

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. CUSTOMER NO.

21 R 0119

528

FORM APPROVED
OMB NO. 0579-0036

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

Cornell University
Ithaca, NY 14853

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	0	187	56	0	243
5. Cats	0	12	6	0	18
6. Guinea Pigs	0	1	0	0	1
7. Hamsters	0	1259	463	38	1760
8. Rabbits	0	23	13	0	36
9. Non-Human Primates	0	0	0	0	0
10. Sheep	0	4	2	0	6
11. Pigs	0	42	2	0	44
12. Other Farm Animals					
COWS	0	231	0	0	231
13. Other Animals					
horses	5	103	118	0	221
donkeys	0	9	0	0	9
hybrid	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)

DATE SIGNED

Nov 25, 09

HEADQUARTERS

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According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 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.

Interagency Report Control
No. 0180-DOA-AN

Fiscal Year: 2009

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL
REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 21-R-0119

Customer Number: 528

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

Cornell University

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary.)

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 on these animals and the reasons such drugs were not used must be attached to this report.)	F. TOTAL NUMBER OF ANIMALS (Cols. C + D + E)
deer	0	126	137	0	263
Mole rats	0	44	0	0	44
woodchucks	0	507	55	0	562
bats	0	6	0	0	6
raccoons	0	0	563	0	563
alpaca	0	2	0	0	2
chinchilla	0	1	0	0	1

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 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 provisions of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL

(b)(6), (b)(7)c

DATE SIGNED

Nov 25, 09

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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. Column W explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number:** 21-R-0119

2. **Number of animals used in this study:** 7

3. **Species (common name) of animals used in the study:** Golden hamsters

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

Seven golden hamsters had either unilateral or bilateral ovariectomies performed by undergraduate students under the supervision of the PI. The protocol stated that the animals were to receive buprenorphine every 12 hours for 48 hours post operatively. These hamsters were placed in Category D on the originally protocol.

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.**

All seven hamsters that had surgery received one dose of butorphanol post operatively; no further analgesia was administered. Five of the animals that had ovariectomies recovered without complication however none had received appropriate post operative analgesia. These 5 animals were retrospectively placed in category E. One animal died after the surgery; it had been placed on a heating pad post operatively and the PI suspected it had become hyperthermic. This hamster was also placed retrospectively in Category E. Another hamster was placed retrospectively in Category E because it was euthanized post operatively when the veterinary staff discovered the animal dehydrated and with a non-weight bearing forelimb lameness making it unable to access food and water.

Immediate corrective actions were taken. Additionally these issues were reported to the IACUC, OLAW and AAALAC.

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, 9CFR 113.02)**

None

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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. Column W explanation must be written so as to be understood by lay persons as well as scientists.

1. **Registration Number:** 21-R-0119

2. **Number of animals used in this study:** 31

3. **Species (common name) of animals used in the study:** Golden hamsters

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

The lab performs recombinant *Leptospira* vaccine trials using the hamster model. In order to analyze the protective efficacy of the vaccine, animals are challenged with a virulent *Leptospira* strain and monitored three times a day to record the development of any clinical signs of the disease. Animals showing clinical signs are given a score (see attached scoring sheet). Animals with scores of 3 and 4 are humanely euthanized immediately. Animals with a score of 1 and 2 are monitored every 2-3 hrs during the day time. Animals with a score of 2 are euthanized if monitoring every 2-3 hrs is not feasible (e.g. during night). Animals listed in category E include all the animals found dead 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.**

As the objective of the study is to determine the efficacy of recombinant *Leptospira* vaccine, the lab has to evaluate if vaccinated animals are protected from the occurrence of clinical disease after inoculation with *L. pomona*. The objective of this study cannot be achieved without the exposure of hamsters to *L. pomona* resulting in clinical disease in some animals (control group). Though monitoring frequency is three times daily, some hamsters do progress rapidly with symptoms of the infection, and hence may be found dead.

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, 9CFR 113.02)**

None

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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.).

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SUMMARY OF APPROVED EXEMPTIONS FOR USDA COVERED SPECIES
USDA Annual Report 2008-2009

- **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 2007-0027** - non-Cornell owned cats- from the SPCA will be kept overnight in the CPC in IACUC-approved cat cages with food, water and litter boxes provided and will be returned to the SPCA, typically at the end of the second day but, on occasions, on the third day, for a maximum of 72 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 and restraint procedures are performed. The cats are checked and cared for multiple times during each day and at least once overnight.
- **Protocol 1989-0068** – Dogs- allow for three survival surgeries and one terminal surgery on dogs. 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 hysterectomy) 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 2008-005 and 2008-0168** – 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.
- **Protocol 2008-0139** – Naked Mole Rats – this is an exotic species which requires special care, housing and husbandry. Exemption is made to mimic the conditions in which they live in Kenya. They never live alone and never come above ground. Their burrows are dark, warm and humid. This means housing colonies together in plexiglas tunnel systems, placing a heating pad under the nest box, cleaning toilets daily but tunnels infrequently (every 3-4 weeks) to minimize disturbance including handling, maintaining colony rooms at warm temperatures, and in silence and near darkness, and feeding a variety of fresh vegetables and fruits daily.

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www.oria.cornell.edu

Nov 25, 2009

Dr. Elizabeth Goldentyer
Eastern Regional Office
920 Main Campus Drive
Suite 200, Unit 3040
Raleigh, NC 27606-5213

Registration Number: 21-R-0119/Customer No. 528

Dear Dr. Goldentyer,

To comply with the requirements for the annual report, Cornell gives assurance to the USDA that professionally acceptable standards governing the care, treatment and use of animals were followed by the research facility, namely Cornell University.

Each Principal Investigator is required to consider alternatives to painful procedures. The initial reviewer of each protocol submitted, namely a CARE Veterinarian, as well as the IACUC members, are required to ensure that this consideration has been carefully and thoroughly made when the protocol is reviewed at our monthly meetings.

Cornell assures the USDA 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. Any exceptions to the USDA standards are reviewed by the IACUC every six months. A summary of the approved exceptions involving USDA covered species is enclosed.

Please note that the animal census report incorporates the recent interpretation provided by the USDA regarding the use of client owned animals for teaching and biomedical research.

If you have any questions, please contact

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Sincerely,

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Encl: USDA Annual report 2008-09