

SUPPORTING STATEMENT FOR INFORMATION COLLECTION

UNITED STATES DEPARTMENT OF AGRICULTURE (USDA)

ANIMAL AND PLANT HEALTH INSPECTION SERVICE (APHIS)

VETERINARY SERVICES (VS)

CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH),

NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)

NAHMS Equine Herpesvirus Study

Part A

**SUPPORTING STATEMENT FOR INFORMATION COLLECTION BY THE
CENTERS FOR EPIDEMIOLOGY AND ANIMAL HEALTH (CEAH),
NATIONAL ANIMAL HEALTH MONITORING SYSTEM (NAHMS)¹
OMB NUMBER 0579-XXXX
NAHMS Equine Herpesvirus Study**

March 14, 2013

A. Justification

1. Explain why the collection of this information is necessary

This submission is a request for approval to initiate the National Animal Health Monitoring System's (NAHMS') Equine Herpesvirus Study, an information collection by the Animal and Plant Health Inspection Service (APHIS). APHIS plans to conduct an Equine Herpesvirus Myeloencephalopathy Study as part of an ongoing series of NAHMS studies on the U.S. livestock population. The purpose of this study is to collect information using questionnaires to identify risk factors for the neurologic form of equine herpesvirus (EHV-1) in horses called Equine Herpesvirus Myeloencephalopathy (EHM). EHV-1 is an infection of horses that can cause respiratory disease, abortion in mares, neonatal foal death, and/or neurologic disease. The virus can spread through direct horse to horse contact, through the air in equine environments, on contaminated equipment, clothing and hands. EHM is endemic to the United States and outbreaks are usually handled by the States affected; USDA becomes involved in cases involving multiple States or interstate movement of horses.

In person or by telephone interview, APHIS-designated data collectors will administer questionnaires to horse owners and trainers of horses infected with EHV-1 during outbreaks that include cases of EHM and horses that are nonclinical and potentially exposed to EHV-1 to serve as controls. The information collected will be used to:

- Understand the risk factors for EHM;
- Make recommendations for disease control; and
- Provide guidance on the best ways to avoid future outbreaks based on a thorough analysis of the data.

The information collected through the Equine Herpesvirus study will be analyzed and organized into descriptive reports and/or peer reviewed publications. Several information sheets could be derived from these descriptive reports and will be disseminated by NAHMS to members of the equine industry, other stakeholders, academia, veterinarians, and any other interested parties. The benefits to the equine industry from the Equine Herpesvirus study include further understanding of the risk factors for EHM the most impactful form of EHV-1 infection. Currently there is not a good experimental challenge model for EHM; thus learning as much as possible from naturally occurring disease outbreaks is the only means to learn more about risk factors for EHM. Identification of risk factors can focus intervention and/or future research related to the prevention or treatment of the disease. Participation in this survey is voluntary. It is up to the horse owner or trainer to decide whether or not it is desirable to participate.

¹ The National Animal Health Monitoring System is responsible for collecting national data on animal health and productivity from voluntary participants.

Collection and dissemination of animal health data and information is mandated by 7 U.S.C. § 391, the Animal Industry Act of 1884, which established the precursor of the APHIS, Veterinary Services, the Bureau of Animal Industry. Legal requirements for examining and reporting on animal disease control methods were further mandated by 7 U.S.C. § 8308 of the Animal Health Protection Act, “Detection, Control, and Eradication of Diseases and Pests,” May 13, 2002. The collection of these data is consistent with the APHIS mission of protecting and improving American agriculture’s productivity and competitiveness. Information about the risk factors for and potential prevention measures to reduce the occurrence of Equine Herpesvirus Myeloencephalopathy is beneficial to industry as well as many Federal and State partners.

