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**Centers for Disease Control and Prevention**
National Institute for Occupational Safety and Health

# Consent to be in a Research Study

## *Occupational exposures to surgical smoke in veterinary personnel*

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| 1 | **Key Information Summary** | The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that studies worker safety and health and is part of the Centers for Disease Control and Prevention (CDC). NIOSH is conducting a research study on surgical smoke and respiratory health in veterinary settings.<br><br>You are being invited to participate in this research study. If you agree to participate, you will be asked to complete:<br>• A baseline questionnaire with questions on demographics, work history, work tasks, potential exposures, use of personal protective equipment, and respiratory health (about 25 minutes, completed virtually/phone at your convenience)<br>• A post-shift questionnaire on respiratory health during our first 5-day site visit (about 8 minutes, completed at the end of each shift)<br>• A post-shift questionnaire on respiratory health during our second 5-day site visit (about 8 minutes, completed at the end of each shift)<br><br>If you use an electrocauterizing device, we will:<br>• Ask you to use your normal device during our first 5-day site visit<br>• Offer the option for you to use a similar device that includes a surgical smoke extraction system during our second 5-day site visit.<br><br>You will be asked to give permission to take part in the study. **Your participation in the study is voluntary**. You may choose to answer any or all questions. You may decline to participate or drop out at any time, for any reason, without any penalties or consequences. |

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| | | Participation in this research involves minimal risks to you. There is a small risk that information collected could be compromised. This risk will be minimized by assigning each participant a unique number and using that unique number (and not participant names) during data collections. Only NIOSH staff who are involved in this research will have access to the data. We will release summaries of information we collect in reports, presentations, and publications. All reported results will be in aggregate and will not identify individual workers.<br><br>While there is no direct benefit, your participation in this research will benefit the veterinary industry by increasing knowledge and understanding of surgical smoke and respiratory health in veterinary settings.<br><br>You will not be paid or reimbursed for participating.<br><br>You may want to participate in this study to help develop our understanding of surgical smoke at work, respiratory health effects, and usage of surgical smoke controls in veterinary settings. However, you may not want to participate in this study if you are concerned about increasing the burden of work during your workday or concerns about your information being released and used against you. The study team would like to reassure you that the benefits of participating in this study outweigh the risks, and precautions have been taken to minimize these concerns. |
| **2** | **Who is conducting the study?** | NIOSH is a federal agency that studies worker safety and health. We are part of the CDC. NIOSH is partnering with three veterinary teaching hospitals, a national network of community veterinary clinics, and two veterinary clinics local to Morgantown, WV. |
| **3** | **What is the purpose?** | The purpose of this research is to examine surgical smoke, respiratory health effects, and use of surgical smoke controls in clinical veterinary settings. We hope to recruit up to 150 participants across all participating facilities. |
| **4** | **What will I do?** | You will be asked to complete:<br>• A baseline questionnaire with questions on demographics, work history, work tasks, potential exposures, use of personal protective equipment, and respiratory health (about 25 minutes, completed virtually/phone at your convenience)<br>• A post-shift questionnaire on respiratory health during our first 5-day site visit (about 8 minutes, completed at the end of each shift) |

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| | | • A post-shift questionnaire on respiratory health during our second 5-day site visit (about 8 minutes, completed at the end of each shift)<br><br>If you use an electrocauterizing device, we will:<br>• Ask you to use your normal device during our first 5-day site visit<br>• Offer the option for you to use a similar device that includes a surgical smoke extraction system during our second 5-day site visit. |
| **5** | **When, where, for how long will I be needed?** | We will conduct part of the study virtually/via phone and part of the study during two site visits to your workplace.<br><br>Your total direct participation time will be:<br>• Approximately 25 minutes for the baseline questionnaire, conducted virtually/via phone during a day/time at your convenience.<br>• Approximately 8 minutes each day, at the end of your shift, for the post-shift questionnaire. This will be offered on each of 5 days during our first site visit.<br>• Approximately 8 minutes each day, at the end of your shift, for the post-shift questionnaire. This will be offered on each of 5 days during our second site visit. |
| **6** | **Are there any risks from participating in the study?** | Participation in this research involves minimal risks to you. There is a small risk that the information you provide could be accidentally released, which could cause mental stress due to a loss of privacy. We will minimize this risk by assigning you a unique number and using that unique number (and not your name) during data collections. Only NIOSH staff who are involved in this research will have access to the data. We will release summaries of information we collect in reports, presentations, and publications. All reported results will be in aggregate and will not identify individual workers.<br><br>There is a very small risk you could get a respiratory infection (e.g., COVID-19, influenza) through an in-person interaction while participating in this study. To minimize your risk of exposure to viruses and maximize your protection against infection, NIOSH researchers follow COVID-19 and other relevant respiratory infectious disease guidance for CDC and NIOSH staff and workplaces.<br><br>If NIOSH researchers see something that poses an imminent danger to yourself or others, the researchers will immediately notify you, other workers, and the management at your company. |

