TITLE: Superior Powered Air-Purifying Respirator Tests and New Technologies (SPARTAN)

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PROTOCOL SUMMARY

This is a controlled study to examine methods for quantifying powered air-purifying respirator (PAPR) performance, usability, and flow rates, as well as to improve effectiveness in healthcare while maintaining device safety and efficacy. Tests will be conducted at the Centers for Disease Control and Prevention (CDC) campuses in Pittsburgh, PA with a sample size of 25 evaluable subjects, and up to 75 subjects enrolled. Subjects will be considered evaluable if they meet screening requirements and fall within an available NIOSH/NPPTL Bivariate Panel cell category to provide representation of facial sizing for the U.S. workforce (Zhuang *et al*., 2007), and complete all study interventions within at least one of three phases. **Phase I** of this study will collect baseline physiological data to determine typical work rates for ten exercises identified in healthcare, without wearing a PAPR. Subjects will complete **Phase II**, replicating the ten activities from Phase I, while trialing eight models of PAPRs at two flow rates (NIOSH minimum and a reduced rate below NIOSH minimum flow rate), to determine simulated workplace protection factor (SWPF) values. **Phase III** will include two exercise regimens comprised of three exercises each, and subjects will trial eight models of PAPRs with the flow rate held constant at NIOSH approved minimum standard rate, to determine work rate effect on SWPF values when exercise regimen is modified by task order, work rate, and time.

The goal of this project is to aid development of a) improved test methods for quantifying PAPR performance and usability, and b) gain better understanding of the relationships between flow rate, work rate, respiratory inlet covering (RIC) design and performance. The SWPF test methods may be used in the future to assess next generation PAPR prototypes. Specific aims include: 1) to determine the effect of PAPR airflow rates on SWPFs; 2) to evaluate the effect of work rates on SWPF; and 3) to evaluate the effect of PAPR RIC design on SWPF. These three variables will also be assessed in terms of comfort and usability.

1.0 BACKGROUND AND SIGNIFICANCE

A PAPR is a respirator that uses a battery-operated blower and a cartridge, canister and/or high efficiency particulate air (HEPA) filter(s)**,** to provide the wearer with purified air through a RIC. A RIC can be categorized into tight-fitting facepiece (TFF), loose-fitting hood/helmet, or a loose-fitting facepiece (LFF)**.** NIOSH certification PAPR test requirements and conditions were established in 1972 (42 CFR 84). However, over the years**,** workplace conditions have changed**,** the need for advanced protection has evolved, and improvements in technology necessitate the updating of PAPR test requirements. Research is needed to progress existing test methods and to develop new evaluations for PAPR performance (PAPR protection), comfort of wearing, and ease of communication. This study will provide important data for standards development organizations (SDOs), manufacturers, and NIOSH certification processes to accommodate future PAPR design and safety. Studies have shown that some users rate current PAPR design as too heavy and noisy, especially in healthcare settings (IOM, 2015)**.** This study will provide data that may aid in the development of smaller lightweight devices with the same particulate protections as presently required, to improve workplace utility for today's diverse workforce.

1.1 Current Standards and Definitions

NIOSH Respiratory Protective Devices Final Rule 42 CFR Part 84

On June 8, 1995 NIOSH published 42 CFR Part 84 Final Rule on Respiratory Protective Devices, replacing NIOSHs original 1972 30 CFR Part 11 Rule. The requirements in 42 CFR

84 added new respiratory filter efficiency classification categories for non-powered air-purifying particulate respirators. In order to continue the approval of PAPRs to existing requirements, NIOSH established subpart KK in the new 42 CFR Part 84 rule 2. By maintaining 30 CFR 11 requirements, PAPRs would continue to be approved based on pre-1970s concepts and knowledge. PAPR blower motors must deliver a minimum flow rate of 170 liters/minute (Lpm) (for loose-fitting) or 115 Lpm (tight-fitting) to meet 42 CFR Part 84 requirements.

OSHA Assigned Protection Factors 29 CFR Parts 1910, 1915, 1926 71: 50121-50192

In a final rule on OSHA's Respiratory Protection standard (Federal Register 63, 1998), OSHA reserved the provisions incorporating Assigned Protection Factors (APFs) (See 63 FR 1152; 29 CFR 1910.134; 71 FR 50122, August 24, 2006.) which went into effect on November 22, 2006 (71 FR 50122). The APF for PAPRs depends on the type of respiratory inlet covering (RIC) and ranges from 25 (using a loose-fitting facepiece or loose-fitting hood) to 1,000 (for a tight-fitting full-facepiece, or for a loose-fitting hood which has been demonstrated by the manufacturer to have protection performance of $\geq$ 1,000.

OSHA Respiratory Protection Medical Evaluation 29 CFR 1910.134

OSHA's revised Respiratory Protection Standard (29 CFR 1910.134 and 29 CFR 1926.103) went into effect April 8, 1998. The standard replaces those adopted by OSHA in 1971. The mandatory OSHA Respirator Medical Evaluation Questionnaire standard was updated in 2012. In this protocol, the Appendix D "OSHA/NPPTL Respirator Medical evaluation questionnaire" is used for the medical screening of test subjects based on this requirement.

Table 1. Protocol Definitions

TERM	DEFINITION / VALUES
Assigned Protection Factor (APF)	The APF for PAPRs depends on the type of respiratory inlet covering (RIC). **Values:** 25 for loose-fitting facepieces or loose-fitting hoods 1,000 for tight-fitting full-facepiece (or for loose-fitting hood which has been demonstrated by the manufacturer to have protection performance of $\geqslant$ 1,000)
Flow Rate	In the United States, to meet 42 CFR Part 84 requirements, PAPR blowers must produce the NIOSH approved minimum flow rate. **Values:** 170 liters/minute (Lpm) for loose-fitting facepieces and 115 Lpm for tight-fitting facepieces
Hood	A respiratory inlet covering that completely covers the head/neck and may cover portions of the shoulders and torso.
Helmet	Differs from a hood only in that it provides a rigid head covering
Loose-fitting facepiece (LFF)	A respiratory inlet covering that is designed to form a partial seal with the face. **Value:** loose-fitting inlet coverings are used on supplied air respirators (SAR) as well as PAPRs. In the U.S., the minimum airflow for LFFs is 170 L/min (CFR, 1995).
Program Protection Factor (PPF)	An estimate of the respiratory protection provided to a worker in the context of a specific respirator program.
Simulated Workplace Protection Factor (SWPF)	SWPF is deduced by measuring a test atmosphere concentration outside (Co) while also testing the inside (Ci) of a properly functioning respirator in a laboratory using test exercises designed to simulate work. **Value:** Calculated as 0 to continuous, and is expected to at minimum be equivalent to APF value designated for the device (at least 25 or 1000 for PAPRs)

Workplace Protection Factor (WPF)	A measure of the protection provided in the workplace, under the conditions of that workplace, by a properly selected, fit tested and functioning respirator while it is correctly worn and used.
U.S. licensed health professional	An individual who is qualified by education, training, and licensure who performs a professional service within his/her scope of practice.

1.2 Literature Review

This literature includes a variety of workplace and laboratory studies assessing performance of PAPRs worn by test subjects. Unlike the U.S. NIOSH respirator certification standard (42 CFR 84) which specifies minimum flowrates allowable for PAPRs, British EN standards have no such requirement of lower limitations (British Standards Institute (a, b), 2008); thus studies of British EN certified PAPRs are included in this literature review, to provide reference for safe and feasible modification of a device to a lower than NIOSH minimum flow rate. This protocol will involve human subject testing with PAPR flow rates below the current NIOSH minimum requirements. Studies that used a supplied air respirator (SAR) are included in this review if flow rates were stated and judged to be within the range of a typical PAPR (170 to about 250 L/min).

Da Roza et al completed one important laboratory study which examined the effects of work rate, blower airflow, and beard growth on penetration of the polyethylene glycol 400 test aerosol in relation to the performance of a tight-fitting half facepiece PAPR and two LFF PAPRs, each fitted with HEPA filters (Da Roza et al., 1990). The half-mask PAPR was varied in flow from 225 to114 Lpm; the two LLF PAPRs had their flow varied from 170 to 86 Lpm and 202 to 114 Lpm. Airflow and differential pressure within the device were measured while the subjects walked on a graded treadmill at gradually increasing work rates. At 80% of each subject's maximum work rate, PAPR airflow rates were varied from those produced by fully charged batteries to rates below the required NIOSH minimum. After four to six minutes' cool-down, additional measurements were taken while subjects performed the following exercises for two minutes each: Bending and squatting, running in place, touching toes, raising arms over head, holding a rod while twisting torso and raising arms, and normal breathing. Each test was conducted with the subject clean-shaven, with three days beard growth, and again after 2-3 months of beard growth. Representative raw penetration data were presented rather than calculated laboratory protection factors. The authors found increasing work rate elevated penetration for both LFFs but did not increase penetration for the tight-fitting PAPR on clean-shaven subjects. Similar results were suggested for varying each device's airflow rates. Beard growth increased penetration of the tight-fitting PAPR, but the effect was not seen with the LFF devices. Negative pressure was seen within all the devices under some of the test conditions. Given the conflicting evidence for particle penetration in this study, further research is warranted for flow rate and work rate effect on PAPR performance.

Clayton et al. (2002) measured SWPF laboratory performance of two full facepiece PAPRs approved under European performance criteria (BSI, 1992). Limitations included failure to fit test the subjects, protrusion of spectacle temple bars through the face seal, and simulated battery failures, and lack of work rate or flow rate reported outcomes. The authors continuously measured facepiece penetration of a sulfur hexafluoride (SF_6) challenge over 3-4 hours of simulated asbestos removal. Work rate was not reported, but the tasks described would likely be classified as moderately heavy work. Neither airflow to the facepiece nor facepiece pressure was

monitored during the tests. Overall reported SWPF values ranged from 2,000 to 20,000 over 20 simulations. The remaining simulation had a SWPF of 400. Our current protocol also incorporates full-facepiece PAPRs to compare their performance to PAPRs with loose-fitting hoods/facepieces, and the design will remove the limitations experienced during this trial.

