DEC 0 1 2016

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Annual Reports and explanations should NOT include PI information such as names (principle investigators and research staff) addresses, protocols, meeting notes (either in part or 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 persons as well as scientists.

1. Registration Number: 21 – R – 0173

2. Number 15 total / 15 category E of animals used in this study.

3. Species (common name) Canine of animals used in the 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.

   Dogs were challenged with one of three different doses of CPV and clinical signs of the illness were allowed to develop including fever, diarrhea, mucus or blood in the feces, depression, inappetence and dehydration.

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

   The objective of the study was to develop an experimental challenge model for canine parvovirus (CPV) infection in dogs. In the future this animal model may be used to test the effectiveness of new experimental veterinary vaccines.

   As per 9CFR113.317, clinical disease must be allowed to prove pathology of the challenge dose of CPV to confirm the virulence of the challenge material in unvaccinated beagles. Effective pain relieving agents would mask the clinical signs. However, animals were monitored at least twice daily including weekends and holidays. If it were suspected that symptoms may become severe after normal working hours, technicians were on site after hours for monitoring purposes. If any animal's condition prolonged or failed to improve, veterinary intervention was escalated up to and including euthanasia.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specified section number (e.g., AHPIS, 9 CFR 113.102):

Agency APHIS, 9CFR 113.117; CVB Notice No. 12-12

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1. Registration Number: 21 – R – 0173

2. Number 30 total / 30 category E of animals used in this study.

3. Species (common name) Canine of animals used in the 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.

   Dogs were challenged with one of six different doses (2 different strains/3 different doses each) of CDV and clinical signs of the illness were allowed to develop including fever, nasal and conjunctival discharges, coughing, vomiting, diarrhea, seizures and death.

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

   The objective of the study was to develop an experimental challenge model for canine distemper virus (CDV) infection in dogs. In the future this animal model may be used to test the effectiveness of new experimental veterinary vaccines.

   As per 9CFR113.306, clinical disease must be allowed to prove pathology of the challenge dose of CDV to confirm the virulence of the challenge material in unvaccinated beagles. Effective pain relieving agents would mask the clinical signs. However, animals were monitored at least twice daily including weekends and holidays. If it were suspected that symptoms may become severe after normal working hours, technicians would be on site after hours for monitoring purposes. If any animal's condition prolonged or failed to improve, veterinary intervention was escalated up to and including euthanasia.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specified section number (e.g., AHPIS, 9 CFR 113.102):

Agency APHIS, 9CFR 113.306

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1. Registration Number: _____21 – R – 0173_____

2. Number __10 total / 9 category E_____ of animals used in this study.

3. Species (common name) _Canine_____ of animals used in the 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.

   Young dogs were challenged with one of two different lots of a canine parvovirus strain (CPV-2c) and clinical signs of the illness were allowed to develop. Clinical signs included inappetence, fever, lethargy/depression, bloody/mucoid stool, diarrhea, dehydration, vomiting and/or death

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

   To evaluate the virulence of each lot of the CPV-2c strain and to collect tissue samples for new stocks of CPV challenge material to be used in future vaccine studies, it was necessary that dogs develop the clinical signs of Parvovirus infection that cause pain and/or distress.

   Regulation, 9 CFR 113.317 was used as a guide to evaluate virulence which requires that challenged animals be allowed to develop the clinical signs of the illness over a 14 day period to assess the virulence of challenge material in unvaccinated animals.
   A literature search was conducted to assure that no alternative methods of assessing the virulence of CPV-2c are available that cause less pain and distress.

   During the challenge period, animals were monitored at least twice daily including weekends and holidays and were assessed for clinical signs of the illness each day. Clinical assessments for CPV-2c infection were performed twice daily during the period when clinical signs were expected to be severe and the Veterinarian personally assessed any animal with clinical signs of CPV-2c infection and recommended euthanasia, when appropriate. If it were suspected that symptoms may become severe after normal working hours, technicians were on site after hours for monitoring purposes.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specified section number (e.g., AHPIS, 9 CFR 113.102):

Agency_____APHIS__CFR___9 CFR 113, 317_____

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1. Registration Number: 21 –R – 0173

2. Number 20 total / 18 category E of animals used in this study.

3. Species (common name) Canine of animals used in the 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.

   Older dogs were challenged with one of three different doses of CPV-2b and clinical signs of the illness were allowed to develop including fever, diarrhea, mucus or blood in the feces, depression, inappetence and dehydration.

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

   The objective of the study was to determine the challenge dose for CPV-2b in older dogs so that valid studies are performed in the future utilizing both 9CFR and the EU monograph definition of a successful study.

   As per 9CFR113.317, clinical disease must be allowed to prove pathology of the challenge dose of CPV to confirm the virulence of the challenge material in unvaccinated beagles. Effective pain relieving agents would mask the clinical signs. However, animals were monitored at least twice daily including weekends and holidays. If it were suspected that symptoms may become severe after normal working hours, technicians were on site after hours for monitoring purposes. If any animal's condition prolonged or failed to improve, veterinary intervention was escalated up to and including euthanasia.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specified section number (e.g., AHPIS, 9 CFR 113.102):

Agency APHIS, 9CFR 1 13.117

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1. Registration Number: 21 – R – 0173

2. Number 20 total / 18 category E of animals used in this study.

3. Species (common name) Canine of animals used in the 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.

   Older dogs were challenged with one of three different doses of infectious canine hepatitis, isolate 248/02-A and clinical signs of the illness were allowed to develop including fever, depression, lethargy, inappetence, conjunctivitis, corneal edema anterior uveitis, ocular discharge, nasal discharge, retching, vomiting, coughing , excessive salivation, photophobia, incterus/jaundice, red buccal mucosa, tonsillitis, xyphoid pain petechial hemorrhages, ecchymotic hemorrhages, abdominal hemorrhages/pain and/or death. .

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

   The objective of the study was to determine the challenge dose for infectious canine hepatitis in older dogs so that valid studies are performed in the future utilizing both 9CFR and the EU monograph definition of a successful study.

   As per 9CFR113.305, clinical disease must be allowed to prove pathology of the challenge dose of ICHV to confirm the virulence of the challenge material in unvaccinated beagles. Effective pain relieving agents would mask the clinical signs. However, animals were monitored at least twice daily including weekends and holidays. If it were suspected that symptoms may become severe after normal working hours, technicians would be on site after hours for monitoring purposes. If any animal's condition prolonged or failed to improve, veterinary intervention was escalated up to and including euthanasia.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specified section number (e.g., AHPIS, 9 CFR 113.102):

Agency APHIS, 9CFR 113.30.5

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