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
32-R-0016

2. Research Facility Headquarters address
UNIVERSITY OF NOTRE DAME
GRAD STUDIES & RSCH, 511 MAIN BUILDING
NOTRE DAME, IN 46556

3. Number of animals used in the study.
Total: 103
Category E: 20

4. Species (common name) of animals used in the study.
Hamsters (Golden Syrian)

5. Explain the procedure producing pain and distress.

Hamsters will be given a single subcutaneous dose of clindamycin at 10 mg/kg one day (24 hr) prior to infection (day -1). C. difficile spores in 0.5 mL sterile saline will be given on day 0 by oral gavage. Treatment with the analogs will start 2 hr after infection. The compounds will be given orally once a day at 3 dose levels for 5 days. Animals will be monitored for survival and stools will be tested for colony counts and toxins. Oral vancomycin (once a day, 25-50 mg/kg) will be used as positive control; vehicle (5% DMSO/water) will be used as negative control. The hamster CDI model is lethal with all infected control animals dying in 2-3 days. Vancomycin treated hamsters start dying 14-21 days after infection, depending on the dose. We will monitor the animals for survival up to 35 days after infection. Feces will be collected at several time points (5-6 time points during the course of the study) and analyzed for spore counts and toxins.

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.

Infected hamsters will develop severe enterocolitis and diarrhea. This parallels the human disease. Survival and death are endpoints, as well as spore count and toxin production. Animals will not be given analgesia because this will interfere with results of the study. Analgesics may actually hasten death due to lowering blood pressure and having a sedative effect.

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):

None

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3. Number of animals used in the study.
Total: 454
Category E: 9

4. Species (common name) of animals used in the study.
Northern Short-tailed Shrew, Southern Flying Squirrel, Deer Mouse, Masked Shrew

5. Explain the procedure producing pain and distress.

The traps used are Sherman traps of different sizes, designed for small mammals of different sizes (shrew, mouse, squirrel). These traps are standard for studies of wild populations of small mammals, and are designed to reduce the stress of capture and confinement. Traps are provisioned with a mixture of sunflower seeds, millet, and dried mealworms to decrease stress during confinement. Our trapping procedures are based upon the the recommendations of trapping guidelines published by the American Society of Mammalogists, and all precautions are taken to avoid unintentional deaths.

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Total: 548
Category E: 30

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5. Explain the procedure producing pain and distress.

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Category E: 30

4. Species (common name) of animals used in the study.
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5. Explain the procedure producing pain and distress.

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