Seiple and Pappas (2003) tested the 3M Breathe Easy PAPR with a butyl rubber hood in a SWPF study. The challenge agent was 20-40 mg/m^3 polydisperse corn oil with a mass median aerodynamic diameter (MMAD) of 0.4-0.6 µm. Laser photometry was used to measure challenge aerosol and penetration on the operating (blower on) PAPR. U.S. Army standard sampling probes were used to collect in-hood samples. Seven standard fit testing exercises plus "sight the rifle," "reach for the floor and ceiling," and "on hands and knees, look left and right" were performed for one minute each by 24 test subjects. All SWPFs were greater than 20,000. Our current protocol also employs a varied set of dynamic exercises to determine the effect of each exercise on particle penetration in the PAPR hood or facepiece, however additionally studies flow rate effects.

Cohen et al. conducted a large SWPF study of loose fitting PAPRs with HEPA filters and supplied air respirators used in the pharmaceutical industry (Cohen et al., 2001). Five PAPRs with hoods, one loose-fitting facepiece PAPR, and six hood-style SARs were tested. Seventeen volunteers (60% men, 40% women) wore the devices in a test chamber. A polyethylene glycol 400 aerosol at a concentration of approximately 17 mg/m^3 and a mass median diameter of 0.44 µm was used as the challenge atmosphere. Light-scattering photometry was used to measure C_o and C_i aerosols; the C_i sample was taken with a nasal cannula beneath the subject's nose. The exercise regimen included 12 two-minute exercises that included "raising arm above head," "twisting at the waist while holding rod and raising and lowering arms," "scooping of pebbles," and "building of concrete block wall" in addition to standard fit testing exercises. Airflow from the PAPR blower or air supply and differential pressure inside the respirator were measured continuously during each test. Lower fifth percentile SWPFs for the five PAPRs ranged from 150,000 to >250,000, defined as the limit of quantification for the experimental setup. Supplied air devices had fifth percentile SWPFs ranging from 86,000 to >250,000, except for one SAR. The fifth percentiles for this device were < 20; the authors attributed this poor performance to an apparent design flaw: The device did not have a bib to tuck into the wearer's clothing. Fifth percentiles for the same device with a bib were four orders of magnitude higher. Additional insights can be gained from the airflow and differential pressure measurements Cohen et al. reported. Mean air flow rates in their study were all above the NIOSH required minimum of 170 L/min, ranging from 176 to 304 L/min. The poorly performing SAR had a mean flow rate of 234 L/min and a minimum of 203 L/min. One hood-style PAPR and the LFF PAPR, were found to have occasional airflow measurements as low as 132 and 149 L/min, respectively. Interestingly, the hood-style PAPR had slightly higher fifth percentile SWPFs. The authors noted “There was no consistent pattern among the relationship of pressure measurements taken inside the facepiece [sic] and the corresponding SWPFs recorded.” The Cohen et al. study appears to support the ideas suggested later by several studies conducted by Johnson and Koh (Johnson et al., 2008; Koh et al, 2011; Johnson et al., 2011; Koh and Johnson, 2012). That is, design characteristics may affect the protective performance of loose-fitting devices in addition to their rate of airflow, **and higher flow rates do not assure a higher level of performance**. The effect of occasional negative pressure spikes on the protection provided by loose-fitting respirators is not great; this could be related to dead volume, e.g., hood vs. LFF. Our current protocol design includes a diverse selection of PAPR designs to determine if the overall type of design (e.g., helmet

mounted blower vs. belt-mounted blower, full shroud vs. loose-fitting facepiece at chin, the use of a tight-fitting full-facepiece) affects particle penetration. In addition to including a diverse selection of PAPR designs, our protocol will also study the effects of subject work rate, PAPR flow rate, and type of exercise on PAPR performance.

1.3 Current State of Knowledge

Previous laboratory studies are inconclusive regarding the effects of flow rate and work rate on simulated protection, likely due to various limitations identified in their protocols, supporting additional research is warranted. Da Roza et al. (1990) concluded no increase in penetration with increasing work rate for a tight-fitting PAPR but did however note an increase with two LFF models. Bolsover et al. (2006) also found increased penetration with decreased flow rate in a single LFF. Conversely, the Cohen et al. study (2001) demonstrates that some negative pressure events (due to increased work rate or decreased airflow) do not significantly affect SWPFs. The work of Johnson and Koh further suggest that design considerations such as shrouds, dead volume and a tortuous path of leaked air to the breathing zone may also contribute to how much contaminated air reaches the respiratory tract (Johnson et al., 2008; Koh et al, 2011; Johnson et al., 2011; Koh and Johnson, 2012).

Additional research is necessary to fully understand how LFF PAPRs provide protection to the user. The literature suggests that if changes are made to PAPR certification requirements, they should be performance oriented. That is, a PAPR must demonstrate the ability to reduce exposure by a specified amount rather than deliver, for example, a specified airflow. Ideally, laboratory performance requirements would be validated with workplace test methods before they are implemented.

2.0 OBJECTIVES AND SPECIFIC AIMS

PAPRs have become an important and attractive type of respiratory protection to defend against high-level respiratory hazards and infectious body fluids in health care settings. But challenges (noise, overall bulkiness, visual impairment, interference with tasks, and issues related to decontamination, among other problems associated with their use) have limited widespread utilization of PAPRs in healthcare settings. This is because PAPRs were originally developed to protect industrial workers (primarily in mining) with heavy work rates. And the designed flow rate of PAPRs is driven by the work rate of users. Since the typical work rates of healthcare workers are significantly lower than those of industrial workers, a lower PAPR air flow rate may be justified to provide a sufficient level of protection. This study will determine whether protection is maintained at lower flows during simulated workplace exercises.

The objectives in this study, including studying the effect of PAPR flow rate, will aid the development of PAPRs, in three ways; 1) offering alternative respiratory protection in the event of a filtering facepiece respirator (FFR) shortage, 2) standards development, and 3) allowing for the development of next generation PAPRs.

2.1 Primary Objectives

a. Understand the relationship between PAPR flow rate and SWPF during routine healthcare exercises
b. Understand the relationship between user work rate and PAPR SWPF

2.2 Secondary Objectives

a. Assess PAPR usability and comfortability at varying work and flow rate conditions
b. Understand the relationship between PAPR RIC design and SWPF

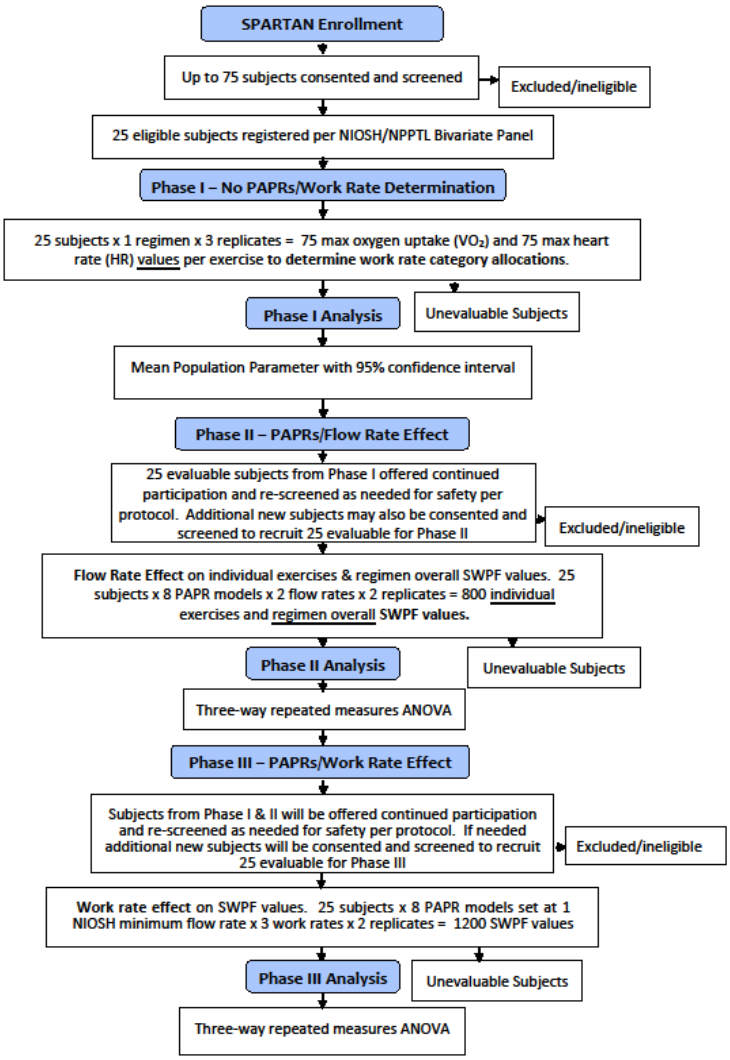
2.3 Exploratory Objectives

a. Develop and evaluate next generation PAPR prototypes using SWPF test methods
b. Evaluate the SWPF test method as a standardized test method for PAPRs with a loose-fitting facepiece

3.0 STUDY DESIGN AND METHODS

This project promotes developed PAPR design through 1) improved test methods for quantifying PAPR performance and usability, 2) better understanding of the relationships between flow rate, work rate, design characteristics, and performance. The multi-disciplinary project team includes collaborators from across NPPTL. The key scientific questions this study will address include the relationships between flow rate and protection as well as work rate and protection. The interaction of design features such as dead volume and the size/configuration of shrouds will also be studied. The answers to these questions will impact potential solutions to make PAPRs quieter and lighter to improve use in a healthcare setting. The information will also guide decisions regarding potential changes to the PAPR standard 42 CFR 84 and OSHA standard 29 CFR Parts 1910, 1915, and 1926. The design of this study includes three phases to be completed in sequential order (Figure 1.).

