

<p>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.</p>		<p><b>OMB APPROVED</b> 0579-0036</p>
		<p>Interagency Report Control No. 0180-DOA-AN</p>
		<p>Fiscal year: 2021</p>
<p align="center"><b>UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE</b></p> <p align="center"><b>Annual Report of Research Facility Column E Explanation</b> (TYPE OR PRINT)</p>		
<p>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.</p>		
<p><b>1. REGISTRATION NUMBER</b> 51-G-0001</p>	<p><b>2. Research Facility Headquarters address</b> Northeast Area Beltsville Location 10300 Baltimore Avenue Beltsville, MD 20705</p>	
<p><b>3. Number of animals used in the study.</b> 243</p>	<p><b>4. Species (common name) of animals used in the study.</b> Chicken</p>	
<p><b>5. Explain the procedure producing pain and distress.</b> Experimental infections with live Eimeria oocysts</p>		
<p><b>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.</b> Anesthetics, analgesics, sedatives, and tranquilizers are contraindicated in this protocol because they would impact primary and secondary immune responses that would otherwise limit multiplication of the parasite. Treatment with anesthetics or analgesics would affect not only the natural infection, but also immune response to the organism thereby interfering with the natural resistance to infection.</p>		
<p><b>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):</b> N/A</p>		
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<b>3. Number of animals used in the study.</b> 1015	<b>4. Species (common name) of animals used in the study.</b> Chicken	
<b>5. Explain the procedure producing pain and distress.</b> Experimental infections with live Eimeria oocysts		
<b>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.</b> Anesthetics, analgesics, sedatives, and tranquilizers are contraindicated in this protocol because they would impact primary and secondary immune responses that would otherwise limit multiplication of the parasite. Treatment with anesthetics or analgesics would affect not only the natural infection, but also immune response to the organism thereby interfering with the natural resistance to infection.		
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<b>3. Number of animals used in the study.</b> 109	<b>4. Species (common name) of animals used in the study.</b> Chicken	
<b>5. Explain the procedure producing pain and distress.</b> Experimental infections with live Eimeria oocysts		
<b>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.</b> Anesthetics, analgesics, sedatives, and tranquilizers are contraindicated in this protocol because they would impact primary and secondary immune responses that would otherwise limit multiplication of the parasite. Treatment with anesthetics or analgesics would affect not only the natural infection, but also immune response to the organism thereby interfering with the natural resistance to infection.		
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<b>3. Number of animals used in the study.</b> 360	<b>4. Species (common name) of animals used in the study.</b> chickens	
<b>5. Explain the procedure producing pain and distress.</b> Infections with Eimeria and/or Clostridium		
<b>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.</b> The use of anesthetics or sedatives is not appropriate for this protocol for multiple reasons. Eimeria and Clostridium infections generally produce mild symptoms. As the natural infection of Eimeria and Clostridium is ubiquitous in the field condition, we are trying to mimic those conditions. Additionally, the strains and doses of Eimeria maxima and Clostridium perfringens that we are using for the trials are attenuated and medium doses. Furthermore, anesthetics and sedatives could affect blood and tissue samples.		
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<b>3. Number of animals used in the study.</b> 200	<b>4. Species (common name) of animals used in the study.</b> chickens	
<b>5. Explain the procedure producing pain and distress.</b> Infections with Eimeria and/or Clostridium		
<b>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.</b> The use of anesthetics or sedatives is not appropriate for this protocol for multiple reasons. Eimeria and Clostridium infections generally produce mild symptoms. As the natural infection of Eimeria and Clostridium is ubiquitous in the field condition, we are trying to mimic those conditions. Additionally, the strains and doses of Eimeria maxima and Clostridium perfringens that we are using for the trials are attenuated and medium doses. Furthermore, anesthetics and sedatives could affect blood and tissue samples.		
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<b>3. Number of animals used in the study.</b> 130	<b>4. Species (common name) of animals used in the study.</b> chickens	
<b>5. Explain the procedure producing pain and distress.</b> Infections with Eimeria		
<b>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.</b> The use of anesthetics or sedatives is not appropriate for this protocol for multiple reasons. Eimeria generally produces mild symptoms. As the natural infection of Eimeria is ubiquitous in the field condition, we are trying to mimic those conditions. Additionally, the strains and doses of Eimeria maxima that are being used for the trials are attenuated and medium doses. In our experiences with Eimeria infections, no significant clinical signs were observed.		
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<b>3. Number of animals used in the study.</b> 144	<b>4. Species (common name) of animals used in the study.</b> Chickens	
<b>5. Explain the procedure producing pain and distress.</b> Immunization of chicks with recombinant protein vaccine followed by challenge of vaccinated birds with Eimeria/C. perfringens.		
<b>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.</b> The use of anesthetics or sedatives would impact blood and tissue samples. Furthermore, some of the trials rely on behavioral observations and vaccine protection efficacy which can be altered by the use of sedatives/anesthetics.		
<b>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):</b> N/A		
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<b>3. Number of animals used in the study.</b> 284	<b>4. Species (common name) of animals used in the study.</b> chickens	
<b>5. Explain the procedure producing pain and distress.</b> Infections with Eimeria		
<b>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.</b> The use of anesthetics or sedatives is not appropriate for this protocol for multiple reasons. Eimeria generally produces mild symptoms. As the natural infection of Eimeria is ubiquitous in the field condition, we are trying to mimic those conditions. Additionally, the strains and doses of Eimeria maxima that are being used for the trials are attenuated and medium doses. In our experiences with Eimeria infections, no significant clinical signs were observed.		
