

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service Centers for Disease Control and Prevention (CDC)

Memorandum

Date July 25, 2024

From Brianna M. Eiter, PhD

Reviewer, NIOSH Institutional Review Board

Subject IRB Approval of New NIOSH Protocol 24-NIOSH-09, "Occupational Exposures to Surgical Smoke in

Veterinary Personnel" (Expedited)

To Ethan D. Fechter-Leggett, DVM, MPV

Project Officer, NIOSH/RHD

The NIOSH IRB reviewed the new protocol 24-NIOSH-09, "Occupational Exposures to Surgical Smoke in Veterinary Personnel." The IRB determined the study poses minimal risk to subjects. The protocol was reviewed in accordance with the expedited review process outlined in 45 CFR 46.110(b)(1), category (7). Continued review is not required for this protocol since it is eligible for expedited review.

The IRB found the additional protections required by Subpart B for Pregnant Women, Human Fetuses and Neonates involved in the research are in place.

The request for waiver of documentation of informed consent is granted per 45 C.F.R. 46.117 (c)(1)(ii) for participants completing the questionnaire component of the study.

Due to the funding and collection of identifiable, sensitive information the project is determined to be covered by a Certificate of Confidentiality under section 301(d) of the Public Health Service Act.

The subjects must have attained the legal age for consent to procedures involved in the research, under the applicable law of the jurisdiction(s) in which the research will be conducted.

Any problems of a serious nature must be brought to the immediate attention of the NIOSH IRB, and any proposed changes to the protocol should be submitted as an amendment to the protocol for NIOSH IRB approval before they are implemented.

NIOSH study activities may not begin with the following collaborators/sites until documentation indicating current IRB approval or IRB Authorization Agreement has been received by the NIOSH Human Research Protection Program (HRPP) and the Principal Investigator has been notified by the HRPP this restriction has been lifted and study activities may begin:

- 1. Cummings School of Veterinary Medicine at Tufts University
- 2. The Ohio State University
- 3. University of Tennessee College of Veterinary Medicine

If other institutions involved in this protocol are being awarded NIOSH funds through the CDC Procurement and Grants Office (PGO), you are required to send a copy of this IRB approval to the CDC PGO award specialist handling the award. You are also required to verify with the award specialist that the awardee has provided PGO with the required documentation and has approval to begin or continue research involving human subjects as described in this protocol.

Investigators are required to report incidents to the HRPP in accordance with CDC/NIOSH policy and procedure. Any proposed changes to the protocol should be submitted as an amendment to the protocol for NIOSH IRB approval before they are implemented.

If you have any questions, please contact the NIOSH Human Research Protection Program (513) 533-8591 or e-mail: <u>NIOSH IRB Mailbox</u>.