United States Department of Agriculture
Animal and Plant Health Inspection Servic

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INSPECTION REPORT

UNIVERSITY OF WISCONSIN-MADISON
RESEARCH ANIMAL RESOURCES CT

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Customer ID: 616
Certificate: 35-R-0001
Site: 001
ALL CAMPUS SITES
Inspection Type: ROUTINE INSPECTION
Date: JUN-20-2007

2.31 (d)(1)(iv)(A)
2.31 (e)(2)
2.31 (e)(3)
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC).

The regulation states, "(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will:
(A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;..."

***Protocol (b)(4) states animals will be inoculated with a challenge infectious agent and that the disease process will result in some animal morbidity and/or death. A description of affected animals is provided and a scoring system for the deterimination of euthanasia as an endpoint is outlined for moribund animals. No analgesics will be provided. There is no written justification of the scientific reasons for withholding of any analgesic treatment. Written justification for withholding analgesics must be provided or analgesics must be used.

Correct by: prior to inoculation of any additional animals with infectious agents.

The regulation states, "(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:...
(2) A rationale for involving animals, and for the appropriateness of the species and numbers of animals to be used...".

***Protocol (b)(4) justifies animal numbers by stating, "The numbers of animals are based on our current animal need, however the number listed often exceeds the number of animals we find to place on this protocol. We have a maximum number that are available at any one time for this study and also a minimum that are required for the various studies we perform." This is ambiguous and leaves it very unclear as to the rationale behind the number of animals requested. The principal investigator must provide a clear rationale as to the number of animals needed.

***Protocol (b)(4) is also unclear as to the rationale for the number of animals needed. While the principal investigator alludes to USDA or EU animal number requirements for a manufacturer seeking to license a product, it is not clear that licensure is the objective of his proposed activities.

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Date: JUN-20-2007

Titl 1062

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Date: JUN-20-2007

Titl

Correct by: August 31, 2007

The regulation states, "(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..."

***A review of animal records from protocol (b)(4) reveal that a surgical procedure is being conducted (neutering of male cats), but there is no mention nor description of this activity in the approved protocol. The review of nine male cat records indicated that all nine cats had undergone neutering.

Correct by: A full description must be provided and approved by the IACUC prior to any additional surgeries.

***The table provided in Protocol (b)(4) describing the approximate time line does not provide a time line. There is a listed vaccine interval, but it is unclear when vaccination is started. Routes of administration of the challenge agent are listed, but time allowed for immunity to develop prior to challenge is unknown. The prinicipal investigator also notes that "experimental design can vary widely between studies" but the experimental design is not clearly stated and what varies widely is unknown.

Correct by: A full description must be provided and approved by the IACUC prior to any additional animal activities.

***Protocol (b)(4) involving the use of skunks indicates that laboratory personnel will "score" all animals on an "at least weekly" basis for signs of disease. However, there is no documentation that this is occurring. Protocol (b)(4) also involves a scoring process for each sick animal, but from the records reviewed, scoring was very rarely used. There is no documentation that this tracking procedure is being accomplished as stated in the approved protocol.

Correct by: Immediately

***Protocol (b)(4) provides a very broad picture of animal use with very few details provided. The objective is to "better understand the cause or mechanism of spontaneous animal diseases". The description of potential blood collection states, "Blood samples are generally collected at arrival then as required (weekly, monthly) or at most twice weekly. The amount of blood collected is approximately 20 ml for adult cattle, or 10 ml from adult sheep, dogs or cats." Ten mls from a cat twice weekly for an unknown number of weeks is too much and will cause the animal to suffer or die. Humane endpoints are vague, as is treatment for pain. There is mention of the number of animals that will undergo surgery per year, but no explanation of what the surgery involves.

Correct by: A complete description must be provided and approved by the IACUC prior to any animal activities.

2.33 (b)(3)

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2.33 (b)(5)

ATTENDING VETERINARIAN AND ADEQUATE VETERINARY CARE.

The regulation states, "(b)(3) Daily observation of all animals to assess their health and well-being; Provided, however, That daily observation of animals may be accomplished by someone other than the attending veterinarian; and Provided, further, That a mechanism of direct and frequent communication is required so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian..."

***Marked alopecia was noted on the tails of eight skunks. An examination of the animal records showed that this appearance had only been recorded in three of the eight records. Changes in appearance should be noted by care staff as well as research staff and discussed and documented with veterinary staff. Lines of communication are essential to ensure the health and well-being of the animals.

It is the responsibility of the research facility and staff to have a mechanism of direct and frequent communication to ensure problems of animal health and/or behavior are conveyed in a timely manner to the the attending veterinarian. Each research facility is required to establish and maintain programs of adequate veterinary care to maintain the health and well-being of the animals.

Correct by: July 31, 2007

The regulation states, "(b)(5) Adequate pre-procedural and post-procedural care in accordance with current established veterinary medical and nursing procedures."

***A review of animal records from Protocol (b)(4) revealed that post-procedural care described in the protocol are not being followed. Monitoring of affected animals is stated as: 3 to 4 times daily after challenge; more often at times that morbidity is greatest; and, when the animals are showing signs of disease or discomfort, the animals are observed at no longer than 8 hour intervals to ensure the animals are euthanized before they die. The records reviewed show that most monitoring has been once (or in a couple of cases, twice) per day when an animal showed signs of disease. Length of time between monitoring points once an animal has begun to show disease signs has lead to unnecessary animal pain and suffering. Monitoring periods should be clearly specified and followed.

Correct by: Immediately

2.36 (a)

2.36 (b)(7)

ANNUAL REPORT.

The regulation states, "(a) The reporting facility shall be that segment of the research facility, or that department, agency, or instrumentality of the United States, that uses or intends to use live animals in research, tests, experiments, or for teaching. Each reporting facility shall submit an annual report to the AC Regional Director for the State where the facility is located on or before December 1 of each calendar year. The report shall be signed and certified by the CEO or Institutional Official, and shall cover the previous Federal fiscal year."

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Title [redacted]

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JUL

***The 2006 Annual Report must be amended to show the correct numbers of animals. During a review of one principal investigator's animal usage (acquisition records), it was found that he ordered 177 dogs, 41 cats, 6 calves and 2 lambs during the period covered by the 2006 Annual Report. However, this investigator reported only 118 dogs and 41 cats, and no calves or lambs for inclusion on the institution's Annual Report.

Correct by: August 31, 2007

The regulation states, "(7) State the common names and the numbers of animals upon which teaching, experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used shall be attached to the annual report..."

***All animals that were used and in which pain and/or distress was identified and in which no analgesics were given (as with some animals in protocol (b)(4) must be reflected in Column E of the 2006 Annual Report. An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to the amended report.

Correct by: August 31, 2007

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