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| **7** | **Are there any benefits?** | You will not receive any direct benefits from participating in this study. Your participation in this research will increase our understanding of surgical smoke and respiratory health in veterinary settings. |
| **8** | **Is my participation voluntary?** | Your participation in the study is voluntary. You may choose to answer any or all questions. You may decline to participate or drop out at any time, for any reason, with no penalty or loss of benefits to which you are otherwise entitled. |
| **9** | **What if I am injured or harmed at a NIOSH research facility or at another location where the NIOSH research project is being conducted?** | NIOSH will summon emergency medical aid by calling 911 if needed. NIOSH will not provide payment for medical care or compensation. If you believe NIOSH has been negligent in conducting the research study and you believe you have suffered a harm as a result, you have the right to pursue a legal remedy under the Federal Tort Claims Act (28 U.S.C. §§ 2671-2680 and 28 U.S.C. § 1346(b)). To learn more about how to file a Federal Tort claim, call the General Law Division of the HHS Office of the General Counsel at (202) 619-2155 or go to https://www.hhs.gov/about/agencies/ogc/key-personnel/general-law-division/index.html. |
| **10** | **Will I be reimbursed or paid?** | You will not be paid or reimbursed for participating. |
| **11** | **What alternative procedures might benefit me?** | No alternative procedures are available for this study. |
| **12** | **Will my personal information be** | NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law. Data for this study are collected under the system of record notice (SORN) CDC Privacy Act System Notice 09-20-0147 and will be maintained in accordance with |

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| | **kept confidential?** | the Federal Privacy Act of 1974.<br><br>You will be given a unique number that we will use to manage your data. This number will be the only link to the data collected. During site visits, all data that can identify you will be on a secure laptop computer; any paper records will be kept in a locked box with the study researchers. When we return from the site visit, paper forms will be kept in a locked file cabinet in a secure area at the NIOSH office, and digital data will be stored in a restricted access computer folder.<br><br>We will not disclose identifiable, sensitive information about you and that was created or compiled for purposes of the research, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, or to any other person not connected with the research, unless you consent to such disclosure. The records identifying you will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. If the results of the study are published, your identity will remain confidential. |
| **13** | **Certificate of Confidentiality** | This research project has a Certificate of Confidentiality from the Centers for Disease Control and Prevention (CDC). Unless you say it is okay, researchers cannot release information that may identify you for a legal action, a lawsuit, or as evidence. This protection applies to requests from federal, state, or local civil, criminal, administrative, legislative, or other proceedings. As an example, the Certificate would protect your information from a court subpoena.<br><br>There are some important things that you need to know. The Certificate DOES NOT protect your information if a federal, state, or local law says it must be reported. For example, some laws require reporting of abuse, communicable diseases, and threats of harm to yourself or others. The Certificate CANNOT BE USED to stop a federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop reporting required by the U.S. Food and Drug Administration (FDA). The Certificate also DOES NOT stop your information from being used for other research if allowed by federal regulations.<br><br>Researchers may release your information when you say it is okay. For example, you may give them permission to release information to insurers, your doctors, or any other person not connected with the research. The Certificate of Confidentiality does not stop you from releasing your own information. It also does not stop you from getting copies of your own information. |

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| **14** | **Will I or anyone else receive study results?** | Responses from all study participants at your facility will be pooled, and we will create a summary report that can be shared with your facility. We will also create a summary report of all study participants across all participating facilities that can be shared with veterinary industry organizations.<br><br>We will not share individual details of your participation with anyone. You may also request the summary results. |
| **15** | **Will my personal information or samples collected from me be used in other research?** | The information that we collect from you may be used in future research studies. We believe that information from this study will aid in future studies in the veterinary industry.<br><br>We may remove your name and other identifiers from the information that we collect during the study and then use the information for future research studies without asking you for additional consent. We also may remove identifiers from the information that we collect and then share it with other researchers without asking you for additional consent. |
| **16** | **Is this a Clinical Trial?** | This is not a clinical trial. |
| **17** | **Did you receive all necessary information?** | We want to provide you with all the information you need to decide if you want to participate in this study. If you did not receive enough information to be able to decide, or if you want to discuss any of this information, please contact the co-principal investigators, Ethan Fechter-Leggett, DVM, MPVM at iun8@cdc.gov or 304-285-6030 and Kim Anderson, PhD at qdk5@cdc.gov or 304-285-6321. |
| **18** | **Who can I talk to if I have more questions?** | For questions about the research study, contact the co-principal investigators, Ethan Fechter-Leggett, DVM, MPVM at iun8@cdc.gov or 304-285-6030 and Kim Anderson, PhD at qdk5@cdc.gov or 304-285-6321.<br><br>For questions about your rights, your privacy, or harm to you, contact the Chair of the NIOSH Institutional Review Board (IRB) in the Human Research Protection Program at 513-533-8591. |