

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

1. REGISTRATION NO. 21-R-0119 CUSTOMER NO. 528 FORM APPROVED OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)
Cornell University
ORIA- 395 Pine Tree Rd
Ithaca, NY 14850

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	7	251	77	0	328
5. Cats	0	7	4	0	11
6. Guinea Pigs	0	3	0	0	3
7. Hamsters	635	660	956	54	1670
8. Rabbits	0	36	54	0	90
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	0	11	0	11
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Cows	0	51	0	0	51
13. Other Animals					
Horses	0	139	67	0	206
Donkeys	0	8	0	0	8
Mules	0	5	0	0	5

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)

b6, b7c

DATE SIGNED

11-27-08

PART 1 - HEADQUARTERS

(AUG 91)

(replaces VS FORM 16-23 (Oct 88), which is obsolete)

NP

SUMMARY OF APPROVED EXEMPTIONS FOR USDA COVERED SPECIES
USDA Annual Report 2007-2008

- **Protocol 1989-0031** - Exemption to regular sanitation of nest boxes to decrease disturbance to pregnant and nursing woodchucks.
- **Protocol 1989-0031** allow woodchuck litter to stay with mother for 6 weeks until weaning, may appear overcrowded but should be less stressful for pups.
- **Protocol 2000-0086** - non-Cornell owned cats from the SPCA will be kept overnight in the CPC in CARE-approved cat cages with food, water and litter boxes provided and will be returned to the SPCA when the lab sessions are completed, typically at the end of the second day but, on occasions, on the third day. The cats would be housed in this area for a maximum of 50 hours. This will give the cats a chance to acclimatize to the cages and the housing area and therefore it would be less stressful to them than moving them back to the SPCA right after physical exams are performed. The cats are checked and cleaned four or more times during each day and at least once overnight.
- **Protocol 2007-0027** - non-Cornell owned cats from the SPCA will be kept overnight in the CPC in CARE-approved cat cages with food, water and litter boxes provided and will be returned to the SPCA when the lab sessions are completed, typically at the end of the second day but, on occasions, on the third day. The cats would be housed in this area for a maximum of 50 hours. This will give the cats a chance to acclimatize to the cages and the housing area and therefore it would be less stressful to them than moving them back to the SPCA right after physical exams are performed. The cats are checked and cleaned four or more times during each day and at least once overnight.
- **Protocol 1989-0068** - allow for three survival surgeries and one terminal surgery. The surgeries will be at least one year apart. Following the initial surgery, a CARE veterinarian will examine the dog prior to the survival surgeries. Surgery (embryo removal by hysterotomy) is performed on dogs that are carriers of inherited SRY-negative XX sex reversal. These animals are not available from any other source (commercial or institutional) and must be produced by the PI's breeding colony. Only carriers can produce affected embryos needed for study. Therefore the exemption is requested for carriers, the number of which is limited by progeny testing to prove carrier status, sex-limited inheritance and canine reproduction. Proven carriers are also the source of breeding stock to maintain the model, so not all can be used to produce embryos. Survival surgeries improve the outcome and efficiency of embryo recovery. In rare cases, surgical insemination will be done and will count as one of the survival surgeries.

- **Protocol 2004-0053** - Siberian hamster housing exemption - allow nursing female and males to live in same primary enclosure. Use of standard mouse cages for housing of dwarf hamsters.
- **Protocol 2008-0052** - horses - post op 4 weeks complete stall rest without walking exercise. Thereafter horses will be on increasing walking program. Exemption is required due to the soft and tenuous nature of the cartilage repair implant. In the target species, being man, the joint would be cast or severely braced. PI cannot do that to the horse's stifle, so limited walking is the compromise.

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: 21-R-0119

2. Number 54 of animals used in this study.

3. Species (common name) Golden Hamsters of animals used in the study.

4. Explain the procedure producing pain and/or distress.

We performed recombinant *Leptospira* vaccine trial using hamster model. In order to analyze the protective efficacy of the vaccine, animals were challenged with virulent *Leptospira* strain and monitored three times a day to record the development of any clinical signs of the disease. Animals showing clinical signs were given a score (see attached scoring sheet). Animals with score of 3 and 4 were humanely euthanized immediately. Animals with score of 1 and 2 were monitored every 2-3 hrs during the day time. Animals with score 2 were euthanized if monitoring every 2-3hrs was not feasible (eg. during night). Animals listed in category E include all the animals with score 3 and 4 and those with score 2 if not immediately euthanized.

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. (For Federally mandated testing, see Item 6 below)

As objective of our study was to check the efficacy of recombinant *Leptospira* vaccine, we had to evaluate if vaccinated animals were protected from the occurrence of clinical disease after inoculation with *L. Pomona*. The objective of this study could have not been achieved without the exposure of hamsters to *L.pomona* resulting in clinical disease in some animals (control group).

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 (e.g., APHIS, 9 CFR 113.102):

Agency _____ CFR _____

Clinical Scoring of hamsters on Leptospirosis study:

0: No clinical signs

1: Mild depression, but no other signs

2: Any of these signs- moderate to severe depression, lethargic, hunched posture, ruffled fur, mild to moderate ataxia/incoordination, inability to stand up on rear legs, body shaking or shivering, eyelid closure

3: Any of these signs: severe depression, severe ataxia/incoordination, recumbent

4: Non-responsive to external stimuli

Note:

- Hamster's normal activity level changes over diurnal cycle, so compare study (inoculated) hamster activity level to non-inoculated hamster activity level.
- If animal is arousable but it returns to inactivity in 2-3 minutes \geq moderate depression.
- Animals with score of 3 and 4 should be euthanized as soon as possible.
- Animals with score of 1 and 2 should be monitored every 2-3hrs during the day time. Animals with score of 2 should be euthanized if monitoring every 2-3 hrs is not feasible (for eg. during night, etc.).