USDA ANNUAL REPORT
Fiscal Year 2019
Registration Number: 85-R-0003

Column E Explanation

Study 1: Swine (48)

Procedure producing pain and/or distress: (b) (4) [redacted]

Animals may experience lethargy, weakness, elevated body temperature, dizziness, disorientation, epilation, effects on consciousness, tremor, seizure, ataxia, purpura, hemorrhaging, bruising from platelet loss and neutropenia, infection, shock, emesis, diarrhea and moribundity.

Analgesia cannot be added to the current studies as the addition would change the lethality in the (b) (4) [redacted] portion of the program.

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Column E Explanation

Study 1: Non-human Primate - Cynomolgus Macaque (37)

Procedure producing pain and/or distress: Exposure to an infectious agent.

Animals may experience weight loss, elevated body temperature, respiratory distress, weakness, lethargy, persistent recumbency, loss of appetite, and unresponsiveness

The giving of pain or stress relieving agents is contraindicated because it may interfere in determining the efficacy of the vaccine which is being studied. Furthermore, we need to study the natural progression of the disease process in the absence or presence of the vaccine without the confounding influence of another agent on the pathophysiological process of animal infection.

Study 2: Non-human Primate – Rhesus Macaque (18)

Procedure producing pain and/or distress: (b) (4)

Animals may experience lethargy, weakness, elevated body temperature, dizziness, disorientation, epilation, effects on consciousness, tremor, seizure, ataxia, purpura, hemorrhaging, bruising from platelet loss and neutropenia, infection, shock, emesis, diarrhea and moribundity.

Analgesia cannot be added to the current studies as the addition would change the lethality in the (b) (4) portion of the program.

Study 3: Non-human Primate – Rhesus Macaque (23)

Procedure producing pain and/or distress: (b) (4)

Animals may experience lethargy, weakness, elevated body temperature, dizziness, disorientation, epilation, effects on consciousness, tremor, seizure, ataxia, purpura, hemorrhaging, bruising from platelet loss and neutropenia, infection, shock, emesis, diarrhea and moribundity.

Analgesia or analgesics cannot be added to the current studies as the addition would change the lethality in the (b) (4) portion of the program as they were not included in model

development, and they would not be representative of a (b) (4) that this model attempts to represent.

tolerated dose.

Study 4: Non-human Primate - Cynomolgus Macaque (2)

Procedure producing pain and/or distress: Evaluation of test article toxicity.

Animals may experience general signs of toxicity, up to and including respiratory distress.

Because the goal of this study is to assess the potentially toxic effects of the test article, no analgesics or anesthetics can be used, as this may mask the effects of the test article.

Study 5: Non-human Primate – Rhesus Macaque (18)

Procedure producing pain and/or distress: Exposure to a test article.

Animals may experience pulmonary edema, respiratory distress, and cyanosis.

(b) (4) and (b) (4) will be administered to mitigate some of the discomfort experienced however, a lethal model is necessary to evaluate the efficacy of a candidate vaccine against the current standard of care.

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Column E Explanation

Study 1: Rabbit (30)

Procedure producing pain and/or distress: Intracameral injection and test article toxicity.

With intracameral injection procedures, animals may experience intraocular hemorrhage, corneal or conjunctival lesions, inflammation, or enlargement of the globe. Animals may also experience mild ocular toxicity associated with the test article such as redness, swelling, corneal opacity, or conjunctival congestion or edema.

This is a toxicity testing study so no analgesic intervention can be used to avoid potential impact on the toxicity evaluation.

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Column E Explanation

Study 1: Guinea Pig (5)

Procedure producing pain and/or distress: Exposure to test article to produce bronchoconstriction.

Animals may experience bronchoconstriction that may be associated with airway discomfort.

No analgesics will be used in order not to abrogate the evoked airway responses. The use of analgesics will make it impossible to interpret the data obtained in this study.

Study 2: Guinea Pig (10)

Procedure producing pain and/or distress: Exposure to test article to produce cough.

Animals may experience unalleviated airway discomfort due to cough responses.

The administration of anesthetics, analgesics, or tranquilizers is contraindicated because they may abrogate the evoked cough responses. The use of analgesics will make it impossible to interpret the data obtained in this study.

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Column E Explanation

Study 1: Dog (8)

Procedure producing pain and/or distress: Evaluation of test article toxicity.

Animals exposed to test article via (b) (4) may experience distress from the exposure including extreme agitation, vomiting, and head ticking.

The objective of this study is to evaluate the potential toxicity of a test article. Anesthetics, analgesics, or tranquilizers cannot be used because they may mask the toxicity of the test article.

Study 2: Dog (30)

Procedure producing pain and/or distress: Evaluation of test article toxicity.

The test article is a (b) (4) which is known to cause side effects similar to other (b) (4) Animals may experience hair loss, bone marrow suppression, increased risk of infection, and gastrointestinal side effects including diarrhea, muscle pains and numbness.

The objective of this study is to evaluate the potential toxicity of a test article. Anesthetics, analgesics, or tranquilizers cannot be used because they may mask the toxicity of the test article.

Study 3: Dog (14)

Procedure producing pain and/or distress: Topical exposure to an allergen.

Animals are expected to experience some level of irritation and potential distress or discomfort due to the allergic skin reaction that occurs; potentially including: dermatitis, skin lesions, and pruritus.

Treatment with anti-inflammatory and analgesic drugs would invalidate the results obtained as they would directly affect the allergic response being studied. The behavioral response to the itch sensation will also be monitored. The use of sedatives would alter behavioral responses and invalidate these results as well.

Study 4: Dog (9)

Procedure producing pain and/or distress: Intracameral injection and test article toxicity.

With intracameral injection procedures, animals may experience intraocular hemorrhage, corneal or conjunctival lesions, inflammation, or enlargement of the globe. Animals may also experience mild ocular toxicity associated with the test article such as redness, swelling, corneal opacity, or conjunctival congestion or edema.

This is a toxicity testing study so no analgesic intervention can be used to avoid potential impact on the toxicity evaluation.

Study 5: Dog (16)

Procedure producing pain and/or distress: Topical exposure to an allergen.

Animals are expected to experience some level of irritation and potential distress or discomfort due to the allergic skin reaction that occurs; potentially including: dermatitis, skin lesions, and pruritus.

Treatment with anti-inflammatory and analgesic drugs would invalidate the results obtained as they would directly affect the allergic response being studied. The behavioral response to the itch sensation will also be monitored. The use of sedatives would alter behavioral responses and invalidate these results as well.

Study 6: Dog (10)

Procedure producing pain and/or distress: Evaluation of test article toxicity.

Animals may experience drug related toxicity such as cardiac arrhythmia, and respiratory distress.

Anesthetics, analgesics, or tranquilizers cannot be used because they conceal toxic effects of the test article which could result in an incorrect conclusion of higher maximum

Study 7: Dog (3)

Procedure producing pain and/or distress: Topical exposure to an allergen.

Animals are expected to experience some level of irritation and potential distress or discomfort due to the allergic skin reaction that occurs; potentially including: dermatitis, skin lesions, and pruritus.

Treatment with anti-inflammatory and analgesic drugs would invalidate the results obtained as they would directly affect the allergic response being studied. The behavioral response to the itch sensation will also be monitored. The use of sedatives would alter behavioral responses and invalidate these results as well.