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OMB APPROVED
0579-0035

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2020

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER 52-R-0011	2. Research Facility Headquarters address University of Virginia, Office of VP for Research P. O. Box 400301 Charlottesville, VA 22904
3. Number of animals used in the study. 147	4. Species (common name) of animals used in the study. rabbits
5. Explain the procedure producing pain and distress. This is a study of <i>Shigella flexneri</i> dysentery in a neonatal rabbit model. The bacterium is administered intra-rectally in isoflurane anesthetized bunnies less than 10 days of age. The bacterium is genetically engineered to study the role of various virulence genes in part by quantifying the severity of inflammation and expression of cytokines associated with the ensuing dysentery.	
6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight. Opiates are due to the changes they cause in gastrointestinal motility. Non-steroidal anti-inflammatory drugs are not administered because of their influence on inflammation, which is quantified as part of the experiment.	
7. What, if any, Federal regulations 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): None	
Agency None	CFR None

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
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Interagency Report Control No. 0180-DQA-AN

Fiscal year: 2020

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER 52-R-0011	2. Research Facility Headquarters address University of Virginia, Office of VP for Research P. O. Box 400301 Charlottesville, VA 22904
3. Number of animals used in the study. 25	4. Species (common name) of animals used in the study. ferrets
5. Explain the procedure producing pain and distress. <p>This is a study of traumatic brain injury with and without hemorrhage simulating battle field injuries. The animal is anesthetized during the cranial impact procedure and local anesthesia is applied to the skull. Analgesia (buprenorphine) is administered as needed after the ferrets are recovered from anesthesia.</p>	
6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight. <p>In general, opiates are medically contra-indicated in traumatic brain or spinal cord injury as they have been shown experimentally to exacerbate the extent of central nervous system injury. Further, opiates are contra-indicated in the ferrets that receive hemorrhage and are being treated for hypovolemic shock. Anxiolytics (valium) is administered to alleviate the distress of the ferrets due to disorientation caused by the injury.</p>	
7. What, if any, Federal regulations 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): <p>None</p>	
Agency Agency	CFR CFR

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0038. The time required to complete this information collection is estimated to average .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0038

Interagency Report Control No. 0180-DDA-AN

Fiscal year: 2020

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER 52-R-0011	2. Research Facility Headquarters address University of Virginia, Office of VP for Research P. O. Box 400301 Charlottesville, VA 22904
3. Number of animals used in the study. 331	4. Species (common name) of animals used in the study. hamsters
5. Explain the procedure producing pain and distress. <p>There are three studies of infectious diseases that use hamsters as a model for human disease. One study is of enterotoxigenic Clostridium difficile examining the role of eosinophils and some cytokines that ameliorate the clinical symptoms of diarrhea and dehydration. The hamsters are euthanized if they lose 20% or more of their body weight during the course of infection.</p> <p>The second two studies use a hamster model of SARS-CoV-2 (Covid-19). Hamsters are given SARS CoV-2 by either an intra-nasal or intra-tracheal route to test of the efficacy of candidate vaccines or therapeutic treatments during the ensuing infection. The hamsters are euthanized if they lose 20% of their body weight or show severe signs of respiratory distress.</p>	
6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight. <p>In the Clostridium difficile experiments no non-steroidal anti-inflammatory analgesia is provided as this is a study that quantifies inflammation, and administering opioids would change gastrointestinal motility.</p> <p>In the SARS CoV-2 experiments no non-steroidal anti-inflammatory analgesia is provided during that time as this is a study that quantifies pulmonary inflammation, and whole body plethysmography is performed to quantify components of breathing and administering opioids would depress respiration.</p>	
7. What, if any, Federal regulations 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): None	
Agency	CFR