



April 1, 2011

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff:

The Pens Institute, in accordance with Assurance A0101-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident to induce hibernation in ground squirrels, an activity not reviewed and approved by the IACUC in a Principal Investigator's (PI) animal study protocol, entitled "Metabolism of polyphenols in ground squirrels." This incident was first reported to Dr. Brent Morse, OLAW, on February 22, 2011 via a telephone call by Justin Thyme, DVM, DAACLAM, Associate Director, Department of Medical Pharmacology.

On February 2, 2011, the Office of Research Compliance received information that pilot experiments to induce hibernation in ground squirrels were performed without prior IACUC review and approval. Some animals died during this pilot experiment. At the time of the discovery of the incident, the protocol did not describe procedures for inducing and maintaining hibernation. The IACUC discussed the incident and requested corrective actions from the PI.

A review of billing records showed that all direct costs associated with the procurement, care, and use of the squirrels during November 2010 – January 2011 were initially paid from NIH Grant 2R01A10004U-10. These costs have been subsequently removed from this account and invoiced to and paid from a nonfederal source. The NIH funding component was notified of the situation.

To address the situation, corrective actions were taken including the submission of an *Animal Study Protocol Amendment* to request a procedural change describing the induction and maintenance of hibernation in ground squirrels. Approval to procure additional ground squirrels was withheld until the IACUC reviewed and approved the PI's response, the corrective action plan and protocol amendment for the procedural change.

The PI expressed in a letter to the IACUC that this was an unfortunate incident and took responsibility for the noncompliance. The PI assured the IACUC that an incident of such nature would not occur again. The IACUC determined that this was an isolated incident and not a programmatic failure.

The following corrective action plan was implemented after the incident:

1. The PI submitted correspondence to the IACUC, dated February 24, 2011, expressing regret for the noncompliance incident and that exclusion of the hibernation procedure from the protocol was an oversight.
2. The PI described corrective measures that had been implemented to prevent recurrence of an incident of this nature. The measures included informing all research staff of the IACUC's requirement for securing approval for all procedures prior to work involving animals.
3. The PI assured the IACUC that all research staff will from now on carefully review and adhere to approved study protocols.
4. The PI submitted a request for a procedural change (*Animal Study Protocol Amendment*) to the protocol. The amendment describing the procedure to perform a pilot experiment to induce and maintain hibernation in ground squirrels was approved by the IACUC on March 17, 2011.

At their meeting on March 17, 2011, the IACUC also reviewed and accepted the corrective action plan as submitted by the PI.

The Pens Institute is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Imma Daughtson, PhD, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

Stanley Cupperson, PhD
Vice President for Research
Institutional Official
The Pens Institute