Figure 1. SPARTAN Protocol Flow Chart (CONSORT 2010)



3.1 Screening Design

A sample of 25 evaluable test subjects will be included in this study and up to 75 subjects enrolled. Following recruitment and consent, subjects will undergo facial measurements to determine if they fit into an available cell category of the NIOSH/NPPTL Bivariate Panel (Fig. 2 and Table 2) used to collect facial dimension representation of the US workforce. The sample size of 25 subjects was first proposed by Landsittel et al. (2014) and later supported by inter-panel variability results reported by Zhuang et al. (2015) and Liu et al. (2016). The numbers in each cell in Figure 2 represent cell category number. The numbers in parentheses indicate the number of subjects to be sampled in that category. When the subject's face length or face width fall on the boundaries, the subject is classified into the higher number cell category.

A sample size of 25 subjects (calculated using G*Power 3.1.9.2.) also provides the researchers with acceptable levels of precision to estimate population parameters and to compare SWPF results across flow rates and work rates. Previous research by the PI has found the standard deviation among sets of SWPF scores for PAPRs to be considerably low when compared to the average. Studies have shown a geometric standard deviation of ~1.5-3.5—while SWPF mean values can be in the thousands. This mean to standard deviation ratio allows for very precise estimates of population parameters with relatively small samples of 25 subjects. It also makes comparison among conditions of the study to be precise. However given that small differences in

SWPF can make a meaningful practical difference the researchers' goal is to estimate precise population parameters and detect small differences between conditions as significant. A sample of 25 and a repeated measures design (as explained below) allow the researchers to detect an effect size of 0.4 as significant. This effect size means that a little less than one half of the standard deviation can be detected as significant when dependent means are compared.

After being determined to fit into an available cell category, thus filling the target population of the U.S. workforce, the remaining screening components assess the subjects' abilities to wear a respirator and perform the required exercises safely. The medical screening components seek a subject population without chronic health problems that may increase the risk when exercising or wearing a respirator. These risk factors may be self-reported by the subjects or physiologically measured.

Subjects will complete the OSHA/NPPTL Medical Evaluation form (Appendix D), the NPPTL Screening Medical Evaluation (Appendix E), and the NPPTL Subject Data Form (Appendix F). Subjects that would like to participate in more than one Phase of this study, which may lead to > one year involvement, will be re consented and re-screened at minimum yearly, as is standard in human subject's research, for collection of potential baseline result changes, for example facial dimension, weight, and maximal heart rate. Because OSHA has determined that fit testing of respirators must be completed annually at minimum due to potential changes in baseline measurements and medical considerations, we will use their suggested length of time determined by OSHA research and expertise in this arena, to base our re-screening timeframe, in the event a subject participates for > one year. Additionally, a yearly medical evaluation has been established in the NPPTL Protocol for Human Subject Testing for Respirator Inward Leakage (IL) (HSRB 14-NPPTL-02).

However, we will additionally at every study visit during each calendar year review changes in health and wellbeing with subjects prior to testing, to also reduce risk in between re-screening each year. If during a routine visit within a calendar year from date of screening, a subject is found to have medical and/or physical changes from baseline that may increase their risk to participate (based on Pre Visit Medical Evaluation with the medical monitor CRNP), consideration for early re-screening or participant discontinuation will be reviewed by medical monitor CRNP and study team.

Figure 2. NIOSH panel based on face length and face width

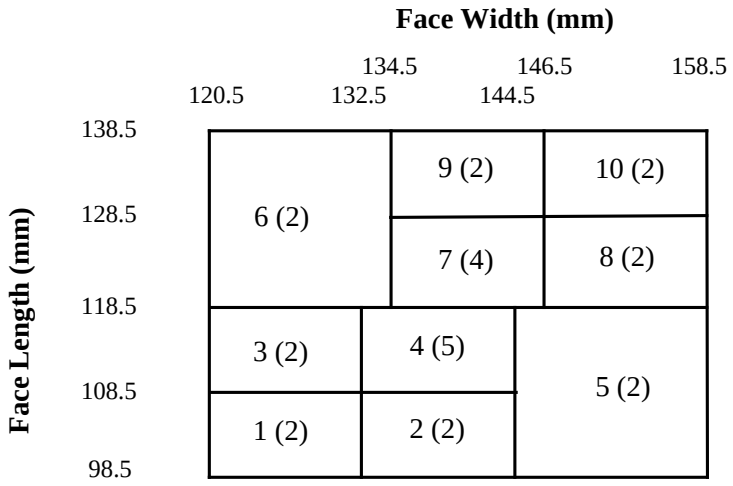


Table 2. Percentage of Population and Number of Subjects by Cell for the Panel

NIOSH BV Cell	Percentage of Population	No. of Test Subjects
1	5.5	2
2	5.3	2
3	10.5	2
4	25.0	5
5	7.1	2
6	5.7	2
7	21.3	4
8	8.7	2
9	5.2	2
10	3.5	2
Total	97.7	25

Fit Testing

Tight fitting PAPR models require an approved OSHA fit test to determine safe and protective seal for the user. To verify NIOSH/NPPTL cell category allocation accuracy, each subject will complete fit testing for all three tight fitting PAPRs to be used in Phase II of this study, even if a subject is anticipated to only participate in Phase I. For the tight-fitting PAPR fit tests, a 2% NaCl solution in distilled water will be used as a generator solution under room conditions (in a laboratory, but outside of a test chamber). A particle generator (Model 8026, TSI, Shoreview, MN) and an OSHA approved condensation nuclei count protocol with PortaCount Plus (Model 8038; TSI) will be used.

Maximal Graded Exercise Test (GXT)

Subjects will undergo a Maximal Graded Exercise Test according to the Bruce protocol (Appendix K) to further review medical eligibility and subject specific termination criteria, such as maximal heart rate, for this study. This test will also obtain physiological measurements

(maximal oxygen uptake and maximal heart rate) that will be used in Phase I calculations. This will take place in the NPPTL physiology lab using a treadmill and metabolic cart. It may also take place in the NPPTL Building 40 environmental test chamber and high bay area, which is also equipped with a treadmill and metabolic cart. See Appendix K for complete procedure and metabolic cart measurements.

3.2 Phase I

Phase I is designed to test a novel healthcare practice-based exercise regimen for SWPF testing of PAPRs with 25 evaluable subjects that represent the US workforce facial measurements. In this phase, subjects will not wear PAPRs, however they will complete one 30-minute regimen that includes ten, 3-minute exercises to determine Work Rate category allocation per exercise. The simulated workplace exercises were created based on: a) exercises from ANSI (American National Standards Institute) and OSHA respirator test protocols (ANSI, 2010; CFR, 1998); and b) routine healthcare activities (Table 3.). This phase will be completed without PAPRs and subjects will have physiological measurements taken with a metabolic cart. During each exercise regimen replicate subjects will be equipped with a heart rate (HR) monitor and silicone-rubber oronasal facemask from the metabolic cart. Expired air sample will be analyzed for oxygen uptake (VO_2), minute ventilation (V_e), and carbon dioxide (VCO_2).

25 subjects x 1 regimen x 3 replicates = 75 max oxygen uptake (VO_2) and 75 max heart rate (HR) values per exercise to determine work rate category allocation (Table 4.). In this study phase, the data will be analyzed after all 25 subjects complete the first of three attempts so that each exercise will have 25 values calculated. Subjects will complete all consent and screening items, along with the first replicate of Phase I during their first visit (~3 hours) and will complete the second and third replicates on a different visit (~3 hours). Phase I will be conducted in conjunction with screening and completed over 2 visits (~6 hours total). It is anticipated that all subjects will complete Phase I/screening in 3-6 months (July 2019-December 2019).

Mean Population Parameter with 95% (1.960) confidence interval will be used to analyze data. For each exercise, if the 95% confidence interval is within theoretical bounds for each work rate, then the second and third replicates will not need to be completed and Phase II of this study will begin. The theoretical bounds can be found under the relative intensity columns in Table 4.

Hypothesized Work Rates

The 10-exercise regimen includes hypothesized light, moderate, and hard work rates. These work rates will be verified during Phase I using a metabolic cart. Average values for work rate will be calculated for each exercise across all individuals test data. The hypothesized work rates in Table 3 will be determined and verified and /or modified for regimen use in Phase II.

These hypothesized work rates will also dictate the order in which the exercise regimen is performed during Phases I and II. Exercises will be selected from Table 3 and performed in the following sequence, with gradually building intensity; 1) light, 2) moderate, and 3) hard. A short break will be given to subjects following a hard exercise to allow the subject's heart rate to return to within 20 bpm of the initial baseline value (~ 10 minutes). They will repeat this sequence (light, moderate, hard, break) once more with three different exercises from Table 3, and then a third time with the remaining four exercises (this time with two light exercises), which will conclude the test.

This sequence was established for subject safety reasons and scientific reasons; 1) to avoid a "carry-over" effect between exercises (i.e. a more intense exercise affecting measurements of the following exercise), 2) to increase the likelihood of subjects completing the full 3 minutes of exercise, and 3) it is less physically demanding to the subjects.