2. *Indicate how, by whom, and for what purpose the information is to be used. Indicate the actual use the Agency has made of the information received from the current collection.*

Statistically summarized information and interpretation are disseminated to a wide variety of constituents. Owners will use the information to implement prevention and control measures both regionally and nationally. Industry groups and veterinarians will use information derived from analyses to improve preventive measures and information outreach efforts. Pharmaceutical and biologics companies will use the information to plan and develop research and marketing strategies for their products. State and Federal officials responsible for regulatory veterinary medicine will use the information to gain a more complete picture of animal health as a basis for program planning and to direct funding. State and Federal officials will use the data to show the scientifically based information used to make decisions. Research scientists will use the information to define current and future animal health issues and direct research funding. Veterinary and agricultural students in universities in the U.S. will use the reports and/or manuscripts for training in epidemiologic investigation and equine health management.

APHIS will use the data collected from the Equine Herpesvirus Myeloencephalopathy Study to:

- Understand the risk factors for EHM;
- Make recommendations for disease control; and
- Provide guidance on the best ways to mitigate future outbreaks based on a thorough analysis of the data.

National Surveys Providing Baseline Information

There have been no previous epidemiologic investigations of EHM across States or across different types of venues (on farm, at equine events, or at veterinary schools). NAHMS published a report on Mitigation of EHM outbreaks in 2008. This report was based on interviews with veterinarians who had been involved in mitigation of previous EHM outbreaks. One of the clear messages from that report was that there needed to be a concerted effort to learn as much as possible from naturally occurring outbreaks of EHM. Due to the limited number of EHM cases in each outbreak, it will require collection of data in

a consistent manner from multiple outbreaks to lead to adequate number of EHM cases for statistical power. The EHM 2008 report is available at URL http://www.aphis.usda.gov/vs/nahss/equine/ehv/equine_herpesvirus_nahms_2008report.pdf

Equine 2013 Data Collection Form

NAHMS-317 EHV-1 Study Questionnaire will be administered to trainers or owners of horses with clinical signs of EHM, EHV-1 cases with no neurologic signs and to those who own or train horses that will serve as controls. The questionnaire will be administered by APHIS designated data collectors to collect data on the type of horse, clinical information, travel information, vaccination information, treatment information, dietary supplement information and diagnostic testing information. The form will be returned to NAHMS for data entry and validation.

3. *Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.*

No automated, electronic, or mechanical techniques will be used to collect information for the Equine Herpesvirus Study at the current time. Approximately 3-5 calls will be made to selected operations to schedule a time for in-person or over the telephone data collection. The data collection instrument will be a hard copy questionnaire at the current time. For respondents that may be located far away from the data collector, telephone interviews will be used to collect data. Respondents will be sent a blank copy of the questionnaire prior to the interview and will follow along as questions are asked. For some of the outbreaks several of the survey questions can be completed by the outbreak mitigator e.g., signalment of the horse, test results etc., which will shorten the time that will be required by the respondent in answering questions on the survey.

4. *Describe efforts to identify duplication.*

Literature searches for existing data relevant to the Equine Herpesvirus study have been performed. Available data was reviewed and compiled from all known sources. Sources reviewed include; cooperative State research, private industry and professional publications, diagnostic laboratories, other Federal and State agencies, and universities. Employees from Federal agencies and academia were consulted in their area of expertise to identify areas of potential duplication. No other entity/source is collecting and analyzing this type of information on the outbreaks of EHM from across States and different types of equine.

5. *If the collection of information impacts small business or other small entities, describe the methods used to minimize burden.*

The study is designed to collect the minimum amount of data required from a minimum number of owners and trainers to ensure statistically and scientifically valid data. APHIS will attempt to complete a questionnaire for every case and will select up to three controls for each case. Industry, owner, trainer, and data collector input is solicited to ensure that information collected is relevant and timely. This is a voluntary study; it is at the discretion of the individual owner or trainer to decide whether or not it is desirable for them to participate. APHIS estimates that 50 percent of the respondents will be small entities – individual horse owners.

6. Describe the consequences to Federal program or policy activities if the collection is not conducted or conducted less frequently, as well as any technical or legal obstacles to reducing burden.

Without this type of data on outbreaks of EHM, the U.S.' ability to understand the risk factors for EHM, make recommendations for disease control, and provide guidance on the best ways to mitigate future outbreaks would be reduced or nonexistent.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**
- **requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

No special circumstances exist that would require this collection to be conducted in a manner inconsistent with the general information collection guidelines in 5 CFR 1320.5.

