Column E Explanation

1. Registration Number
    a. 51-F-0024
2. Number of animals used in this study.
    a. Column E = 7
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

Column E Explanation

1. Registration Number
    a. 51-F-0024
2. Number of animals used in this study.
    a. Column E = 36
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 = 8
3. Species of animals used in this study
    a. Hamster
4. Explain procedure producing pain and/or distress.
    a. Hamsters are injected with infectious L. donovani, which can cause swelling of the liver and spleen, lethargy, and an increase in visceral parasite burden. Before the animals exhibit severe discomfort, they will be euthanized. The mortality rate due to parasite infection varies with the virulence of the strain injected. The live attenuated strains to be developed as part of this study are not expected to cause disease or to be fatal.
5. Attach or include an explanation with the reason/s for why anesthetics, analgesics and tranquilizers could not be used.
    a. The use of drugs and analgesia would not be effective and would complicate interpretation of the results. The experiments endpoints are based on years of experience with this model and need for the animals to develop advance disease to see if the experimental vaccine is effective.
6. What, if any, federal regulations require this procedure?
    a. N/A