Table 3. Exercise Regimen

Exercise #	Test exercise	Approximate Duration (min)	*Hypothesized Work Rate*
1	**Normal breathing**: normal breathing while standing	3	Light
2	**Reading:** reading the rainbow passage while standing	3	Light
3	**Moving head side-to-side:** moving head side-to-side at approximately 10 times/min while standing	3	Light
4	**Moving head up and down:** moving head up and down at approximately 10 times/min while standing	3	Light
5	**Twisting at waist with weight:** Twisting at waist to the left while holding with both hands a 10-lb bag equipped with a handle, raising and lowering arms and then repeat this to the right, at a rate of 12-15 sets/min.	3	Moderate
6	**Reaching up and stepping out (Modified jumping jack):** bending the left knee slightly while reaching up both arms overhead & looking up and stepping the right leg out to the side, then repeat with the other leg, at a rate of 10-12 sets/min.	3	Moderate
7	**Walk on a treadmill**: walking upright on a treadmill at a speed of 3 mile/h without movement of the head, and without speech.	3	Moderate
8	**Bending and Picking up weight**: bending to pick up two weighted bags equipped with a handle (5-lb bag/each hand) and carrying them from side-to-side of the testing chamber at a moderate walking pace, then bending to put down weights. Repeat for 3 minutes.	3	Hard
9	**Perform CPR/AED:** perform CPR on a training manikin by compressing chest cavity ~1.5 - 2 inches at a rate of 80-100 compressions/min. 2 min of CPR followed by 1 minute of AED use.	3	Hard

10	**Stair climbing:** stair climbing (using a 3-step ladder) climb rate ~ 10-12 cycles/min (one cycle = up 3 steps and back down 3 steps).	3	Hard

Work Rates

Average work rates will be determined for each individual exercise for each subject, and the mean values will be then calculated for each exercise for all 25 test subjects. Work rate classifications are listed in Table 4 below (American College of Medicine, 2013).

Table 4. Work Rate Classifications for Physical Activities

Classification of Physical Activity Intensity

	Relative Intensity		Absolute Intensity Ranges (METs) Across Fitness Levels			
Intensity	$\dot{V}O_2R$ (%) HRR (%)	Maximal HR (%)	12 MET $\dot{V}O_{2max}$	10 MET $\dot{V}O_{2max}$	8 MET $\dot{V}O_{2max}$	6 MET $\dot{V}O_{2max}$
Very light	<20	<50	<3.2	<2.8	<2.4	<2.0
Light	20–39	50–63	3.2–5.3	2.8–4.5	2.4–3.7	2.0–3.0
Moderate	40–59	64–76	5.4–7.5	4.6–6.3	3.8–5.1	3.1–4.0
Hard (vigorous)	60–84	77–93	7.6–10.2	6.4–8.6	5.2–6.9	4.1–5.2
Very hard	≥85	≥94	≥10.3	≥8.7	≥7.0	≥5.3
Maximal	100	100	12	10	8	6

The information from the GXT (Appendix K) has a screening purpose and a research purpose. It will be used for 1) safety screening prior to participation and establishment of test termination criteria (Section 7.4) and 2) relative workload determination for the desired work-related activity in Table 3. Work rates in Table 4 will be determined for each exercise as a percentage of the subjects' maximum oxygen uptake and maximum heart rate, both of which are measured during the GXT.

3.3 Phase II

Phase II is designed to test flow rate effects on individual exercises & regimen overall SWPF values. This phase will include the 25 evaluable subjects from Phase I if they are interested in continued participation. If subjects from Phase I decline or are no longer eligible, additional subjects may be consented and screened for recruitment utilizing the modified screening requirements from Phase I (Appendix A, Study Calendar 1). Phase II will use the exercise regimen (Table 3.) and work rates determined in Phase I, with eight different PAPR models and two flow rates for each PAPR. Subject's will complete one 30-minute regimen = ten, 3 minute exercises completed in sequential order from light to hard work rates with breaks following the hard exercises (see Section 3.2) for sequence. 25 subjects x 8 PAPR models x 2 flow rates x 2 regimen replicates = 800 overall SWPF values (based on 10 exercises). Three Way Repeated Measures ANOVA will be used to analyze the data.

Each subject will come in to test 2 PAPRs and 2 flow rates per visit for approximately 3 hours, for a total of 4 visits (~12 total hours) to complete the first replicate of tests. The subjects will repeat the same procedure for the second replicate, meaning each subject will complete Phase II over the course of 8 visits of approximately 3 hours per visit (~24 total hours). It is estimated that this phase will take 6 to 9 months (November 2019-July 2020).

PAPR Models

Eight PAPR models (4 PAPRs with loose-fitting hoods, 2 loose-fitting facepiece PAPRs with helmets, and 2 tight-fitting PAPRs) were selected for this study (Table 5.). The models were selected based on: 1) prevalence of respirators in healthcare (Wizner, 2016) and 2) their commercial availability. The assigned protection factors for each PAPR is 25 or 1000. Tight fitting full facepieces (models 1-2) have a tight seal along the chin and sides of face. Loose-fitting full hoods (models 3-6) have a shroud covering the shoulders down to the mid-torso. Loose-fitting facepieces (models 7-8) have a cuff that loosely contacts the chin and the sides of the face. Each PAPR device weight will be measured and recorded. All PAPR devices used in this study will be set at the same airflow rate. Each subject will be asked to complete the comfort survey after each PAPR tested with all three flow rates in Phase II (Appendix M).

Table 5. Phase II PAPR Models

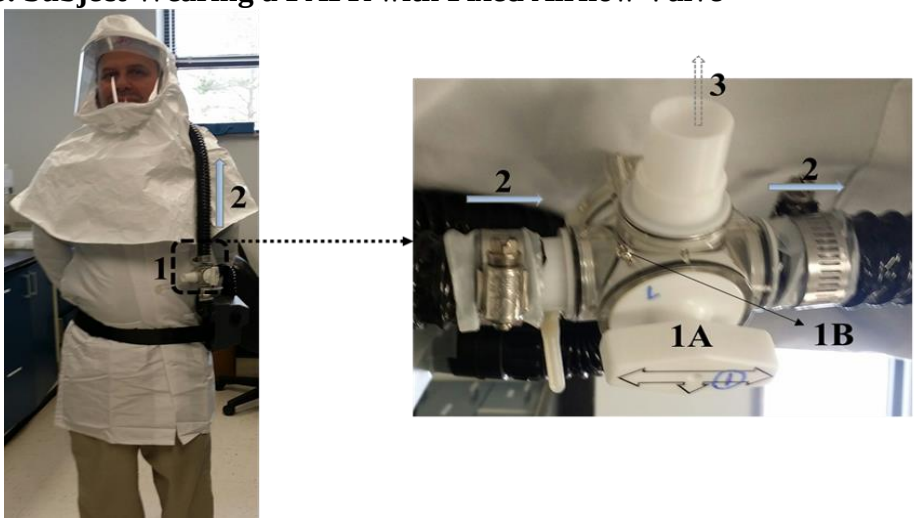
#	PAPR MODEL	OSHA APF	RIC DESIGN
1	**Bullard EVA**	1000	tight-fitting full facepiece
2	**MSA OptimAir**	1000	tight-fitting full facepiece
3	**3M Versaflo** hood (S-403L (M/L size) hood (S-403S (S/M size)	 1000 1000	loose-fitting full hood
4	**ILC Dover Sentinel XL** S-2019-10 (one-size)	 1000	loose-fitting full hood
5	**Bullard EVA** 20TIC hood (one-size)	 1000	loose-fitting full hood
6	**Maxair Helmet CAPR w/ HE filter (Bio-Medical Devices, Inc.)** 2261-01ML 2261-01SM	 25 25	loose-fitting full hood
7	**Maxair Helmet CAPR w/ HE filter (Bio-Medical Devices, Inc.)**	25	loose-fitting facepiece

8	**3M VersaFlow w/ S133 cuff facepiece**	25	loose-fitting facepiece

Flow Rates

The two PAPR airflow rates tested in Phase II include: 1) 170 L/min for loose-fitting PAPRs and 115 L/min for tight-fitting PAPRs (based on the current NIOSH minimum certification airflow rates) and 2) 125 L/min for loose-fitting PAPRs and 100 L/min for tight-fitting PAPRs (experimental airflow rates below the NIOSH certification requirement). Flow rates at and below the NIOSH certification minimum, PAPRs will be modified and therefore not NIOSH certified. Modifications to these devices will reduce airflow by one of two ways as determined by the study team: 1) controlling voltage to the PAPR motor, 2) installing a 3-way valve into the blower hose (if equipped) to bleed-off excess flow (Figure 3).

Figure 3. Subject Wearing a PAPR with Fixed Airflow Valve



Simulated Workplace Protection Factor

SWPF testing will take place in both Phase II and Phase III, following the work rate determination in Phase I. Test subjects wearing PAPR will enter the test chamber and complete the exercise regimen (Table 3.) against a corn oil challenge aerosol.

For this test, a TSI Rear Light Scattering Laser Photometer, model 8587A, will be used to measure aerosol concentration inside of the respirators. A TSI model 8520, Dustrak Aerosol Monitor will be used to monitor chamber particle concentrations. Data collected by the laser photometer will be recorded on the NIOSH Dynamic Fit Software. Data will be analyzed using a three-way repeated measures ANOVA with subject number, model, and work rate, and the log transformed SWPF of each test as the dependent variable. The relative importance of each variable to PAPR performance will be determined. The SWPF will be calculated in two steps as follows:

1. Ratio of the Upstream and Downstream Particle Concentrations

$$SWPF_i = \frac{C_{out}}{C_{in}}$$

Where: SWPF = simulated workplace protection factor; i = exercise number; C_{out} = upstream particle concentration; C_{in} = downstream particle concentration

2. Overall SWPF for Each PAPR Model

$$Overall\ \ SWPF = \frac{n}{\frac{1}{SWPF_1} + \frac{1}{SWPF_2} + \bullet\bullet\bullet + \frac{1}{SWPF_{n-1}} + \frac{1}{SWPF_n}}$$

Where: $SWPF_n$ = simulated workplace protection factor for a given exercise; n = number of exercises used during an SWPF test.

