Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 21-G-0002

2. Number of animals used in this study: 36

3. Species (common name) of animals used in the study: Pigs

4. Explain the procedure producing pain and/or distress.

   Pain and distress are caused when reproducing diseases (FMD, ASF, CSF, VSV) in experimental animals during vaccine trials and studies on immune response and pathogenesis. To evaluate the efficacy and potency of a new vaccine or biotherapeutic candidate, research requires challenge of the animals with these diseases.

   Less than 50% of swine are inoculated with FMD or VSV and may experience fever, lameness and lethargy, oral and or pedal vesicular lesions.

   More than 50% of swine are inoculated with ASF or CSF and may experience fever, weight loss, lethargy, diarrhea, hemorrhages, neurological dysfunction, skin and or mucosal discoloration.

5. Attach or include an explanation with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below)

   All animals are anesthetized prior to painful procedures. To evaluate 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 swine after challenge with virulent virus. Treatment with opioid and NSAID analgesics would interfere with evaluation of study results and integrity of experimental data. Therefore analgesics can only be used once study objectives have been met. All animals are closely monitored for treatment and humane endpoints. The attending veterinarian has full authority to treat or euthanize experimental animals should severe 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.

6. 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

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 21-G-0002

2. Number of animals used in this study: 42

3. Species (common name) of animals used in the study: Mice

4. Explain the procedure producing pain and/or distress.

   Pain and distress are caused when reproducing 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 biotherapeutic candidate, research requires challenge of the animals with these diseases.

   All mice inoculated with FMD may experience fever, lameness and lethargy, and neurological signs including ataxia in the hind limbs.

5. Attach or include an explanation with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below)

   All animals are anesthetized prior to painful procedures. To evaluate 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 they would interfere with evaluation of study results and integrity of experimental data. All animals are closely monitored for humane endpoints. The attending veterinarian has full authority to euthanize experimental animals should severe 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.

6. 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