

2022 Category E Explanations Revised
Registration # 74-R-0003
Customer # 1512

Study #1

6 marmosets

Animals were exposed to MPTP and treated with a novel therapy. The induced impairment cannot be alleviated with antidepressants, sedatives or tranquilizers. The animals in this study were monitored at least twice each day and scored for clinical signs of developing morbidity.

Out of 6 animals used, 6 animals are classified as category E animal use.

Study #2

124 hamsters

The purpose of this study is to develop candidate antibody therapy against SARS-CoV-2. Analgesics were not used as they may have the potential of affecting the course of infection and the development of the model. Animals are monitored daily for clinical signs of morbidity; euthanasia criteria were created to minimize the pain and distress animals may experience while still allowing time to collect sufficient data to evaluate disease progression.

Out of 169 animals used, 124 animals are classified as category E animal use.

Study #3

9 Cynomolgus Macaque

Animals received candidate vaccine and were challenged with an intramuscular dose of a filovirus. Analgesics were not used because they may have the secondary effect of masking clinical signs of infection that would prevent evaluation of disease severity. In addition, other analgesics may exacerbate clotting issues and there may be unintended consequences with interactions between the candidate drug and the analgesic. Animals are monitored for clinical signs of morbidity at a minimum of twice daily; euthanasia criteria were created to minimize the pain and distress animals may experience while still allowing time to collect sufficient data to evaluate disease. Supportive care such as parenteral nutrition may alter the outcome of the disease and thus invalidate the study.

Out of 20 animals used, 9 animals are classified as category E animal use.

Study #4

1 Marmoset

The purpose of this study is to develop an animal model to evaluate for short and long term effects of traumatic brain injury including cognitive function, sensorial function, motor function, and histological analysis. Over 1.7 million American's experience a TBI that leads to hospitalization each year including people within the military services. Although initial analgesics and prophylactic antibiotic treatments were administered, as this is a model development this animal is reported as a category E until further development and assessment of cognitive, behavioral, and imaging data is reviewed.

Out of 1 animal used, 1 animal is classified as category E animal use.

Study #5

5 Rhesus Macaques

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The purpose of this study is to assess efficacy of potential complementary therapies in the development of treatment regimens against tuberculosis with a global impact. Analgesics and antibiotics were not used because they may have the potential of affecting the course of infection; however supportive care in the form of fluid and nutritional support were administered. Animals are monitored for clinical signs at a minimum of twice daily.

Out of 5 animals used, 5 animals are classified as category E animal use.

Study #6

1 Guinea Pig

The purpose of this study is to evaluate candidate vaccines against arenaviruses. For clinical signs of disease, no analgesics will be used since their use may have the secondary effect of masking clinical signs of infection that would prevent evaluation of disease severity. Euthanasia criteria were created to help minimize the pain and distress the animals experience while still allowing time to collect sufficient data to evaluate disease progression. Supportive care such as parenteral nutrition may alter the outcome of disease and invalidate the study.

Out of 1 animal used, 1 animal is classified as category E animal use.

Study #7

7 Baboons

The purpose of this study is to demonstrate efficacy of candidate vaccines and provide further support for development of therapeutics against SARS-CoV-2. For clinical signs of disease, no analgesics were used since their use may have the secondary effect of masking clinical signs of infection that would prevent evaluation of disease severity. The euthanasia criteria created helped minimize the pain and distress the animals experienced while still allowing time to collect sufficient data to evaluate disease progression. Supportive care such as parenteral nutrition could alter the outcome of disease and thus invalidate the study.

Out of 10 animals used, 7 animals are classified as category E animal use.

Study #8

13 Rhesus Macaques

The purpose of this study is to develop an aerosol exposure model of filovirus. Analgesics were not used because they may have the secondary effect of masking clinical signs of infection that would prevent evaluation of disease severity. In addition, other analgesics may exacerbate clotting issues and there may be unintended consequences with interactions between the aerosol exposure and analgesic. Animals are monitored for clinical signs of morbidity at a minimum of twice daily; euthanasia criteria were created to minimize the pain and distress animals may experience while still allowing time to collect sufficient data to evaluate disease. Supportive care such as parenteral nutrition may alter the outcome of the disease and thus invalidate the study.

Out of 20 animals used, 13 animals are classified as category E animal use.

Study #9

9 Rhesus Macaques

The purpose of this pilot is to evaluate early immune responses in the study of SARS-CoV-2. All animal manipulations are performed under sedation and disease progression will be monitored by daily observations and frequent clinical

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analysis. Animals were monitored twice a day with criteria for euthanasia developed with the guidance of veterinarians; in addition animals were provided with fluids and warming pads. Extra enrichment and high protein food items were offered. Analgesics may mask clinical signs of infection and thus invalidate the pilot and were not used.

Out of 9 animals used, 9 animals are classified as category E animal use.