Test Chamber

The SWPF testing will be conducted inside a 16' x 16' x 10' charged corn oil test chamber in Building 40 of the National Personal Protective Technology Laboratory in Pittsburgh, PA. SWPF test setups are displayed in Figures 4A and 4B.

A 99% stock corn oil (CAS #8001-30-7) with the commercial product names Maise/Maize, Maydol, and/or Mazola oil will be used for test aerosol. It will be aerosolized using an MSP Model 2045 High Output Aerosol Generator capable of maintaining 5 to 100 mg/m^3 of corn oil challenge aerosol concentrations for the required test duration. For SWPF testing, the test chamber will be maintained at ~20-40 mg/m^3. The output aerosol will be dried with 30% dilution air, followed by neutralization with a Kr-85 charging source before entering into the exposure testing chamber. The aerosol will have a Mass Median Aerodynamic Diameter (MMAD) of 0.4 to 0.6 µm, with a geometric standard deviation of less than 2.0. This size distribution will be measured once daily using a Scanning Mobility Particle Sizer (SMPS) system. This system is comprised of the TSI model 3080 Electrostatic Classifier, TSI model 3775 Condensation Particle Counter, and 3081 Long Differential Mobility Analyzer (DMA).

The aerosol in the exposure chamber will be mixed using four internal fans positioned in the top four corners of the charged corn oil test chamber, and the chamber conditions will be tracked by a humidity/temperature sensor. Corn oil aerosol particles will be continuously dispersed into the chamber, while an open exhaust port will remove excess air and maintain neutral pressure.

Figure. 4A: Aerosol Chamber Testing System for Loose-Fitting PAPRs

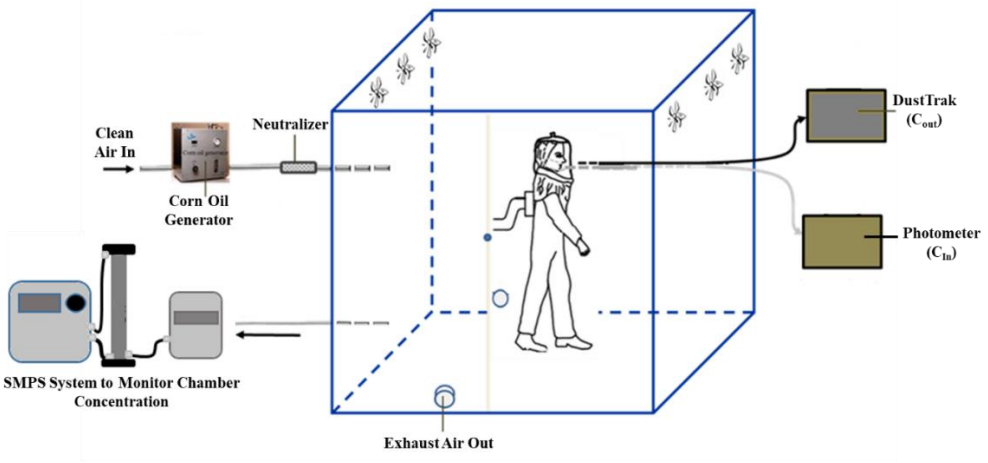
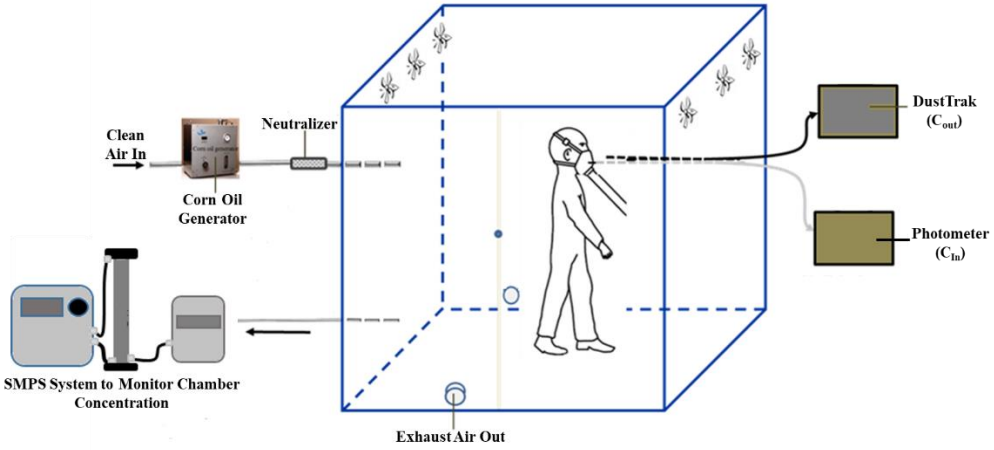


Figure. 4B: Aerosol Chamber Testing System for Tight-Fitting PAPRs



Subject Monitoring

During testing subjects will be equipped with a fingertip-pulse oximeter (AG Industries, St. Louis, MO) to monitor oxygen saturation information during testing. **If the subject's O_2 saturation level goes below 90%, the test will be terminated.** Subjects will also be equipped with a differential pressure line and a CO_2 line for monitoring CO_2 accumulation in the RIC. A CO_2 gas analyzer (CD-3A carbon dioxide analyzer and S-3A/I oxygen analyzer, AEI Technologies, Chicago, IL (or equivalent) will be used to continuously monitor CO_2 gas (percentage by volume) inside the PAPR facepiece during SWPF testing. The PAPR facepiece will be fitted with a sampling probe; flexible tubing will transport the in-mask sample to the CO2 analyzer which will be located outside of the corn oil chamber.

3.4 Phase III

This phase will include 25 evaluable subjects from Phase I and/or II if they are interested in continued participation. If subjects from Phase I and/or II decline or are no longer eligible, additional subjects may be consented and screened for recruitment utilizing the screening requirements from Phase 1 (Appendix A, Study Calendar 1). Design for testing as described in Phase II to include: simulated workplace protection factor, test chamber, and subject monitoring will be used once more in this phase, minus flow rate adjustments.

This phase includes alteration of the exercise regimen used in Phase I & II by number of exercises, order of exercises, and length of time per exercise to determine Work Rate Effect on individual exercise and overall regimens SWPF values. For this phase, two sets of 3-exercise regimes will be used (Table 6), representing low, moderate, and hard expected work rates, with each exercise taking approximately five minutes. The flow rates in this phase will be constant at the NIOSH minimum for certification (170 L/min for loose-fitting and 115 L/min for tight-fitting).

Two 15-minute regimens (Table 6.) were selected from the exercise regimen in Phase I and II (Table 3.). A ten-minute break for subjects will occur between each regimen in this phase but not in between each exercise within a regimen. Exercise regimens were designed to simulate light, moderate, and hard healthcare activity work rates as determined in Phase I.

25 subjects x 8 PAPR models set at 1 NIOSH minimum approved flow rate x 3 work rates x 3 replicates = 1200 overall SWPF values (based on 2-exercise regimens). Three Way Repeated Measures ANOVA will be used to analyze the data.

Each subject will come in to test 4 PAPRs and 3 work rates (30 min) per visit for an approximate 3 hour test session, meaning subjects will complete the first replicate in 2 visits (~6 hours total). The subjects will repeat this procedure for the second replicate for a total of 4 visits (~12 hours total) to complete Phase III. It is estimated that this phase will take 3-6 months (April 2020-September 2020).

Test subjects wearing the PAPRs will enter the chamber and perform two different exercise regimens (Table 6.). SWPF testing and chamber set up will be the same as during Phase II (Section 3.3). Laser photometer and Dustrak will be used to measure aerosol concentration inside and outside of the respirator, respectively. The SWPF for all particle sizes (10–1,000 nm) inside and outside the respirator will be determined. Each subject will be asked to complete the comfort survey after each PAPR tested in Phase III (Appendix N).

Table 6. Phase III Exercise Regimens

Exercise regime	Exercise #	Test exercise	Approximate Duration (min)	*Hypothesized* Work Rate
A	2	**Reading:** read the rainbow passage while standing	5	Light
	6	**Reaching up and stepping out (Modified jumping jack):** bending the left knee slightly while reaching up both arms overhead & looking up and stepping the right leg out to the side, then repeat with the other leg, at a rate of 10-12 sets/min.	5	Moderate
	9	**Perform CPR/AED:** perform CPR on a training manikin by compressing chest cavity ~1.5 - 2	5	Hard

		inches at a rate of 80-100 compressions/min. 2 minutes of CPR followed by 1 min AED, followed by 2 more minutes of CPR		
Minimum of 10 minute break in between regimens and vital signs return to within baseline limits				
B	3	**Moving head side-to-side:** moving head side-to-side at approximately 10 times/min while standing	5	Light
	7	**Walk on a treadmill**: walking upright on a treadmill at a speed of 3 mile/h without movement of the head, and without speech.	5	Moderate
	10	**Stair climbing:** Stair climbing (using a 3-step ladder) climb rate ~ 10-12 cycles/min (one cycle = up 3 steps and back down 3 steps).	5	Hard

4.0 HEALTHY HUMAN SUBJECTS

Minority Inclusion and Non-Discriminatory Statement: Subjects will be recruited from the general population of western Pennsylvania and West Virginia regions. No exclusion criteria will be established based on race, ethnicity, or gender. Subjects will be at least 18 years of age and less than age 55, and no prisoners will be used for this study. The upper age range of 55 was imposed due to the intensive exercise components of this study. Both men and women will be included in the study; however, subjects for either gender should not exceed 68% of total evaluable subjects to better demonstrate US workforce representation (i.e. no more than 17 evaluable subjects should be used from one gender)

4.1 Inclusion Criteria

- Ability to understand, the willingness to participate, and the completion of a written informed consent document
- Understands spoken and written English language as required for consent and instruction
- Age $\geq$ 18 years old and < 55 years old
- OSHA/NPPTL Medical Evaluation Form completed by the participant and reviewed/signed by a U.S. licensed health professional such as a registered nurse or certified registered nurse practitioner (Appendix D.)
- If a subject reports “yes” to any medical condition listed on the OSHA/NPPTL Medical Evaluation Form (Appendix D.) in Part B for Questions 2, or 10 to 15, a Certified Registered Nurse Practitioner/Registered Nurse must review the subject’s current and past medical history and provide written documented clearance for the subject to participate.

