

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 Exp.: 10/31/2018
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
UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE		1. REGISTRATION NUMBER 42-F-0008
ANNUAL REPORT OF RESEARCH FACILITY (TYPE OR PRINT)		2. HEADQUARTERS RESEARCH FACILITY (Name, address, and telephone number as registered with USDA, include ZIP Code) CVB VS APHIS USDA PO Box 844 AMES, IA 50010
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)

--	--

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	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	352	174	57	583
7. Hamsters	0	2213	91	700	3004
8. Rabbits	0	0	41	0	41
9. Non-human Primates	0	0	0	0	0
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals	0	3	0	0	3
13. Other Animals					

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 (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

	DATE SIGNED 01-FEB-2018
--	-----------------------------------

NP 1/8/18

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 a lay persons as well as scientists.

1. Registration Number: 42-F-0008
2. Number 218 (57 in Cat E) _____ of animals in this study.
3. Species (common name) Guinea Pigs _____ of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Potency testing of tetanus toxoids and antitoxins - an animal getting insufficient protection from the tetanus antitoxin becomes sick from tetanus toxin challenge.

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)

Pain relieving drugs cannot be used because they will interfere with the interpretation of the test. However, in accordance with 9CFR 117.4 and CVB Notice 12-12, animals that are observed in a moribund state will be euthanized after consultation with the contact person and counted as dead. Disease progression could be rapid and animals may not be observed in this state. Observation frequency will increase once clinical signs are noted.

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):

APHIS, 9CFR 113.114 and 113.451

FY2017

01 DEC 2017

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 a lay persons as well as scientists.

1. Registration Number: 42-F-0008
2. Number: 3004 (700 in Cat. E) of animals in this study.
3. Species (common name) –Hamsters- of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Evaluation of Leptospira Bacterins and maintenance of challenge cultures cause animals to experience Leptospirosis.

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)

Drugs may affect the progression of clinical disease. The Leptospira potency tests mandated by the 9CFR use death as an endpoint; however, in accordance with 9 CFR 117.4 and CVB Notice 12-12, hamsters that are observed in a moribund state will be euthanized after consultation with the contact person and counted as dead. Disease progression may be rapid and animals may not be observed in this state.

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):

APHIS, 9CFR 113.101, 113.102, 113.103, and 113.104 which are all Leptospirosis tests.

FY 2017

01 DEC 2017