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<b>3. Number of animals used in the study.</b> 240	<b>4. Species (common name) of animals used in the study.</b> Chickens	
<b>5. Explain the procedure producing pain and distress.</b> Infections with <i>C. perfringens</i> and <i>Eimeria</i>		
<b>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.</b> The use of anesthetics or sedatives is not appropriate for this protocol for multiple reasons. Anesthetics and sedatives affect blood and tissue samples. Trials rely on behavioral observations and vaccine protection efficacy which would be altered by the use of sedatives/anesthetics.		
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<b>3. Number of animals used in the study.</b> 100	<b>4. Species (common name) of animals used in the study.</b> chickens	
<b>5. Explain the procedure producing pain and distress.</b> Infections with Eimeria		
<b>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.</b> The use of anesthetics or sedatives is not appropriate for this protocol for multiple reasons. Eimeria generally produces mild symptoms. As the natural infection of Eimeria is ubiquitous in the field condition, we are trying to mimic those conditions. Additionally, the strains and doses of Eimeria maxima that are being used for the trials are attenuated and medium doses. In our experiences with Eimeria infections, no significant clinical signs were observed.		
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<p><b>3. Number of animals used in the study.</b> 400</p>	<p><b>4. Species (common name) of animals used in the study.</b> chickens</p>	
<p><b>5. Explain the procedure producing pain and distress.</b> Infections with Eimeria and/or Clostridium</p>		
<p><b>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.</b> The use of anesthetics or sedatives is not appropriate for this protocol for multiple reasons. Eimeria and Clostridium infections generally produce mild symptoms. As the natural infection of Eimeria and Clostridium is ubiquitous in the field condition, we are trying to mimic those conditions. Additionally, the strains and doses of Eimeria maxima and Clostridium perfringens that we are using for the trials are attenuated and medium doses. Furthermore, anesthetics and sedatives could affect blood and tissue samples.</p>		
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<b>3. Number of animals used in the study.</b>  <b>10</b>	<b>4. Species (common name) of animals used in the study.</b>  <b>Mouse</b>	
<b>5. Explain the procedure producing pain and distress.</b> Citrobacter rodentium infection. C. rodentium is an E. coli like organism that naturally infects mice causing disease in mice similar to pathogenic E. coli infections in humans. Thus, this is a useful model for gaining insight into the pathogenesis and immune response to an important class of pathogens.		
<b>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.</b> The use of analgesics, anesthetics, sedatives or tranquilizers are contraindicated in this protocol for several reasons. First, some of these compounds can alter immune function and thus could alter the inflammatory response of the host to infection. Since we are looking for pro- or anti-inflammatory dietary effects, any agent that could potentially interfere with the normal inflammatory response would completely void any results obtained. It has been demonstrated that the administration of analgesics can alter normal immune or physiological responses and can affect the activity of enzymes (e.g., prostaglandin synthesis, myeloperoxidases) and the clinical status of the research model.		
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<b>3. Number of animals used in the study.</b>  <b>21</b>	<b>4. Species (common name) of animals used in the study.</b>  <b>Mouse</b>	
<b>5. Explain the procedure producing pain and distress.</b> Citrobacter rodentium infection. C. rodentium is an E. coli like organism that naturally infects mice causing disease in mice similar to pathogenic E. coli infections in humans. Thus, this is a useful model for gaining insight into the pathogenesis and immune response to an important class of pathogens.		
<b>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.</b> The use of analgesics, anesthetics, sedatives or tranquilizers are contraindicated in this protocol for several reasons. First, some of these compounds can alter immune function and thus could alter the inflammatory response of the host to infection. Since we are looking for pro- or anti-inflammatory dietary effects, any agent that could potentially interfere with the normal inflammatory response would completely void any results obtained. It has been demonstrated that the administration of analgesics can alter normal immune or physiological responses and can affect the activity of enzymes (e.g., prostaglandin synthesis, myeloperoxidases) and the clinical status of the research model.		
<b>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):</b>  <b>N/A</b>		
<b>Agency</b>		<b>CFR</b>



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.		<b>OMB APPROVED</b> 0579-0036
		Interagency Report Control No. 0180-DOA-AN
		Fiscal year: 2021
<b>UNITED STATES DEPARTMENT OF AGRICULTURE</b> <b>ANIMAL AND PLANT HEALTH INSPECTION SERVICE</b>  <b>Annual Report of Research Facility</b> <b>Column E Explanation</b> (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.		
<b>1. REGISTRATION NUMBER</b>  51-G-0001	<b>2. Research Facility Headquarters address</b> Northeast Area Beltsville Location 10300 Baltimore Avenue Beltsville, MD 20705	
<b>3. Number of animals used in the study.</b>  6	<b>4. Species (common name) of animals used in the study.</b> Mouse	
<b>5. Explain the procedure producing pain and distress.</b> Subcutaneous inoculation with parasitic nematode species of Nippostrongylus brasiliensis.		
<b>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.</b> Analgesics cannot be administered because of the significant effects of narcotics or other pain medications on gut function, including constipation and/or diarrhea that will affect their expression of resistance or susceptibility to the parasitic infections being evaluated. Likewise, other analgesics such as aspirin may cause damage to the stomach and small intestine or can result in bleeding disorders that may also alter the immune processes in ways that would interfere with the objectives of the study.		
<b>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):</b>  N/A		
<b>Agency</b>		<b>CFR</b>