Appendix D. Informed Consent

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

	Consent to be in a Research Study ***Advancing Equitable PPE Protection for Women Working in Hazardous Environments***	
1	**Key Information Summary**	The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that studies worker safety and health. NIOSH is part of the Centers for Disease Control and Prevention (CDC). NIOSH is conducting a study to learn about challenges related to equitable personal protective equipment (PPE) protection for women across sectors and occupations. We particularly aim to discuss PPE use, availability, accessibility, acceptability, and knowledge. We aim to identify drivers and barriers to improve equitable PPE protections for female workers in healthcare, public safety, construction, and mining sectors. We will conduct focus groups with frontline female workers and management/administrative personnel separately. For example, separate focus groups consisting of female public safety employees; administrators/managers in public safety organizations. Each focus group will last 60 minutes. Before starting the focus group, we will ask you to verbally indicate whether you agree to participate. We will ask questions about health and safety factors related to PPE. We will document answers in writing, but we will not record conversations. Participation in this research is voluntary. You may refuse to answer any questions, and stop your participation at any time without any consequences. We will conduct focus groups during work hours. Participation in this research involves minimal risks. There is a small risk that collected information will be accidentally released. We will minimize the risk by identifying each focus group with a unique code that cannot be linked back to a workplace or to you. You can self-assign how you want to be addressed during the focus group. Due to a group setting, we are not able to guarantee actions of peers who participate in the focus groups once finished. However, the focus group ground rules will stress the importance of not sharing any of the discussion outside of the focus group. We will further minimize risk by releasing only summaries of information in reports, presentations, and publications. Only NIOSH researchers in this project will have access to focus group data.

* This template is based on a previous NIH Protocol Template for Behavioral and Social Sciences Research Involving Humans. It maintains much of the content and structure of the NIH template but has been tailored to CDC/National Institute for Occupational Safety and Health research.

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2	**Who is conducting the study?**	The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC).
3	**What is the purpose?**	The purpose of this research is to better understand challenges related to PPE use and knowledge across sectors and occupations for women. No framework exists to help recognize and overcome these challenges. Participating in this study will identify drivers, resources, and tools that can support both the selection and use of PPE for female workers as well as information to inform updated PPE designs.
4	**What will I do?**	You will be asked to voluntarily participate in a focus group – either in-person or virtual. A NIOSH researcher will ask about PPE use and protective factors. We will take notes to capture all answers. Participation in the focus group will take no more than 60 minutes.
5	**When, where, for how long will I be needed?**	If we are conducting virtual focus groups, we will meet via a virtual platform (i.e., Microsoft Teams). Or we will meet in-person at your place of employment or an pre-arranged place (e.g., conference room). You will participate during your usual work hours. The focus groups will last no more than 60 minutes, including time for consent.
6a	**Are there any risks from participating in the study?**	If you participate in a group discussion, there is a potential risk of a loss of confidentiality because you will be sharing your opinions among the group. Although we are asking all participants in the group to keep information shared confidential, NIOSH cannot ensure this aspect of your confidentiality, causing a slight risk that the information we collect could be accidently disclosed to someone else. This may cause you to experience psychological or social stress due to your loss of privacy. We will minimize this risk by identifying all data by code and by only releasing summaries of all data. Your name, email, and phone number were only collected for the purpose of scheduling the focus group. All of this information will be destroyed once the focus group is conducted.
6b	**Are there any risks related to COVID-19 during participation in this study?**	For research that is being conducted virtually, there is no risk you could get COVID-19 through an in-person interaction while participating in this study. For research that is being conducted in-person, scheduling occurred due to hospitalization rates in your area being low, minimizing the risk of SARS-CoV-2 infection. The option to wear barrier face coverings is available to reduce exposure risk.
7	**Are there other benefits?**	No one will be reimbursed or paid for participation. However, participants may indirectly benefit in that their efforts will be used to improve equitable PPE for female workers across high-risk industries.

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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 kept confidential?**	NIOSH will protect your information to the extent allowed by law. In this study, results are anonymous as we are not collecting or recording personal identifiers. You will be assigned a code throughout the study and in no records or notes will you be referenced by name.

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13	**Certificate of Confidentiality**	This research project has a Certificate of Confidentiality from 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. 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. 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.
14	**Will I or anyone else receive study results?**	If you wish, we will provide an aggregated report of results within 6 months of study ending. We will not share individual results with the organization, union, or individual employees.
15	**Will my personal information or samples collected from me be used in other research?**	We may remove other identifiers from the information that we collect and then use the information for future research studies without asking you for additional consent. We also may share it with other researchers without asking you for additional consent.
18	**Who can I talk to if I have more questions?**	For questions about the research study, contact the primary study contact Katherine Yoon at NYoon@cdc.gov or 412-386-6752. You can also contact the principal investigator Patrick Dempsey at PDempsey@cdc.gov or 412-386-6480. 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.
19	**Waiver of signature**	The study was explained to me. My questions were answered. I agree to be in the study.