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## SETTLEMENT AGREEMENT

### CITATION AND NOTIFICATION OF PENALTY

We believe that you violated the Animal Welfare Act (7 U.S.C. § 2131 et seq.) (AWA), as described below.

#### **Date of Violation: April 17, 2008**

**9 C.F.R. § 2.31(d)(1)(ii)** IACUC: The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals

The written narrative of the methods and sources used to determine that alternatives were not available to the potentially painful or distressful procedures described in the proposal for animal use did not include the procedure of tracheostomy in rabbits that is described in the proposal.

#### **Date of Violation: April 17, 2008**

**9 C.F.R. § 2.33(b)(2)** Attending Veterinarian and Adequate Veterinary Care: Each research facility shall establish and maintain programs of adequate veterinary care that include: (2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries.

Protocol 2007-346 states that each rabbit will undergo approximately 12-14 needle insertions per session. There was no written documentation showing that the needle insertions were performed as described in the approved protocol.

#### **Date of Violation: February 4, 2009**

**9 C.F.R. § 2.31(e)(3)** IACUC: A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following: (3) A complete description of the proposed use of the animals.

You failed to have a complete description of the proposed use of the animals in a protocol, as evidenced by the fact that you used different procedures than those listed in the protocol regarding the method of administration of anesthesia and the interval of weighing rabbits.

#### **Date of Violation: February 4, 2009**

**9 C.F.R. § 2.36(b)(3)** Annual Report: The annual report shall:(3) Assure that the facility is adhering to the standards and regulations under the Act, and that it has required that exceptions



to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions must be attached to the facility's annual report. In addition to identifying the IACUC –approved exceptions, this summary must include a brief explanation of the exceptions, as well as the species and number of animals affected.

The annual report submitted for FY2008 did not include a summary or an explanation of the exception to AWA Standards that had been approved by the IACUC pertaining to the use of a room that is not a dedicated surgical space to perform major survival surgery in non-rodents (specifically cats and rabbits).

**Date of Violation: February 4, 2009**

**9 C.F.R. § 2.33(b)(5)** Attending Veterinarian and Adequate Veterinary Care: (b) Adequate pre-procedural and post-procedural care.

You failed to follow approved protocols regarding weighing the rabbits at the described interval, conditioning the rabbits upon arrival, and observing the animals post-surgery.

**Date of Violation: April 22, 2009**

**9 C.F.R. § 2.32** Personnel Qualifications: (a) ...responsibility of the research facility to ensure that all...personnel involved in animal care...are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.

On April 22, 2009, rabbit #179680 had surgery under general anesthesia, using Protocol #2008-479 and the rabbit died unexpectedly. The IACUC investigation into the death concluded that the laboratory staff was inadequately trained in the proper techniques of animal monitoring during anesthesia, proper use of a pulse oximeter and thermal blanket, and to recognize the need to contact veterinary personnel for advice. The IACUC found that this lack of training contributed to the death of the rabbit.

**Date of Violation: April 28, 2010**

**9 C.F.R. § 2.31(c)(3)** The IACUC, as an agent of the research facility, shall (3) Prepare reports of its evaluations conducted...and submit the reports to the Institutional Official of the research facility. The reports shall be reviewed and signed by a majority of the IACUC members. The reports must distinguish significant deficiencies from minor deficiencies and they must contain a reasonable and specific plan and schedule with dates for correcting each deficiency.

The semi-annual report dated July 30, 2009 that was submitted by the IACUC to the Institutional Official was reviewed and signed by a majority of the IACUC members; however the report was incomplete and did not contain a specific plan and schedule with dates for correcting the minor deficiencies that were identified by the IACUC during the facility inspection.



**Date of Violation: April 28, 2010**

**9 C.F.R. § 2.31(c)(7)** IACUC functions: (7) Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities.

In Protocol #2008-464: The PI used a method to administer general anesthesia on December 9, 2009 that was not included in the IACUC approved protocol. The rabbit died unexpectedly. Neither the IACUC nor the veterinarian was aware of the deviation from protocol until the death of the rabbit was reported.

**Date of Violation: April 28, 2010**

**9 C.F.R. § 2.31(e)(3)** IACUC (e) A proposal to conduct an activity involving animals, or to make a significant change in an ongoing activity involving animals, must contain the following:  
(3) A complete description of the proposed use of the animals.

You failed to have a complete description of the proposed use of the animals in a protocol, as evidenced by the fact that several inconsistencies were noted in Protocol # 2010-616, including the approved method of restraint, the use of anesthesia, scheduling of post procedure x-rays, as well as the body part on which the procedure was to be conducted and the number of animals in the study.

**Date of Violation: April 28, 2010**

**9 C.F.R. § 2.33(b)(5)** Attending veterinarian and adequate veterinary care: (b) Each research facility shall establish and maintain programs of adequate veterinary care that include:(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures.

The PI deviated from the approved methods for inducing general anesthesia under Protocol #2008-464, resulting in the unexpected death of a rabbit on December 9, 2009.

The penalty for the alleged violations described above is \$12,429.