Column E Explanation

This form is intended as an aid to complete the Column E explanation. It is not an official form and its use is voluntary. Annual Reports and explanations should NOT include PII information such as names (principle investigators and research staff), addresses, protocols, meeting notes (either in part of in full), the animals room numbers, grant information, veterinary care programs, and the like. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: 31-R0028

2. Number 2 of animals categorized as column E used in this study.

3. Species (common name) Woodchuck of animals used in this study.

4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

   Woodchucks arrive at our facility with hepatic tumors secondary to inoculation with woodchuck hepatitis virus, a model for hepatitis B. The study includes treatment with experimental therapies followed by serial CT imaging to monitor clinical response. The two animals for which category E applies both experienced unrelieved discomfort and distress, and one also experienced neurological abnormality (circling) as an unplanned physiologic complication of severe hepatic disease associated with the virus and progressive hepatic tumor load.

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For federally mandated testing, see Item 6 below).

   Supportive care, anesthesia and analgesia were not withheld.
   Abnormal neurological status (circling) was secondary to hypoglycemia - IV dextrose and nutritional support was provided, returning the woodchuck to near-normal mentation within 24 hours. Food intake and blood glucose were closely monitored throughout the remainder of that animal's tenure on study.
   Animals were afforded supportive care throughout their time on site (IV fluid support under anesthesia, soft bedding, hiding boxes, fresh vegetables & nutritional supplementation, etc.).

6. 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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

   Agency n/a CFR n/a

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1. Registration Number: 31-R-0028
2. Number 1 (of 7) of animals categorized as column E used in this study.
3. Species (common name) Rabbit of animals used in this study.
4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

   This rabbit was received from the vendor following a breeding career. Following acclimation, he underwent an ultrasound-guided prostate tumor inoculation. As part of this study, rabbits receive immune-suppressant medication daily and undergo occasional ultrasound scans to monitor tumor growth. This rabbit experienced the unintended complication of fatal intestinal ileus.

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For federally mandated testing, see Item 6 below).

   Supportive care, anesthesia and analgesia were not withheld. Following anesthesia, this rabbit was routinely provided fresh leafy greens, hay, and pelleted food as well as subcutaneous fluids and B vitamins to support hydration and appetite. These measures were unsuccessful. Post mortem exam revealed gastric impaction and scant intestinal contents indicating severe intestinal ileus, despite supportive care.

6. 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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

   Agency n/a CFR n/a

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1. Registration Number: 31-R-0028
2. Number 2 (of 7) of animals categorized as column E used in this study.
3. Species (common name) Rabbit of animals used in this study.
4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

   These rabbits underwent a surgery to place indwelling jugular catheters for substance administration. Following a recovery period, they were inoculated (IV) with a fungal agent and then subsequently treated with (IV) an experimental treatment. The fungal disease progressed much more rapidly than anticipated. Both rabbits acutely died from severe systemic fungal disease.

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For federally mandated testing, see Item 6 below).

   Supportive care, anesthesia and analgesia were not withheld. Surgical anesthesia and analgesia were appropriate. Food and fluids were not withheld. These animals experienced extremely rapid clinical decline and death, as they were found dead in their respective cages within 24 hours of vet staff and lab personnel observing them to be quiet but hydrated and responsive.

6. 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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

   Agency n/a CFR n/a

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1. Registration Number: 31-R-0028
2. Number 4 (of 7) of animals categorized as column E used in this study.
3. Species (common name) Rabbit of animals used in this study.
4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

   Four rabbits underwent surgery to create a tracheal stoma as early model development. The study proposes to create a stoma and, once healed open, create a tracheal injury proximal to the stoma in order to test a treatment aimed at preventing mucosal constriction. These rabbits experienced unintended physiological complications from the surgery leading to severe respiratory compromise as below:
   (1) & (2) Acute death secondary to tracheal obstruction (fibrinous plug & blood clot) - both found deceased in the cage
   (3) & (4) Severely reactive upper respiratory mucosa with copious mucus production and secondary aspiration pneumonia

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For federally mandated testing, see Item 6 below).

   Supportive care, anesthesia and analgesia were not withheld.
   The first two animals were found deceased in the cage approximately 5 hours after they were observed to be QAR and eupneic in their cages. Due to lack of evidence that the animals were experiencing complications, no intervention was pursued. Post mortem examination revealed the tracheal obstruction
   The other two rabbits developed worsening congestion and clear mucoid drainage in the days following the stoma surgery. All post-op animals were provided additional humidification to support tracheal mucosa, in addition these were also treated with post-operative steroids to help with inflammation and post-op antibiotics. Despite supportive care, both rabbits continued to deteriorate and were euthanized at veterinarian discretion and were found to have some degree of aspiration pneumonia on PM exam.

6. 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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

   Agency n/a CFR n/a