- NPPTL Screening Medical Review completed by participant and U.S. licensed health professional (Appendix E.)
- Two head and face measurements using a tape measure and calipers, values recorded on the anthropometric data form (Appendix J)
- NIOSH/NPPTL Bivariate Panel (Fig. 2 and Table 2) facial measurements and cell category availability based on their allocation to provide representation of the US workforce (if a cell category is full the subject will be considered a screen fail, however can rescreen at a later date if a subject in their cell category is not considered evaluable).
- Subject will pass fit testing for three models of tight fitting PAPRs, with sizes provided by the NIOSH/NPPTL Bivariate Panel
- Subject completion of the Subject Data Form (Appendix F), including agreement to refrain from caffeine consumption 12 hours prior to and during testing and smoking 1 hour prior to and during testing
- Complete maximal graded exercise testing with treadmill protocol (Appendix K) and achieve a maximal oxygen consumption **above** "Poor" category (e.g. Fair to Excellent categories required for inclusion) based on American College of Sports Medicine Fitness Categories for Maximal Aerobic Power (treadmill test)
- Review of the NPPTL General Photo Release Form (Appendix U).

4.2 Exclusion Criteria

- Facial hair, jewelry, or head and neck injury which may interfere with wearing a PAPR
- Chronic or current pulmonary or lung problems reported by subject (reports "yes" to any item in Part B. questions 3 or 4) on OSHA/NPPTL Medical Evaluation Form (Appendix D.) These are absolute exclusions.
- Self-reported chronic or current cardiovascular problems (reports "yes" to any item in Part B. questions 5 or 6) on OSHA/NPPTL Medical Evaluation Form (Appendix D.). These are absolute exclusions.
- Self-reported medications for chronic problems (reports "yes" to any item in Part B. question 7) on OSHA/NPPTL Medical Evaluation Form (Appendix D.) This is a relative exclusion and will be reviewed by a medical monitor CRNP to determine if it is contraindicated with the tests for the study. Documentation of review and rationale will be completed by the medical monitor CRNP.
- Prior problems using a respirator as reported in Part B. question 8 of the OSHA/NPPTL Medical Evaluation Form (Appendix D.). This is a relative exclusion, and must be reviewed by medical monitor certified registered nurse practitioner and PI on a case by case basis. If it is determined to not affect risk for the study interventions in this trial, consideration for subject participation may be permissible and should be documented with rationale on why it is not applicable to this study as an exclusion.
- Pregnancy. All female subjects of child-bearing potential will be required to complete a urine pregnancy test provided by NPPTL prior to enrollment in the study and again prior to each study visit, not to exceed more than once every seven days, at the first visit of that week. A U.S. licensed health professional will interpret the pregnancy test and approve or deny participation based on results. A woman is considered non-child bearing if she reports menopause or surgical sterilization, and therefore would not require pregnancy testing.
- Experiencing any clinically contraindicated signs or symptoms during the maximal graded exercise testing with a treadmill protocol, such as abnormalities deemed to be a

risk during the continuous EKG.

- Self-reported diabetes or chronic kidney disease (reports "yes" to question 2b in Part B of Appendix D.). This is an absolute exclusion.
- Self-reported nutritional supplements, reported on NPPTL Medical Screening Evaluation (Appendix E). This is a relative exclusion and will be reviewed by a medical monitor CRNP to determine if it is contraindicated with the tests for the study. Documentation of review and rationale will be completed by the medical monitor CRNP.

5.0 PROCEDURES AND EVALUATIONS

5.1 Screening

1) Subjects will be identified by volunteerism using a Recruitment Flyer (Appendix B) which will be placed in local public places.
2) Study staff will review the Informed Consent Form (Appendix C) with each subject explaining all risks and benefits as well as subject responsibilities for participation. All questions will be answered for subjects. If a subject decides to participate, they must sign and date the consent form and a delegated study staff member must sign and date the consent form thereafter. A copy must be provided to the subject upon completion,
3) Once a subject is consented, they will first undergo two facial measurements used to place the subject into a NIOSH/NPPTL Bivariate Panel cell category. If the cell category is full, based on a first come first serve basis, the subject will be screen failed, and informed they will be contacted for re-screen in the event an opening occurs later on in their cell category.
4) Subjects will next complete the OSHA/NPPTL Medical Evaluation form (Appendix D), the NPPTL Screening Medical Review (Appendix E), the Subject Data Form (Appendix F), and the NPPTL General Photo Release (Appendix U). The medical questionnaires and evaluations will be reviewed by a U.S. licensed health professional at NPPTL to determine eligibility for safety.

Urine Pregnancy Test

- A U.S. licensed health professional will inform female subjects of childbearing potential the instructions on how to complete the urine pregnancy test in a private setting. A private bathroom will be provided to the subject during the test and the U.S. licensed health professional will wait outside of the restroom to read the result.
- If the result is positive, the U.S. licensed health professional will provide the subject with a private area to talk, and instruct the participant that they should consult with their primary care provider for follow up confirmation and education. They will also be informed they will be excluded from the study at this time, as per the consent.
- If negative, the participant will be able to continue screening
- Whether positive or negative the result will be added to the Point of Care Testing data capture form (Appendix G) **and a same-day copy will be provided to the subject if they would like a copy, with instruction to provide it to their primary care provider.**

5) If safe to proceed after medical evaluations and based on NIOSH/NPPTL bivariate panel cell category, subjects will next complete quantitative fit testing for two tight-fitting

PAPR models to confirm bivariate panel allocation.

6) Lastly, if eligible based on all above screening requirements, subjects will undergo a Maximal Graded Exercise Test (Appendix K) according to the Bruce protocol (Wasserman, 2012) to provide individual subject safety parameters and additional medical evaluations.
7) Finally, if eligibility for registration is confirmed by the study team, the subject will be registered and scheduled for their study visits. If a subject screen fails for any reason, their data will be kept and a study team member will inform them of their exclusion. If a subject screen fails due to their cell category in the bivariate panel being full, they will be informed that they may be called back for participation and in the event a subject in their cell category becomes unevaluable during the study.

5.2 Work Rate Determination Test Procedures

1) Subjects will be equipped with a silicone-rubber oronasal facemask connected to a metabolic cart, which will measure expired air for CO_2 and O_2, and minute ventilation (V_e). They will also be equipped with a heart rate monitor.
2) Test subjects will be instructed on how to communicate with the test operator whenever they feel unable to continue. The tests will be terminated immediately if a subject or investigator notes any potential adverse events or safety parameters reached.
3) After connecting the subjects to the metabolic cart, the subject will perform the 10-exercise regime shown in Table 3.
4) After completing the regime, the subjects will be disconnected from the metabolic cart.

5.3 SWPF Test Procedures

1) Subjects will wear a Tyvek suit or lab coat and foot protection, based on subject preference, to cover their personal clothes and shoes during testing.
2) PAPR batteries will be tested by study staff to make sure they are fully charged per the manufacturer's instructions. Batteries will be charged for at least 12 hours prior to use.
3) A test operator will: a) turning the blower on, b) adjust/verify the PAPR flow rate, and c) assist the subject with donning each PAPR model using the manufacturer's directions.
4) During Phase II only, the PAPR flow rate first to be tested will be the fixed manufacture flow rate.
5) A fingertip-pulse oximeter will be worn by each subject in order to obtain oxygen saturation information. When wearing the PAPR, the test subjects will be instructed on how to communicate with the test operator whenever they feel unable to continue. The tests will be terminated immediately if a subject or investigator notes any potential adverse events or safety parameters reached (Section 7)
6) Once the corn oil aerosol concentration in the chamber reaches approximately 20-40 mg/m, the subject will enter the chamber wearing the PAPR model assigned with the blower running. The test operator will connect: 1) a pressure line and 2) all sample lines to particle detector systems. Dustrak and Laser photometer will be used to measure simultaneously to measure the upstream (outside the PAPR) and downstream (inside the PAPR) test aerosol (Fig. 4A & Fig. 4B).
7) After connecting all sample lines, the subject will perform either the 10-exercise regimen shown in Table 3 (Section 3.3), or one of the three 2-exercise regimes in Table 6 (Section 3.4) dependent on the Phase they are enrolled into. Data from the Dustrak and Laser photometer will be recorded and each individual exercise SWPF will be calculated as a ratio of the upstream and downstream particle concentrations.

8) After completing testing with a PAPR and specified flow rate, the subject will exit the test chamber and remove the PAPR. Subjects resting vital signs must return to near baseline and a minimum of a ten-minute break must be provided to the subject between each exercise regimen test if multiple scheduled in one day.