- 8. Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting form, and on the data elements to be recorded, disclosed, or reported. If applicable, provide a copy and identify the date and page number of publication in the Federal Register of the agency's notice, soliciting comments on the information collection prior to submission to OMB.**

Consultants Used for Planning the Equine Herpesvirus Study:

Dr. Paul Lunn, Dean of College of Veterinary Medicine at North Carolina State University, researcher on EHV-1 and lead author of the American College of Veterinary Medicine (ACVIM) consensus statement of EHV-1, North Carolina State University, 1060 William Moore Dr. Raleigh, NC, 27607, 919-513-6210.

Dr. Hugh Townsend, University of Saskatoon, Western College of Veterinary Medicine Professor, Department of Veterinary Microbiology and Professor, Large Animal Medicine, Large Animal Clinical Sciences, Alberta, Canada, 306-966-1514 and 306-966-2354.

Dr. Paul Morley, Colorado State University College of Veterinary Medicine and Biomedical Sciences, Clinical Sciences Department, 300 West Drake Road, Fort Collins, CO, 80523, 970-297-0374.

APHIS is currently seeking Office of Management and Budget approval to collect this information. The emergency approval will be valid for 6 months and will allow APHIS to collect the information immediately. Once APHIS has this emergency approval, it will publish a notice in the Federal Register announcing the availability of the form and solicit comments from the public on this information collection activity.

- 9. Explain any decision to provide any payment or gifts to respondents, other than remuneration of contractors or grantees.**

There will be no payments or gifts provided to respondents.

- 10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation or agency policy.**

Only outbreak summaries will be reported to the public. The completed questionnaire contains a cover sheet with owner name and horse name. This information will be linked to a NAHMS ID number. Information from the cover sheet will not be entered into the database used for analysis; records will only be referred to by the NAHMS ID. All information, reports and/or manuscripts generated by this activity will refer to the respondent by a numeric code, which will be assigned by NAHMS. The link between participant and numeric code will be destroyed once data collection, entry, validation and report dissemination are complete. All completed survey forms will be stored securely in a limited access records room.

Several U.S. Codes apply to data collected by NAHMS:

Title 7, Section 2276 - Confidentiality of Information.

Title 18, Section 1902 - Disclosure of Crop Information and Speculation Thereon.

Title 18, Section 1905 - Disclosure of Confidential Information Generally.

7 U.S.C. 8791.

- 11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.**

Some of the survey questions may be sensitive such as drug treatment given to horses. These questions are essential to assess risk factors.

- 12. Provide estimates of the hour burden of the collection of information. Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated.**
 - A.** A total of 778 burden hours are needed to complete the Equine Herpesvirus Study over the collection period for this information collection. A detailed burden estimate has been included on the enclosed APHIS 71 Form.
 - B.** Respondent costs: Estimated respondent costs for the information collection proposed are calculated based on a data collection estimate of \$16.57 per hour. The total respondent cost for the Equine Herpesvirus Study is \$12,891.41. (778 hours x \$16.57).
 - C.** \$16.57 is the hourly rate derived from the U.S. Department of Labor, Bureau of Labor Statistics May 2011 Report - Occupational Employment and Wages in the United States. See <http://www.bls.gov/news.release/pdf/ocwage.pdf>
- 13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information (do not include any hour burden shown in items 12 and 14).**

There are no capital/start-up costs or ongoing operations and maintenance costs associated with this information collection.

14. Provide an estimate of annualized cost to the federal government.

The estimated cost to the Federal Government is \$11,805.26. For more specific information, please see the enclosed APHIS 79 form.

15. Explain the reasons for any program changes or adjustments reported in items 13 or 14 of the OMB form 83-I.

This is a new collection.

16. For collections of information whose results are planned to be published, outline plans for tabulation and publication.

Any published summary data will be available at <http://nahms.aphis.usda.gov> or in a [peer reviewed publication](#).

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

APHIS is not seeking an exemption to display the expiration date for OMB approval.

18. Explain each exception to the certification statement identified in under “Certification for Paperwork Reduction Act.”

APHIS is able to certify compliance with all provisions under the Act.