Form Approved
OMB No. 0920-0109
Exp. Date xx/xx/20xx

Consent to be in a NIOSH Study NIOSH Respirator Approval Program Testing		
1	**Key Information**	Respirators are used in a wide range of occupations to help keep millions of workers protected from hazards in the workplace. To be effective, the respirator must seal almost entirely to the face, forcing inhaled breath to pass through the filtering media and not around the edges of the respirator. The Occupational Safety and Health Administration (OSHA) requires specific "fit tests" be performed to evaluate how well specific respirator models or designs seal to the face. The NIOSH Respirator Approval Program—housed in the National Personal Protective Technology Laboratory—oversees the approval of respirators worn in the workplace. NIOSH tests these respirators, with some tests using human participants to assess the fit abilities of respirators. Your participation will inform how different respirator models and designs fit the full spectrum of U.S. workforce to ensure that all workers are adequately protected. Your first visit will include an overview of the testing and facial measurements using calipers. During each testing visit, you will be asked to perform fit tests on different respirators. Participation in this testing is completely voluntary, and you may leave at any point with no loss of compensation due to you.
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 these testing activities is to gather information on how well different respirators protect the wearer in support of the NIOSH Respirator Approval Program.
4	**What will I do?**	• You will have your face measured using calipers. • If you have any facial hair, you may not be selected for testing certain respirator types. • You will be shown how to properly put on and adjust the respirator.

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		• You will wear a respirator and perform various tasks depending on the type of test. These tasks may include moving your head and body in various positions while a non-hazardous test chemical is present (corn oil, isoamyl acetate), talking/listening while wearing a respirator, being in a cold temperature, or fit testing per the OSHA fit test protocol.
5	**When, where, for how long will I be needed?**	The study will be done at NIOSH, 626 Cochrans Mill Road, Pittsburgh PA 15236. The first visit will last one hour including completing the consent form and facial measurements. Each testing visit may take up to 1 hour per test; you may be able to conduct multiple tests per day. If you are eligible and you choose to participate in these testing activities, you may be asked to visit the NIOSH laboratory several times a year, depending on the testing needs and your availability.
6a	**Are there any risks from participating in the study?**	• Risk of physical injury low and testing will not present any known risks. • There is some risk of discomfort due to sweating or dry mouth, or potentially inhaling sodium chloride or corn oil. The tests generally include very low intensity body movements from standing or sitting with normal breathing to talking or bending over at the waist. Walking or running during these movements may lead to fatigue, muscle cramps, or blusters. • Some respirators are slightly hard to breathe through and the skin under the respirator may feel warm or hot. • Some of the respirators you will test are not yet approved by NIOSH. This means they have not been tested to meet NIOSH standards. • Slips, trips, and falls are also a risk. NIOSH staff are required to keep the chambers clean and clutter free to lower the risk of these occurring. • You may feel claustrophobic while wearing the respirator. • A loss of confidentiality of personal information is also considered a risk. • The data will be collected without any identifiers that will link this information to you. Every effort will be made to keep the information collected during these activities confidential. Collected data will not use personal identifiers. A code will be assigned to each participant and the linkage information to connect the participant to any collected data will stored in a locked cabinet.

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6b	**Are there any risks related to COVID-19 during participation in this study?**	COVID-19 is a disease caused by a virus called SARS-CoV-2. COVID-19 most often causes respiratory symptoms that can feel much like a common cold, the flu, or pneumonia. Most people with COVID-19 have mild symptoms and some may have no symptoms, but some people can become severely ill, including hospitalization or even death. COVID-19 spreads when an infected person breathes out small droplets and particles that contain the virus. These droplets and particles can be breathed in by other people or land on their eyes, noses, or mouth. There is a very small risk you could get COVID-19 through an in-person interaction while participating in this study. To minimize your risk of exposure to COVID-19 and maximize your protection against infection, NIOSH researchers are taking several extra precautions, including: • Staying up to date with COVID-19 vaccines or screening negative for infection by testing. • limiting the amount of time spent closely interacting with you. • wearing masks. Most people who are infected with the virus that causes COVID-19 do not experience severe illness. However, some people may be at increased risk such as older adults (the risk increases with advancing age, especially above 50); pregnant people; persons with a variety of underlying medical conditions, and persons not up to date with COVID-19 vaccines. Serious illness from COVID-19 could result in healthcare expenses to you and could potentially result in temporary loss of income due to missed work time. Illness resulting from COVID-19 could also result in hospitalization, long term sickness, disability, death, and/or psychological effects that are currently uncertain or unknown. If you want to learn more about persons who may be at increased risk of severe illness from COVID-19, please visit CDC's webpage: People with Certain Medical Conditions | CDC. If a researcher learns he or she has COVID-19 within 48 hours of close contact with you or your co-workers, we will notify you and your company and provide information on testing and treatment. Symptoms of COVID-19 are listed on the CDC website. Please contact your medical provider if you are experiencing symptoms that are concerning to you. Test samples will not be shared among test participants. Equipment, reusable respirators, and surfaces will be frequently disinfected. Personnel involved with testing will comply with general CDC and NIOSH safety guidance including ensuring availability of handwashing facilities or hand sanitizer, avoiding handshaking, and disinfecting

