OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: FY21

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

51- R- 0018

2. Research Facility Headquarters address

University of Maryland, Baltimore
10S Pine Street, MSTF Building, room G100
Baltimore, MD 21201

3. Number of animals used in the study.

20

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

Hamster

5. Explain the procedure producing pain and distress.

Subsequent to testing efficacy of vaccine candidates in mice, hamsters (the gold standard for Clostridium difficile infection (CDI)) will be used to evaluate vaccine candidates in an effort to develop human therapies for the leading cause of nosocomial antibiotic-associated diarrhea and the etiologic agent of pseudomembranous colitis.

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.

This protocol will evaluate the efficacy of immune based interventions (vaccine and antibody therapies) against CDI. CDI in hamsters is fulminant and almost always rapidly fatal unless treated. Only new therapeutics that show excellent results in mice will be tested in hamsters. Analgesics cannot be used in this work because they mask clinical signs of disease and alter behavior. Clinical signs such as lethargy, depression and hunched posture are critical for determining severity of disease and alternative endpoints and it will satisfy the need for pre-clinical safety and efficacy data prior to conducting clinical trials in humans.

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):

Agency	CFR

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38

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

Swine

5. Explain the procedure producing pain and distress.

Animals may experience unrelieved pain and/or distress as a result of major morbidity/mortality due to acute radiation sickness. Steps will be taken to minimize pain and/distress among animals including administration of analgesics for pain and humane euthanasia when animals meet the criteria for euthanasia due to major morbidity or upon Veterinary recommendation due to unrelieved pain and/or distress.

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.

Buprenorphine (0.01-0.05mg/kg) will be administered subcutaneously starting one day prior to irradiation and thereafter 2 times daily every 8-12 hours. If breakthrough pain is noted, buprenorphine may be administered up to 3 times daily (TID) every 8-10 hours. Per previous studies, animals respond well to buprenorphine every 8-12 hours will an increase in dose given, if breakthrough pain is observed.

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):

Agency FDA

CFR CFR Title 21 part 58

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27

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

Ferret

5. Explain the procedure producing pain and distress.

Exposing animals to blast in the absence of anesthesia to accurately model what occurs during actual battlefield events may cause momentary unrelieved distress before CCI surgery. Animals will be anesthetized and taking to CCI surgery immediately after the blast injury.

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.

Animals will receive buprenorphine (0.1-0.5 mg kg) every 8-12 h for 3 days after the poly trauma (blast + CCI).

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):

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121

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

Guinea pig

5. Explain the procedure producing pain and distress.

Animals will be exposed to supra-lethal doses of chlorpyrifos, which could cause signs of acute toxicity including profuse secretions, respiratory distress, and convulsions. The conventional antidotal therapy will consist of a muscarinic receptor antagonist (atropine or trihexyphenidyl) and the cholinesterase reactivator pralidoxime (also known as 2-PAM).

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.

Unfortunately, this experimental scenario is necessary for the identification of an antidotal therapy that effectively and safely reduces the maternal and fetal toxicity of OP insecticides and improves survival. Animals will be euthanized as soon as signs of acute toxicity become life-threatening,

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):

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