6.0 SUBJECT DISCONTINUATION

Subjects may be removed from the study for the following reasons:

- Do not meet screening safety and/or inclusion eligibility. Note that for subjects whom complete facial measurements allocating them to a cell category that is full, they can be re-contacted and re-screened in the event a registered subject in their cell category becomes unevaluable.
- New conditions that prevent the subject from wearing a PAPR or completing the study exercises
- New conditions that prevent the subject from completion of the study interventions and/or evaluations
- Adverse events experienced by the subject
- Subject decides to withdraw from the study
- Subject non-compliance with study requirements, confirmed by the site PI
- For any reason the PI deems is necessary to protect the safety, data integrity, and/or confidentiality of the subject

7.0 SAFETY PLAN

This study will be conducted according to all conditions of the protocol, including Privacy Act confidentiality, in accordance with applicable local legal/regulatory requirements, and U.S. Code of Federal Regulations (45 CFR 46). Study personnel conducting research for this protocol will have documented Collaborative Institutional Training Initiative (CITI) Program certification and annual CDC competency training. Screening medical safety measures that will be assessed and monitored by a U.S. licensed health professional include: OSHA/NPPTL Medical Evaluation, NPPTL Screening Medical Evaluation, and Maximal Graded Exercise test.

7.1 Recruitment

A recruitment flyer (Appendix B) will be placed at various locations to provide opportunity for up to 75 healthy volunteers to participate in western Pennsylvania and surrounding areas. Subjects recruited may also have participated in previous respiratory protection studies at NPPTL. The Common Rule defines minimum risk for non-prisoners, as "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (45 CFR 46.[10]2). This study is not minimal risk, though steps were taken to reduce risk; thorough review of current and past medical history, a maximal graded exercise test, active study evaluations, and medical monitoring by a certified registered nurse practitioner. Risks and benefits will be discussed with subjects during the recruitment and consent processes, and only subjects that meet screening safety test eligibility to minimize risk will be included.

The benefit of this research is to gain data that may be used to improve loose fitting PAPRs used by healthcare workers which will ultimately aid patient care and worker safety for the U.S. population.

Subjects will be reimbursed $40.00 per hour for their time. Each visit is expected to last about 3 hours. If the visits last longer than 3 hours, the subjects will be reimbursed at a rate of $10 per quarter hour (15 minutes), rounding up to the nearest quarter hour. Subject payment is disbursed by check via mail by a government contractor (AECOM). The subject will need to complete Internal Revenue Service Form W-9 Request for Taxpayer Identification Number and Certification (Appendix S) which includes the subject's name, address, and social security number. This will be completed at the conclusion of the first visit and will not need to be completed again through the duration of the study, with an exception of a change in the subject's mailing address. Study investigators will transmit the W-9 forms via Federal Express Letter (secure mailing) to the AECOM Germantown Service Center. The address for the Service Center is: AECOM, 20501 Seneca Meadows Parkway, Suite 300, Germantown, Maryland 20876 c/o Kathy Fidder, Fixed Asset Administrator, General Ledger D. The test subject payment form (Appendix T) will be completed at the conclusion of each visit and emailed to AECOM. AECOM will also be notified via email when a W-9 is sent to Germantown by including the test subject name and the date mailed.

If subjects complete approximately 14 visits for 3 hours each at $40/hour, the total possible reimbursement is about $1,680 (for 42 total hours).

7.2 Informed Consent

In order to meet the new requirements of the new common rule, including the reasonable person requirement, we provide the prospective subject with a written document, the consent form (Appendix C), written in lay language that contains a description of the information that we believe, based on many years of experience recruiting subjects for our protocols, a reasonable person would want to know regarding participation in the protocol.

Based on the Bivariate Panel, NPPTL is seeking a diverse population of study subjects, in terms of face sizes and shapes. Other than filling an available cell panel and obtaining roughly a 50/50 gender (i.e. no more than 17 evaluable subjects from one gender), the only other criteria subjects must fulfill is to be healthy enough to safely complete the required exercises and wear a respirator. The subject population will be selected without regard to race or socioeconomic status. However, based on prior experience of subject matter experts at NPPTL, we can speculate that those that would choose to participate in this study would likely enjoy exercise and have interest in improving the state of occupational health. Subjects will be recruited from local athletic organizations and emergency response organizations through use of a flyer (Appendix B.).

The Reasonable Person Standard

The informed consent information includes the time commitment, the nature of the activities that the subject will participate in during the conduct of the research, the anticipated rare risks and discomforts that the subject may experience, the methods used to mitigate the risks and discomforts, the reimbursement for the subjects time spent during participation in the protocol, and the contact information of the key individuals (principle investigator; chair, IRB) with whom the subjects may wish to speak. Based on 20+ years of subject matter expertise by the PI of this trial, these are the key information a subject would want to know about this study. In addition to the PI's extensive experience with this type of study, members of the study team have previously worked with a similar study population in the recently concluded project 12-NPPTL-02

"Respirator performance against engineered nanoparticles under laboratory and workplace settings." In that project, test subjects wore PAPRs and performed exercises in a sodium chloride aerosol test chamber; the particle leakage into the PAPR hood was determined using particle counting instrumentation (results currently in draft for publication). There are similarities in procedures from the previous study to those of the SPARTAN study, including training the subjects on how to don and wear PAPRs, instructing subjects on how to do the test exercises, and collecting particle penetration data. The population in this project 12-NPPTL-02, like Project SPARTAN, filled a respirator fit test panel and was a local population (western Pennsylvania region). They were recruited through an NPPTL pool of 200 subjects, many of whom had worn a respirator in prior NPPTL studies. The study team is well equipped with the experience and knowledge needed to disclose the information material to prospective subjects to satisfy the reasonable person requirement.

In addition to providing written materials (reading level estimated at Flesch-Kincaid Grade Level 9.9) we orally brief the subject on the details of the study as outlined previously in this statement. The briefing will include informing the subjects that they are able to voluntarily withdraw themselves from the study at any point without prejudice to themselves and reviewing study risks and benefits with each subject and ensuring subject comprehension of risks prior to participation. This accomplishes two important things, 1) an oral briefing assures that the subject has not only received the information and can ask questions of the investigator or team member of interest to the subject and have those questions answered, and 2) overcomes the issue of functional illiteracy and the inability of the subject to read and comprehend the written material, including the consent form, in which the study is described.

In addition to informed consent, we will offer a Future Contact Consent at the end of the written informed consent document, to allow subjects to sign up for future contact about other potential trials at NPPTL they may be interested in reviewing and/or participating in. Subjects that would like to participate in future contact for future trial participation opportunities at NIOSH will be included into a secured database accessible only by Personal Identification Verification cards at NPPTL. Because this population of typically athletic and emergency response subjects enjoy participating in novel exercise studies to improve personal protective equipment, they may want the option to sign up for Future Contact to review additional trial participation options.

7.3 Subject Safety Evaluations

Screening Evaluations

In order to recruit healthy subjects and prevent underlying medical disorder exacerbation due to study activities, study subjects will complete the OSHA/NPPTL Respirator Medical form (Appendix D), NPPTL Screening Medical Evaluation (Appendix E), which will be conducted and reviewed by a U.S. licensed health professional. Activities assigned to the U.S. licensed health professionals involved in this study, which in the case of this study will be a certified registered nurse practitioner and/or a registered nurse, are listed on the Delegation of Authority Log (Appendix R). Responsibilities fall within the scope of practice for these professionals. Per the NIOSH Requirements and Guidance for Human Subjects Research Protocols Involving Exercise, approved on 7/7/2020, eligibility decisions will be made on an individual basis. Direct physician supervision is not warranted per the aforementioned NIOSH Policy document. The identities and backgrounds of the U.S. licensed health professionals can be found in Appendix Q and the duties in Appendix R. All physical exams will be conducted in a private area with just the U.S. licensed health professional.

Supplement use will be assessed and documented by a U.S. licensed health professional on the NPPTL Screening Medical Evaluation question 8 (Appendix E). Subjects are asked to indicate the reason for taking any given supplement, so that the U.S. licensed health professional can determine if the participant is using it to treat an exclusionary disease or condition. Any information relating to relevant exclusion criteria will be documented on Appendix E. This question helps determine if the participant is taking something that could affect the outcome of the test or increase their risk of an adverse event during the study. If subjects are excluded due to supplement use, they will be informed they were excluded because those supplements, or the conditions they are treating, are exclusionary criteria and could increase their risk of experiencing an adverse event while participating in this study.

The rationale for the inclusion of the supplement use question is to identify any additional risk factors such as pulmonary or cardiovascular problems (both exclusion criteria) that someone treats with supplements. It is also intended to identify supplements that a subject may be taking which could affect their heart and/or respiration rate or breathing patterns (e.g. caffeine). Today's market has so many supplements that claim to treat many different ailments or increase exercise performance. It is possible that participants who regularly exercise may take some supplement to enhance their workout. We are trying to identify anything a participant uses that could affect the study or increase their risk.

A supplement is any dietary treatment that is used to enhance one's health or performance. Ingredients of concern, but are not limited to, include caffeine, energy drinks, nicotine, Ma huang, Yohimbine, Ginseng, Ephedra, Khat, Licorice root, Bitter orange, Goldenseal, or any other supplement that could affect the subject's heart rate or blood pressure. Supplements not listed will be evaluated at the discretion of the U.S. licensed health professional.

As a part of the Subject Data form (Appendix F), completion of which is a required inclusion criterion, subjects will be asked if they are willing to refrain from caffeine consumption for 12 hours prior to and during testing and smoking 1 hour prior to and during testing. The rationale for asking participants to refrain from smoking for 1 hour prior to and during testing is based on the recommendation from TSI, Inc., the manufacturer of the PortaCount for fit tests. Failure to refrain from smoking could lead to false particle counts in the respirator due to residual smoke particles being exhaled by the wearer. Specific tobacco products participants must refrain from using are cigarettes, cigars, and electronic cigarettes. Participants are asked to refrain from caffeine consumption because it is a stimulant, therefore increasing the participant's heart rate and increases the risk of an adverse event. It could raise a participant's heart rate beyond the limitations for the study, causing test termination and the exclusion of the subject for that day.

