This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

See reverse side for additional information.

Interagency Report Control No 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NO. 43-R-0009 **CUSTOMER NO.** 1399

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, include Zip Code)*

Midwest Research Institute
425 Volker Blvd
Kansas City, MO 64110
(816) 753-7600

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS *(sites)*

See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use APHIS FORM 7023A)*

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number 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 must be attached to this report)*	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs					
5. Cats	62	58			58
6. Guinea Pigs					
7. Hamsters		1	12	206	219
8. Rabbits					
9. Non-Human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferret		6	12		18

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). **A summary of all the exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143)

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*

b6,b7c

DATE SIGNED 11/21/08

APHIS FORM 7023 **(AUG 91)** (Replaces VS FORM 18-23 (Oct 88), which is obsolete

PART 1 - HEADQUARTERS

NOV 25 2008 ✓

Column E Explanation
Facility Registration Number: 43-R-009

Number of animals used in study: 202 (197 were category E)

Species: Hamsters

Explain the procedure producing pain and/or distress.

Propagation of strain 263K scrapie in hamsters provides reagent material utilized in prion clearance studies for FDA approved human therapeutics. Scrapie strain 263K is accepted as an animal model of human transmissible spongiform encephalopathy and was specifically selected for propagation in hamsters.

To propagate strain 263K hamster scrapie, hamsters were anesthetized and dosed (intracerebral) with 0.050 mL of 263K infected hamster brain homogenate. Once clinical symptoms have been observed twice over a period of at least 3 days (to ensure a high prion titer), then the animal is humanely euthanized and the brain harvested.

Provide scientific justification why pain and/or distress could not be relieved.

Hamster number 91 was found dead November 9, 2007. Clinical signs consistent with prion infection had been observed twice for group 1 (animals 1-101) and group 1 was scheduled for euthanasia/brain harvest the same day hamster #91 was found dead (November 9, 2007). To ensure the scrapie prions reach a high titer in the hamster brains, it is necessary to observe clinical symptoms twice over a 4-10 day period.

The remaining animals were euthanized following two positive observations for clinical prion symptoms. It is necessary for the animals to exhibit clinical signs for more than one day to ensure sufficiently high titers of prion in the brain. Hamsters 1-101 were euthanized November 9 and 12, 2007 and hamsters 102-202 were euthanized November 13, 2007.

Column E Explanation
Facility Registration Number: 43-R-009

Number of animals used in study: 16 (9 were category E)

Species: Hamsters

Explain the procedure producing pain and/or distress.

Propagation of strain 263K scrapie in hamsters provides reagent material utilized in prion clearance studies for FDA approved human therapeutics. Scrapie strain 263K is accepted as an animal model of human transmissible spongiform encephalopathy and was specifically selected for propagation in hamsters.

MRI participated in a study to train employees to recognize clinical scrapie symptoms in hamsters. This training will qualify MRI to run FDA regulated scrapie clearance studies. Hamsters were anesthetized and dosed (intracerebral) with 0.050 mL of 263K infected hamster brain homogenate. Once clinical symptoms have been observed twice over a period of at least 3 days (to ensure a high prion titer), then the animal is humanely euthanized and the brain harvested.

Provide scientific justification why pain and/or distress could not be relieved.

Animals were euthanized following two positive observations for clinical prion symptoms. It is necessary for the animals to exhibit clinical signs for more than one day to ensure sufficiently high titers of prion in the brain. Hamsters 13-16 were euthanized November 30, 2007, hamsters 1-4 were euthanized December 26, 2007, and hamster number 12 was euthanized on January 15, 2008.

Attachment 2

Column E Explanation Form for Regulated Species

This form is intended as an aid to completing the Column E explanation. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

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1. **Registration Number: 43-R-0009**

2. **Number of animals used under Column E conditions in this study. _____**

3. **Species (common name) of animals used in this study. Hamster**

4. **Explain the procedure producing pain and/or distress, including reason(s) for species selected.** ***(from ASP, Section F)***

See attached documents.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.** ***(from ASP, Section F)***

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Information below will NOT be forwarded to USDA as part of the Annual Report

IC_____ ASP Number_____ ASP Title_____

NOV 25 2008