Column E Explanation

1. Registration Number
    a. 51-F-0024
2. Number of animals used in this study.
    a. Column E = 24
3. Species of animals used in this study
    a. Guinea Pig
4. Explain procedure producing pain and/or distress.
    a. Guinea pigs will be inoculated with a mixture of Diphtheria Toxin (one concentration) and Diphtheria Antitoxin (four concentrations) in order to measure the amount of neutralization conferred by the antitoxin. Guinea pigs inoculated with lower amounts of antitoxin in the Toxin/Antitoxin mixtures will begin to display signs of Diphtheria Toxin related toxicity between 24-96 hours post inoculation.
5. Attach or include an explanation with the reason/s for why anesthetics, analgesics and tranquilizers could not be used.
    a. The onset of symptoms related to Diphtheria Toxin toxicity is used to determine the potency of the antitoxin. As such, anesthetics, analgesics and tranquilizers cannot be used as they might mask the onset of the clinical symptoms thereby rendering the assay useless.
6. What, if any, federal regulations require this procedure?
    a. FDA/NIH Minimum Requirements for Diphtheria Antitoxin and Diphtheria Toxoid.

Column E Explanation

1. Registration Number
    a. 51-F-0024
2. Number of animals used in this study.
    a. Column E = 109
3. Species of animals used in this study
    a. Hamster
4. Explain procedure producing pain and/or distress.
    a. This study involves infection of animals with the SARS-CoV-2. Infected hamsters are expected to develop varying degrees of illness, weight loss, and respiratory symptom. Young healthy hamsters make a full recovery following infection within approximately one week.
5. Attach or include an explanation with the reason/s for why anesthetics, analgesics and tranquilizers could not be used.
    a. This study involves infectious disease research that requires continuation after clinical signs are evident without the use of analgesia. The use of analgesic or anti-inflammatory drugs would complicate evaluation of therapeutic interventions or prevention strategies.
6. What, if any, federal regulations require this procedure?
    a. N/A

Column E Explanation

1. Registration Number
    a. 51-F-0024
2. Number of animals used in this study.
    a. Column E = 1
3. Species of animals used in this study
    a. Ferret
4. Explain procedure producing pain and/or distress.
    a. The highly pathogenic avian influenza (HPAI) virus will be used as a positive control to compare pathogenicity with modified influenza viruses. Animals in the control group, infected with HPAI virus, may develop severe illness due to virus replication and inflammation in organs including lung tissue.
5. Attach or include an explanation with the reason/s for why anesthetics, analgesics and tranquilizers could not be used.
    a. Anesthetics and analgesics are not palliative for all symptoms of flu and affect the immune system which could negatively alter the outcomes of studies.
6. What, if any, federal regulations require this procedure?
    a. N/A