OMB APPROVED
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Interagency Report Control No. 0180-DOA-AN

Fiscal year: FY2021

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

21-G-0002

2. Research Facility Headquarters address

Plum Island Animal Disease Center
Foreign Animal Diseases Research Unit
PO Box 848
Greenport, NY 11944

3. Number of animals used in the study.

69

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

Swine

5. Explain the procedure producing pain and distress.

Varying degree of pain and/or distress may occur when reproducing diseases (Foot and Mouth Disease [FMD], African Swine Fever [ASF], Classical Swine Fever [CSF], Vesicular Stomatitis) in experimental animals during vaccine trials and studies on immune response and pathogenesis. To evaluate the efficacy and potency of a new vaccine or bio therapeutic candidate, research requires challenge of the animals with these diseases is required.

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.

All animals are anesthetized prior to painful procedures. To evaluate the virulence of attenuated virus variants and the safety and efficacy of the various vaccine candidates that will be tested, it is necessary to determine if any clinical signs occur upon inoculation with live-attenuated viruses and if the vaccine/antiviral candidates are able to protect pigs after challenge with virulent virus. Treatment with opioid and NSAID analgesics is withheld because they would interfere with evaluation of study results and integrity of experimental data since it could interfere with disease onset and progression. However, all animals are closely monitored for treatment once the disease has developed and clinical scoring sheets have been developed to determine objective humane endpoints according to the approved protocols. The attending veterinarian has full authority to treat or euthanize experimental animals should pain and distress occur. The PIADC attending veterinarian and IACUC strive to reduce pain to the lowest level possible and still meet the critical scientific needs.

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):

N/A

Agency	CFR

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

Cattle

5. Explain the procedure producing pain and distress.

Varying degree of pain and/or distress may occur when reproducing diseases (Foot and Mouth Disease [FMD]) in experimental animals during vaccine trials and studies on immune response and pathogenesis. To evaluate the efficacy and potency of a new vaccine or bio therapeutic candidate, research requires challenge of the animals with these diseases is required.

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.

All animals are anesthetized prior to painful procedures. To evaluate the virulence of attenuated virus variants and the safety and efficacy of the various vaccine candidates that will be tested, it is necessary to determine if any clinical signs occur upon inoculation with live-attenuated viruses and if the vaccine/antiviral candidates are able to protect cattle after challenge with virulent virus. Treatment with opioid and NSAID analgesics is withheld because it would interfere with evaluation of study results and integrity of experimental data since it could interfere with disease onset and progression. However, all animals are closely monitored once the disease has developed and clinical scoring sheets have been developed to determine objective humane endpoints according to the approved protocols. The attending veterinarian has full authority to treat or euthanize experimental animals should pain and distress occur. The PIADC attending veterinarian and IACUC strive to reduce pain to the lowest level possible and still meet the critical scientific needs.

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Agency	CFR