

## Column E Explanation

This form's intention is an aid to completing the Column E explanation. It is not an official form and use is voluntary. Names, address, protocols, veterinary care programs, and the like are not required as part of an explanation. Laypersons as well as scientists must understand the written Column E explanation.

1. Registration Number: 21-G-0002
2. Number of animals used in study: 28
3. Species (common name) of animals used in study: Cow
4. Explain the procedure producing pain and /or distress.

Pain and distress are caused by 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.

All cows inoculated with FMD may experience fever, salivation due to oral vesicles, lameness due to coronary band vesicles, and lethargy.

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

Painful procedures performed upon previously anesthetized animals. To evaluate the safety and efficacy of the various vaccine candidates 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 cows after challenge with virulent virus. Treatment with opioid and / or Non-Steroidal Anti-inflammatory Drugs (NSAIDs) analgesics withheld because they would interfere with evaluation of study results and integrity of experimental data, in the opinion of the investigator. 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, 9CFR 113.102):

N/A

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1. Registration Number: 21-G-0002
2. Number of animals used in study: 72
3. Species (common name) of animals used in study: Mice
4. Explain the procedure producing pain and /or distress.

Pain and distress are caused when reproducing diseases (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.

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

5. Attached or included an explanation with the reason(s) for why anesthetics, analgesics and tranquilizers 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 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.

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1. Registration Number: 21-G-0002
2. Number of animals used in study: 248
3. Species (common name) of animals used in study: Pig
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 bio therapeutic 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, weight loss, lethargy, diarrhea, hemorrhages, neurological dysfunction, skin and or mucosal discoloration.

5. Attached or included an explanation with the reason(s) for why anesthetics, analgesics and tranquilizers 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 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, 9CFR 113.102):

N/A