

According to the Paperwork Reduction Act of 1996, 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 0579-0036
		Interagency Report Control No. 0180-DOA-AN
		Fiscal year: 2022
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 55-R-0003	2. Research Facility Headquarters address Duke University Office of Animal Welfare Assurance 2424 Erwin Road, Suite 606, Durham, NC 27705	
3. Number of animals used in the study. 122	4. Species (common name) of animals used in the study. 86 ferrets and 36 hamsters	
5. Explain the procedure producing pain and distress. All animals were non-invasively infected with a virus (influenza in ferrets and SARS-CoV-2 in hamsters) as part of a research study approved by the Duke Institutional Animal Care and Use Committee (IACUC). Some of the animals showed clinical signs of respiratory viral infection. Specific clinical signs varied based on the model and individual animal's response but may have included: weight loss, elevated body temperature, respiratory signs (rapid breathing, sneezing, coughing, nasal discharge, etc.), lethargy, and/or inappetence. The pain and distress that can accompany respiratory viral infection can greatly differ based on the individual.		
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. These animals were used in a research study approved by the Duke IACUC. The purpose of this studies was to establish a symptomatic model of emerging and re-emerging respiratory viral infection disease models that accurately reflects the human disease and determine the efficacy of potential vaccinations and/or therapeutics (e.g., vaccinations, experimental treatments, drugs, antibodies). It was determined intervention with anesthetics and/or analgesics to alleviate clinical signs would likely have a direct impact on viral replication, the course of infection, the resulting clinical signs, and/or the robustness of the resulting immune response. In addition, it would mask clinical signs used to determine the response to vaccinations and/or therapeutics. All animals were frequently monitored (at a minimum daily) post-infection and evaluated based on clearly defined, IACUC approved humane-endpoints, to quickly identify any signs of infection. The research team and clinical veterinarians worked together to ensure that no animal had signs of severe disease that was not relieved.		
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): N/A		
Agency N/A		CFR N/A

According to the Paperwork Reduction Act of 1996, 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 0579-0036
		Interagency Report Control No. 0180-DOA-AN
		Fiscal year: 2022
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 55-R-0003	2. Research Facility Headquarters address Duke University Office of Animal Welfare Assurance 2424 Erwin Road, Suite 606, Durham, NC 27705	
3. Number of animals used in the study. 122	4. Species (common name) of animals used in the study. 86 ferrets and 36 hamsters	
5. Explain the procedure producing pain and distress. All animals were non-invasively infected with a virus (influenza in ferrets and SARS-CoV-2 in hamsters) as part of a research study approved by the Duke Institutional Animal Care and Use Committee (IACUC). Some of the animals showed clinical signs of respiratory viral infection. Specific clinical signs varied based on the model and individual animal's response but may have included: weight loss, elevated body temperature, respiratory signs (rapid breathing, sneezing, coughing, nasal discharge, etc.), lethargy, and/or inappetence. The pain and distress that can accompany respiratory viral infection can greatly differ based on the individual.		
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. These animals were used in a research study approved by the Duke IACUC. The purpose of this studies was to establish a symptomatic model of emerging and re-emerging respiratory viral infection disease models that accurately reflects the human disease and determine the efficacy of potential vaccinations and/or therapeutics (e.g., vaccinations, experimental treatments, drugs, antibodies). It was determined intervention with anesthetics and/or analgesics to alleviate clinical signs would likely have a direct impact on viral replication, the course of infection, the resulting clinical signs, and/or the robustness of the resulting immune response. In addition, it would mask clinical signs used to determine the response to vaccinations and/or therapeutics. All animals were frequently monitored (at a minimum daily) post-infection and evaluated based on clearly defined, IACUC approved humane-endpoints, to quickly identify any signs of infection. The research team and clinical veterinarians worked together to ensure that no animal had signs of severe disease that was not relieved.		
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): N/A		
Agency N/A		CFR N/A