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0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: FY20

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.

3

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

Nonhuman primate

5. Explain the procedure producing pain and distress.

Some animals may experience pain and/or distress as a sequela to 5% bone-marrow-sparing total body irradiation.

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.

Analgesics (buprenorphine) will be administered when signs of potential pain are observed at any time throughout the study.

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

Sheep

5. Explain the procedure producing pain and distress.

An artificial lung will be implanted onto the animal. Animals will be restrained in a in a modified metabolic stanchion for 10 days after surgical procedure, during which time it may be difficult for the animal to perform species-specific behavior.

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.

Analgesics, including flunixin meglumine and fentanyl, will be used. Prolonged restraint is necessary to minimize the possibility of dislodgement of cannulae, incisional dehiscence, pneumo-/hemothorax during the recovery period.

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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3. Number of animals used in the study.

22

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

Rabbit

5. Explain the procedure producing pain and distress.

Potentially painful and/or distressful procedures include hemorrhagic shock and trauma. No supportive care will be given after the surgery other than analgesic.

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.

Analgesics (buprenorphine, meloxicam or carprofen), and local anesthetics (marcaine) are administered after major surgeries.

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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3. Number of animals used in the study.

80

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

Guinea pig

5. Explain the procedure producing pain and distress.

Animals will be exposed (via oral administration) to lethal doses of chlorpyrifos, which could cause signs of acute toxicity including profuse secretions, respiratory distress, and convulsions. These experiments are necessary to study potential treatments for people who may suffer from the effects of organophosphate intoxicants used as chemical weapons.

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 that receive supra-lethal doses will receive atropine (standard treatment for organophosphate toxicity) or experimental treatments, but may still experience acute signs of toxicity that may be 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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18

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.

Animals that receive supra-lethal doses will receive of a muscarinic receptor antagonist (atropine or trihexyphenidyl) and the cholinesterase reactivator pralidoxime (also known as 2-PAM but may still experience acute signs of toxicity that may be life-threatening. 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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3

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):

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3. Number of animals used in the study.

42

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 due to acute radiation sickness.

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):

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3. Number of animals used in the study.

41

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

Ferret

5. Explain the procedure producing pain and distress.

Potentially painful and/or distressful procedures include in vivo electrophysiology and in vivo calcium imaging. Animals are restrained ("point restraint") at the head to a stereotaxic frame. Animals undergo multiple major survival surgeries.

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.

Analgesics (buprenorphine and carprofen), and local anesthetics (marcaine) are administered after major surgeries.

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

Rabbit

5. Explain the procedure producing pain and distress.

Potentially painful and/or distressful procedures include acute radiation syndrome include myelosuppression, multiorgan dysfunction and/or failure that may result in animal pain 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.

Analgesics (buprenorphine) will be administered when signs of potential pain are observed at any time throughout the study.

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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