

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO. 14-R-0035

#130

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)  
University of MA Medical Center  
55 Lake Avenue North  
P.O. Box 9110  
Worcester, MA 01655  
Status: Active

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)

Same as Above

Jamica Plain Campus ,305 South Street Jamaica Plain, Ma 02130

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	0	12	0	12
5. Cats	0	0	0	0	0
6. Guinea Pigs	25	267	87	470	824
7. Hamsters	121	210	370	182	762
8. Rabbits	92	241	105	0	346
9. Non-human Primates	0	0	9	0	9
10. Sheep	4	0	18	0	18
11. Pigs	7	0	296	0	296
12. Other Farm Animals					
13. Other Animals					
Chickens	0	0	120	0	120
Toads/frogs	222	262	34	0	296
Opossum	0	0	3	0	3

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

CERTIFICATION BY HEADQUARTES 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)

SIGNATURE OF \_\_\_\_\_

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

(b)(6) + (b)(7)(C)

DATE SIGNED

1/23/99

which is obsolete )

(b)(6) + (b)(7)(C)

PART 1 - HEADQUARTERS

14R0035

## Optional Column E Explanation Form

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: 14-R-0035
2. Number 470 of animals used in this study.
3. Species (common name) guinea pigs of animals used in this study.

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

The challenge of vaccinated animals with unattenuated toxins of tetanus, diphtheria and pertussin to prove that vaccinations are effective. The challenge procedure necessarily results in the death of a positive control and higher dose groups. The use of other agents during this critical period of assessments might alter animal responses, thereby obscuring the true end-point, and in turn, might falsely affect the final determination of vaccine potency. The criteria for the tests are requirements of the U.S. Food and Drug Administration for establishing the safety and efficacy of vaccines prior to release for therapeutic use in humans.

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 question 6 below)

Federally-mandated Testing

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 FDA CFR 21 CFR 620.1-620.4

°FR Doc. 79-11451

°FDA Docket No. 78D-0438

°Minimum requirements, Division of  
Biologics Standards, NIH, 8/25/53;  
4th Revisions 3/1/47 and 12/15/52;  
Amendment No. 1, 11/28/56

TOTAL P.02