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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

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 14-R-0021

Customer Number: 118

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

Northeastern University  
(b)(2)High, (b)(7)f  
360 Huntington Ave  
Boston, MA 02115

Telephone: (617) 373 3958

NOV 30 2009

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

Northeastern University (Address Above)

(b)(2)High, (b)(7)f

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 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)
4. Dogs					
5. Cats					
6. Guinea Pigs					
7. Hamsters		998	411	54	1443
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferret		2			2

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  
(Chief Executive Officer (C.E.O.) or Legally Responsible Institutional Official (L.O.))  
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

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

DATE SIGNED

11/25/09

36 12-4-09

## Column E Explanation

NOV 30 2009

1. Registration Number: 14-R-0021
2. There were 132 animals used in this study
3. Hamsters were used in this study
4. Explain the procedure producing pain and/or distress.

Syrian hamsters will be infected with *Clostridium difficile* and treated with new drugs with the goal of eradicating the infection. The drugs used in these efficacy studies will have already been tested in vitro and in vivo test for efficacy and acute toxicity. Thus, the drugs are expected to have a very good therapeutic index. Disease symptoms included watery diarrhea, hunched posture, lethargy, weight loss, distended abdomen and wet tail (proliferative ileitis). Following inoculation, hamsters will be monitored for signs of disease until animals appear to be in a moribund state, at which point will be euthanized, or have recovered from the drug therapy.

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).

The specific objectives of this project are to test the efficacy of new drugs for the treatment of *Clostridium difficile* infection. The Syrian hamster is exquisitely sensitive to *C. difficile* infection and disease progression is similar to the most severe disease progression in humans, with eventual development of pseudomembranous colitis. For this reason hamsters need to be infected without any additional therapeutic intervention in order to assess the drug efficacy accurately. Criteria used to determine if the animals are in a moribund state include: loss of 20% of their starting weight, inactivity, diarrhea and poor fur coat.

When the animals meet these four criteria, they will be euthanized by CO<sub>2</sub> asphyxia followed by thoracotomy as a physical method of euthanasia.

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):

N/A

NOV 18 2009