		surfaces.
7	**Are there other benefits?**	You will not receive any direct benefits from participating in this study. Indirect benefits include informing how different respirator models and designs fit the full spectrum of U.S. workforce to ensure that all workers are adequately protected. This information will assist in the approval of respirators to be worked in the workplace.
8	**Is my participation voluntary?**	Your participation in these testing activities 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 due. Your participation in the study may be ended without your consent if you are unable or unwilling to follow the required study protocols or if we believe there is a risk to your safety or health. If you are a NIOSH employee, your decision to participate or withdraw from participation does not affect your NIOSH employment status, performance evaluations, compensation and benefits, assignment opportunities or career progression.
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 NIOSH finds your injury was a direct result of participation in the study and if appropriate documentation is provided, NIOSH may provide short-term medical treatment that it deems necessary to treat the immediate medical needs arising from the injury. In general, no long-term medical care or financial compensation of research-related injuries will be provided by NIOSH, the CDC, or the Federal Government unless a claim is filed with the Department of Labor (DOL), Office NIOSH will summon emergency medical aid by calling 911. If NIOSH finds your injury was a direct result of participation in the study and if appropriate documentation is provided, NIOSH may provide short-term medical treatment that it deems necessary to treat the immediate medical needs arising from the injury. In general, no long-term medical care or financial compensation of testing-related injuries will be provided by NIOSH, the CDC, or the Federal Government unless a claim is filed with the Department of Labor (DOL), Office.
10	**Will I be reimbursed or paid?**	No compensation will be provided at this time. This may change in the future. Your participation is voluntary, and you may withdraw your consent and your participation in this

		study at any time without penalty or loss of benefits to which you are otherwise entitled. If you are a NIOSH employee, see Section 18 of this consent form regarding administrative leave.
11	**What alternative procedures might benefit me?**	No alternative procedures are available for this study.
12	**Will my personal information be kept confidential?**	NIOSH is authorized to collect your personal information and will protect it to the extent allowed by law. There are conditions under the Privacy Act where your information may be released to collaborators or contractors, health departments or disease registries, to the Departments of Justice or Labor, or to Congressional offices. Information obtained in the course of your testing may be retained indefinitely with disposal at the discretion of NIOSH's Respirator Approval Program and any applicable laws or guidance from appropriate federal entities. Identifiers will be deleted for some uses of the information; however, the medical screening form will retain your name and other identifiable information. There is the potential that the information collected throughout the test may be used for other purposes in the future. For example, it may be used to evaluate how well specific respirator products fit individuals with your facial dimensions. Your identifiable private information will not be disclosed for these other purposes. Your identifiable private information will only be used to ensure that you are medically capable of participating in today's test. The findings of today's tests may be made available to the applicant as necessary; however, your identifiable private information will not be disclosed.
13	**Will I or anyone else receive study results?**	No participants will receive study results. The testing results are only going to be used to develop and evaluate respirator performance standards and guidance.
14	**Will my personal information or samples**	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

	collected from me be used in other research?	information that we collect and then share it with other researchers without asking you for additional consent.
15	**Is this a Clinical Trial?**	This study is not a clinical trial.
16	**Did you receive all necessary information?**	Are there any further questions you have about the study?
17	**Who can I talk to if I have more questions?**	For questions about the test, contact: Jeremy Brannen at 412-386-5209 or email JJBrannen@cdc.gov or, Jeremy Simons at 412-386-5789 or email JSimons@cdc.gov. For questions about your rights, your privacy, or harm to you, contact the Ethicist and Human Research Regulatory Administrator, Angela M. Morley, J.D., M.P.H. at Amorley@cdc.gov, or (513) 533-8222.
18	**Special Considerations for NIOSH Staff Participants**	I have been informed that: 1. You are aware that other NIOSH staff will be present during the procedure and will observe and hear you during testing. To safeguard your privacy, the medical screening will be performed by only a healthcare professional/provider with no other NIOSH staff able to observe or hear that discussion. Additionally, the minimum number of staff necessary to support the test procedures will be present. Furthermore, the applicant/approval holder who submitted the application to NIOSH will not be permitted to witness testing. 3. I am free to volunteer for this NIOSH study without pressure from supervisors or coworkers and without positive or negative expectations about my employment. 4. (Civil Service Employees) I must use supervisor-approved leave if my voluntary participation in this study is performed during my usual on-duty time, as follows: a. Annual leave, leave without pay (LWOP), compensatory time, or credit hours used (if working under an AWS) if monetary compensation is offered and accepted. If there is no monetary compensation, I still may request these types of leave. b. Administrative leave (excused absence, excused leave)

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<tr><th colspan="3">Consent to be in a NIOSH Study
NIOSH Respirator Approval Program Testing</th></tr>
<tr><td></td><td></td><td>may be authorized if I receive no monetary compensation. If you are unaware of this option and wish to pursue it, please inform the Test Administrator before the test occurs as authorization needs to be obtained in event. If administrative leave is approved for this purpose, and all other purposes, it cannot exceed 8 workdays during any calendar year.
5. (Commissioned Corps) I must take annual leave or supervisor-approved station leave for participation during my normal tour of
duty
6. If I participate during duty time, it cannot detract from duty
assignments or conflict with applicable fellowship, guest program,
contractor, or similar requirements or policies.
7. If I participate during off-duty time, it cannot conflict with fellowship,
guest program, contractor, or similar requirements or policies that
apply to me.

Any staff who wish to participate outside of their tour of duty, or while using any form of personal leave, you will be capped at 80 hours of participation in a single calendar year unless that participation is momentarily compensated. Staff may use both administrative and voluntary time without compensation in a single calendar year. These caps provide additional protections to staff by limiting their participation without any form of compensation.</td></tr>
<tr><td>19</td><td>Your signature</td><td>The study was explained to me. My questions were answered. I agree to be in the study.

_____
_____
Printed name of participant

_____
_____
Participant signature
Date

I have accurately described this study to the participant.</td></tr>
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		_____ NIOSH representative signature Date
20	**Additional consent**	N/A