Column "E" Explanation

1. Registration Number: 55-R-0003
2. Number of animals categorized as column E used in this study by species or common name: 49 ferrets and 317 hamsters
3. Explain the procedure that may have caused more than slight or momentary pain or distress:

   All animals were non-invasively infected with a virus (influenza in ferrets and SARS-CoV-2 in hamsters) as part of a research study approved by the Duke Institutional Animal Care and Use Committee (IACUC). The animals showed clinical signs of respiratory viral infection. Specific clinical signs varied based on the model and individual animal's response but may have included: weight loss, elevated body temperature, respiratory signs (rapid breathing, sneezing, coughing, nasal discharge, etc.), lethargy, and/or inappetence. The pain and distress that can accompany respiratory viral infection can greatly differ based on the individual.

4. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during the procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

   These animals were used in a research study approved by the Duke IACUC. The purpose of this studies was to establish a symptomatic model of emerging and re-emerging respiratory viral infection disease models that accurately reflects the human disease and determine the efficacy of potential vaccinations and/or therapeutics (e.g., vaccinations, experimental treatments, drugs, antibodies). It was determined intervention with anesthetics and/or analgesics to alleviate clinical signs would likely have a direct impact on viral replication, the course of infection, the resulting clinical signs, and/or the robustness of the resulting immune response. In addition, it would mask clinical signs used to determine the response to vaccinations and/or therapeutics.

   All animals were frequently monitored (at a minimum daily) post-infection and evaluated based on clearly defined, IACUC approved humane-endpoints, to quickly identify any signs of infection. The research team and clinical veterinarians worked together to ensure that no animal had signs of severe disease that was not relieved.

5. What, if any, federal regulation 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)

   Agency: N/A
   CFR: N/A

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