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| According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.   |   | <b>OMB APPROVED</b><br>0579-0036                               |
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|   |   | Interagency Report Control No. 0180-DOA-AN<br><br>Fiscal year: |
| <b>UNITED STATES DEPARTMENT OF AGRICULTURE</b><br><b>ANIMAL AND PLANT HEALTH INSPECTION SERVICE</b><br><br><b>Annual Report of Research Facility</b><br><b>Column E Explanation</b><br>(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.  |   |  |
| <b>1. REGISTRATION NUMBER</b><br><br>21-G-0002  | <b>2. Research Facility Headquarters address</b><br>Plum Island Animal Disease Center<br>Foreign Animal Diseases Research Unit<br>PO Box 848<br>Greenport, NY 11944 |  |
| <b>3. Number of animals used in the study.</b><br><br>24  | <b>4. Species (common name) of animals used in the study.</b><br>Mice   |  |
| <b>5. Explain the procedure producing pain and distress.</b><br><br>Varying degree of pain and/or distress are caused when reproducing diseases (Foot and Mouth Disease [FMD]) in experimental animals during virulence studies, vaccine trials and studies on immune response and pathogenesis. To evaluate virulence of attenuated virus variants and the efficacy and potency of a new vaccine or bio therapeutic candidate, challenge of the animals (mice) with these with FMD virus (FMDV) is required.   |   |  |
| <b>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.</b><br>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 mice 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 several times a day for humane endpoints according to the approved protocol. 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. |   |  |
| <b>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):</b><br><br>N/A  |   |  |
| <b>Agency</b>   | <b>CFR</b>  |  |



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| <b>3. Number of animals used in the study.</b><br><br>24  | <b>4. Species (common name) of animals used in the study.</b><br>Cattle   |  |
| <b>5. Explain the procedure producing pain and distress.</b><br><br>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   |   |  |
| <b>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.</b> 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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| <b>3. Number of animals used in the study.</b><br><br>151   | <b>4. Species (common name) of animals used in the study.</b><br>Pigs   |  |
| <b>5. Explain the procedure producing pain and distress.</b><br><br>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.  |   |  |
| <b>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.</b> 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. |   |  |
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