauser, Melinda R; Cole, Lori Scheyd; (b) (6)  
**Subject:** RE: Non-Compliance Self Report - University of Tennessee, Knoxville  
**Date:** Tuesday, April 28, 2020 7:21:00 AM

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Thank you for providing this report Dr. Thompson. We will send an official response soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

**From:** Thompson, Jim (Jim) <jthomp70@utk.edu>  
**Sent:** Monday, April 27, 2020 2:54 PM  
**To:** Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Cc:** Hauser, Melinda R <mhauser@utk.edu>; Cole, Lori Scheyd <lcole21@utk.edu>; (b) (6)  
(b) (6)  
**Subject:** Non-Compliance Self Report - University of Tennessee, Knoxville

Monday, April 27, 2020

Animal Welfare Assurance # D16-00397

Brent Morse, DVM, DACLAM  
Director, Division of Compliance Oversight  
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Sincerely yours,

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