

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)	1. CERTIFICATE NUMBER: 31-R-0028 CUSTOMER NUMBER: 234	FORM APPROVED OMB NO. 0579-0036
Case Western Reserve University 10900 Euclid Ave Cleveland, OH 44106 Telephone: (216) -368-4432		

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, 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 animal 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 reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	19		103		103
5. Cats	4		11		11
6. Guinea Pigs	17	44	344	20	388 ✓
7. Hamsters	70	148	9	12	177 ✓
8. Rabbits	29	28	110		150 ✓
9. Non-human Primates	0				
10. Sheep	0				
11. Pigs	24	78	422		500
12. Other Farm Animals					
13. Other Animals					
Ferret	0		20		20
Woodchuck	0		7		7

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, 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 an Institutional Animal Care and Use Committee (IACUC). A summary of all such 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)

b6, b7c

DATE SIGNED
11/14/08

NOV 17 2008

b6, b7c

42 rabbits entered into this study exhibited severe clinical lameness for 1 week prior to scheduled euthanasia. All were able to feed and maintain body condition during this time.

- 6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number.**
-

- 1. Number of animals used in this study:** 20
- 2. Species (common name) of animals used in this study:** hamster
- 3. Explain the procedure producing pain and/or distress.**

Hamsters are infected with the scrapie prion protein and observed for the development of neurodegenerative disease.

- 4. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine than pain and/or distress would interfere with test results.**

The study requires analysis of brain tissue taken from animals in the terminal stages of spongiform encephalopathy. No palliative treatment is available for spongiform encephalopathy. Animals are checked daily after the onset of symptoms. Animals ultimately lose the ability to move and feed themselves. Criteria for interventional euthanasia of severely ill hamsters have been established. Animals unable to ambulate and/or feed are euthanized.

- 5. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number.**

Column E Explanation

This form is intended as an aid to completing the column E explanation. It is not an official form and its use is voluntary. 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.

1. **Registration number:** 2006-0161
2. **Number of animals used in this study:** 12
3. **Species (common name) of animals used in this study:** rabbit
4. **Explain the procedure producing pain and/or distress.** This study involves creation of a rabbit model of rheumatoid arthritis so that experimental therapies involving modulation of complement expression may be tested. Antigen-Induced Arthritis is a modified Arthus reaction in which immune complexes are deposited in articular collagenous tissues, where they activate complement. Ovalbumin emulsified in Freund's complete adjuvant will be administered in multiple IM and SC sites. A booster immunization will be done using Freund's incomplete antigen.
5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine than pain and/or distress would interfere with test results.** In theory, inflammation due to arthritis in the knee joint may cause the rabbits significant pain. However, given the sedentary lifestyle of the rabbits in the laboratory environment, we do not anticipate that the rabbits will be in significant discomfort. It is considered opinion of both of the veterinarians who have reviewed this protocol that the rabbits will not be in significant discomfort due to arthritis. Consistent with this prediction, none of the published studies that we have reviewed report administering any analgesic or anesthetic to the rabbits to control pain due to arthritis (1-10). Since most anti-inflammatory drugs are going to affect the inflammatory process in some way, and perhaps alter the outcome of this arthritis study, it is preferable to avoid their use unless required to reduce significant discomfort of the animals. We will closely monitor the rabbits in the study for any signs of significant discomfort. This will include daily observations of the rabbit's appetite, water consumption, stool and urine production, activity, general appearance, and response to handling. If contrary to our expectations, we observe any evidence of significant distress or discomfort of the rabbits in the study (e.g., inability to ambulate, prolonged anorexia leading to 15% loss of pre study weight), we will euthanize the animals, terminate the study and submit a revised protocol for review that includes use of a selected analgesic. *Post approval monitoring of the rabbits in this protocol revealed that 12 of the*