**OMB APPROVED**
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2022

# UNITED STATES DEPARTMENT OF AGRICULTURE
# ANIMAL AND PLANT HEALTH INSPECTION SERVICE

## Annual Report of Research Facility
## Column E Explanation

*(TYPE OR PRINT)*

**This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.**

**1. REGISTRATION NUMBER**

42-F-0008

**2. Research Facility Headquarters address**

P.O. Box 844
Ames, IA 50010

**3. Number of animals used in the study.**

173 (6 in Cat. E)

**4. Species (common name) of animals used in the study.**

Guinea Pigs

**5. Explain the procedure producing pain and distress.**

Potency testing of tetanus toxoids and antitoxins - an animal getting insufficient protection from the tetanus antitoxin becomes sick from tetanus toxin challenge. Guinea pigs are injected subcutaneously in the ventrolateral abdominal area with toxin-antitoxin mixture. Clinical signs progress from tight back end, to curvature of the back, pronounced curvature and hopping, extensor muscle paralysis and finally inability to rise.

**6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.**

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.

**7. 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):**

9CFR 113.114 & 113.451

| **Agency** | **CFR** |
|---|---|
| APHIS | 9 CFR 113.114 & 113.451 |

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93 (36 in Cat. E)

**4. Species (common name) of animals used in the study.**

Guinea Pigs

**5. Explain the procedure producing pain and distress.**

Guinea pigs are challenged intramuscularly with a suspension of Clostridium chauvoei, C. haemolyticum, or C. septicum. Animals become ill from challenge with these organisms. Clinical signs include swelling or focal lesion at the injection site.

**6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.**

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, if guinea pigs observed in a moribund state, they will be euthanized after consultation with the contact person and counted as dead. Disease progression could be rapid and animals may not be observed during this state.

**7. 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):**

9CFR 113.106 & 113.107

| **Agency** | **CFR** |
|---|---|
| APHIS | 9 CFR 113.106 & 113.107 |

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404 (174 in Cat. E)

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Hamster

**5. Explain the procedure producing pain and distress.**

Evaluation of Leptospira Bacterins and maintenance of challenge cultures cause animals to experience Leptospirosis. Hamsters inoculated intraperitoneally, intramuscularly, or subcutaneously with leptospira can develop outward clinical signs (observable hemorrhage, ruffled hair coat, weight loss, lethargy, and isolation).

**6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.**

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.

**7. 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):**

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

| **Agency** | **CFR** |
|---|---|
| APHIS | 9 CFR 113.101-104 |

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13(4 in Cat. E)

**4. Species (common name) of animals used in the study.**

Rabbit

**5. Explain the procedure producing pain and distress.**

Rabbits are injected intramuscularly (IM) in the large muscles of the hind leg with a suspension of Clostridium chauvoei, C. haemolyticum, or C. septicum. Clinical signs include swelling or focal lesion at the injection site. Disease progression towards death is often rapid. The non-vaccinated control animals usually die in less than 24 hours before clinical signs of disease are expressed and observed.

**6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.**

These tests are based on death as the endpoint falling within a specified time. Drugs cannot be used without validation for specific vaccine products because they may delay death and/or cause erroneous results. To comply with the requirements of the 9CFR and manufacturers' outlines of production no drugs may be given without validation data for that product. 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.

**7. 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):**

9CFR 113.5 using manufacturers' Outlines of Production

| **Agency** | **CFR** |
|---|---|
| APHIS | 9 CFR 113.5 |