Additionally, subjects will perform a maximal graded exercise test (Appendix K) with a treadmill using Bruce protocol (Wasserman, 2012). Testing will provide a baseline health review to promote reduced risk of clinically contraindicated signs or symptoms for exercise studies included in this protocol. Subjects must achieve a maximal oxygen consumption of "Fair" to "Excellent" score during this test based on recommendations for exercise testing safety from the American College of Sports Medicine Fitness Categories for Maximal Aerobic Power (treadmill test). During this test Maximal Heart Rate and Maximal Ventilated Oxygen will be obtained to provide individual subject safety parameters that will be used during study interventions. Additionally, a continuous electrocardiogram (EKG) will be completed and assessed by a U.S.

licensed health professional to determine if any unknown underlying arrhythmias or heart conditions that would exclude the subject from participation during the Bruce protocol.

Active Study Evaluations

Once a subject is eligible and registered for the study, daily pre and post visit medical evaluations, as well as monitoring by a U.S. licensed health professional intra testing, will be conducted on the NPPTL campus in a designated laboratory to aid continued safety and prevention of exercise induced adverse events. A NPPTL Pre Visit Medical Evaluation form (Appendix L) will be completed by a U.S. licensed health professional with each subject at the start of each study visit to promote safety. A NPPTL Post Visit Medical Evaluation form (Appendix O) will be completed by a U.S. licensed health professional with each subject at the conclusion of each visit, and subject will not be discharged until the U.S. licensed health professional subject safety. Supplemental nourishment in the form of milkshakes (i.e., Ensure®) or sports drinks (i.e., Gatorade®) will be available in the NPPTL Physiology Laboratory/ Building 40 laboratory to assist in hydrating the subject if needed (e.g., cold Gatorade®, cold bottled water).

We believe the daily pre-test evaluation (Appendix L) is appropriate and sufficient for determining the subject's readiness to safely participate in study activities on a given day. Pre-participation screening items consist of a review of medical history, symptoms, and medications, vital sign check, and urine pregnancy test, all of which are recommended in the NIOSH Policy Document- NIOSH Requirements for and Guidance for Human Subjects Research Protocols Involving Exercise. Because of these intensive screening components, the PI has determined that inclusion of a drug test, as a part of daily screening or initial screening, not to be necessary.

Subjects that have joined the study will have previously agreed to refrain from caffeine use 12 hours prior to and during testing and smoking one hour prior to and during testing. This will be assessed on a daily basis using the NPPTL Daily Pre-Test Evaluation (Appendix L).

Urine Pregnancy Testing

Pregnancy is an exclusion criterion for participation in this study (because of potential changes in subject facial dimensions which could alter initial fit testing results over the course of a few months as well as to prevent rare events in which an expecting mother and/or fetus may experience an adverse event due to exertional activities). Female subjects will be advised, at the time of consent that they will need to disclose if they may be pregnant. Subjects that are not childbearing potential due to surgical sterilization and/or post menopause will not be required to complete pregnancy testing. Subjects that report they are of child, bearing potential must complete periodic urine pregnancy testing using a commercially available, off-the-shelf, urine hCG pregnancy test provided by NPPTL and a U.S. licensed health professional, at the start of each visit, but not more than once per week. The urine pregnancy test will be taken in a private restroom. A U.S. licensed health professional will review the results with applicable subjects and in the event of a positive test the subject will be referred to their primary care provider and study interventions will be held. Subjects determined to be pregnant will be screen failed or removed from the study. Subjects that self-report pregnancy will not be tested.

It is possible that a potential participant would be advised to follow up with his/her medical provider at the discretion of the U.S. licensed health professional. Circumstances could include abnormal vital sign measurements or abnormal physical examination results. These will be

marked as such on the medical evaluation forms (Appendices D, E, L, or O). Depending on the degree of abnormality/change from prior status, the U.S. licensed health professional will make this advisory.

Photo Release

As part of the screening process, subjects will be asked to review the optional NPPTL Photo Release (Appendix U). This release allows photos taken during study participation to be utilized in presentations, publications, or webinars. Participants may decline completing this form (and if they decline, they will not be included in any photos). Documented verification of agreement or decline must be addressed before registration to study.

Photos will not contain participant identifiers, including their name. Subjects' names will not be published in a research paper or presentation, and videos will not be taken. Since photos can be considered personal identifiers, the draw feature on a photo editor program will be used to obstruct view of participants' eyes and faces to lessen the risk of a participant being identified in a photo. Photos may be used in any publication format, including manuscripts, presentations, and webinars. The photo release was added to allow NIOSH to visually document study activities for publications and presentations. It may be helpful in sharing the work being conducted at NIOSH to relevant stakeholders.

7.4 Management of Events

Adverse events (AEs) refer to any untoward medical occurrences, whether considered study intervention-related or not. Serious adverse events (SAEs) refer to anything that causes death, is considered a life-threatening event, requires hospitalization, leads to incapacity, is a substantial disruption of a subject's quality of life, or causes a congenital anomaly/birth defect. All AEs or SAEs encountered during the study will be evaluated on an ongoing basis according to the NCI Common Toxicity Criteria Adverse Events (CTCAE) version 5.0. Unanticipated problems (UAPs) are those not anticipated to have occurred and were not addressed as a potential risk during the initial review. SAEs and UAPs must be reported to the IRB immediately and at minimum within 48 hours from notification of the incident onset. Other, non-serious adverse events must be reported within five (5) business days.

Exercise Risk Mitigation

Subjects will be screened for medical disorders, including cardiovascular and pulmonary disease, and orthopedic disorders or injuries. Traumatic injuries will be minimized by having investigators positioned near the testing chamber to immediately address potential slips and falls. One of these sources of potential slips and falls occurs during the stair climbing exercise (Exercise #10 on Tables 3 and 7). This risk is mitigated through anti-slip tread on the steps and hand railings along both sides of the steps. Additionally, the exercises are structured from low intensity gradually building to higher intensity during Phases I-III, and the Maximal Graded Exercise test will conclude with a gradual walking down of the treadmill, both of which are strategies to minimize muscle soreness or spasm.

Site investigators and research personnel will review recruitment, AEs, SAEs, deviations, and UAPs during monthly study meetings. Modifications necessary to improve subject safety and decisions to continue or close the study will also be discussed at these meetings. If literature becomes available, which changes the risk/benefit ratio or suggests that conducting the trial is no longer ethical, the IRB will be notified in the form of an UAP submission and the study may be

terminated.

Site study personnel and a U.S. licensed health professional will monitor subjects for adverse events during each study visit and at the conclusion of each visit before discharging the subject. Site study personnel and a U.S. licensed health professional will follow NPPTL standard operating procedures including contacting 911 or referring a subject to their primary care provider as applicable upon assessment of an adverse event. Study personnel will be trained in CPR/AED use and first aid and will be familiar with abnormal or unsafe subject responses. In the event of an emergency, an emergency plan has been developed (Appendix P), which includes the process for activating the local Emergency Medical Services. In the event of a medical emergency, this plan will be implemented. Protocol medical evaluations and study specific safety parameters have been reviewed and created by NIOSH physicians, certified registered nurse practitioners, registered nurses, and exercise physiologists to aid in best practice and subject safety (Table 7.).

Table 7. Safety Parameters

Test Termination Criteria	**Test Phase**				
Signs and Symptoms	**Screening**	**Phase I Exercise Regimen**	**Phase II Exercise Regimen**	**Phase III Exercise Regimen**	**Pre/Post Test Medical Evaluation**
Subject indicates the desire to stop the test due to maximal fatigue or any other reason	X	X	X	X	X
Abnormal symptomatic response to the activity (e.g. lightheadedness or dizziness, chest pain, nausea, or muscle cramps)	X	X	X	X	X
Urine Pregnancy Test Positive Result	X				X
Electrocardiographic abnormalities (e.g., life-threatening dysrhythmias, ventricular tachycardia, ST-T waves changes, or any evidence of ischemia) during Maximal Graded Exercise Test (Appendix K) by physiologists and/or medical monitor certified registered nurse practitioner	X				
Abnormal blood pressure response to exercise (e.g., hypotensive response) as taken during Maximal Graded Exercise test and pre/post test medical evaluation by physiologists and/or medical monitor certified registered nurse practitioner	X				X
Abnormal signs (e.g., cyanosis)	X	X	X	X	X
Clinical testing equipment is not working properly	X	X	X	X	X
Symptom-limited VO_{2max} has been reached; VO_{2max} has been reached when an increase in workload and does not result in a concurrent increase in oxygen consumption for a period of at least one minute	X	X			
Oxygen saturation $\leqslant$ 90% or a 10% decrease from baseline	X	X	X	X	X
HR $\geqslant$ 90% of measured HR_{max} for a period of at least one minute	X	X	X	X	X
At the discretion of the investigator/ U.S. licensed health professional	X	X	X	X	X
$[CO_2]$ in the PAPR $\geqslant$ 6% of atmospheric by volume for a period greater than one minute			X	X	

Maximal aerobic capacity (VO_{2max}) of subjects is monitored as part of the screening process and to provide safety during study interventions. The screening maximal graded exercise test includes the determination of underlying cardiopulmonary issues that may exclude the subject for safety purposes. Additionally the Maximal Graded Exercise test will allow the study team to determine the level of exercise at which the subject reaches their maximal oxygen uptake (VO_{2max}). If VO_{2max} has been reached, as determined during screening, the study team will terminate the exercise and remove subject from study to promote safety. The maximal heart rate achieved at VO_{2max} is also measured during the maximal graded exercise screening test. If the subject reaches ≥ 90% of their maximal heart rate (HR_{max}) over the course of one minute, the study test will be terminated and the subject removed from study for safety. For example, if the subjects HR_{max} is 190 $b \cdot min^{-1}$, the test would be terminated when the subjects HR reaches 171 $b \cdot min^{-1}$ over the course of one minute during testing. The procedure for the Maximal Graded Exercise Test, as well as monitoring from the metabolic cart, is described in Appendix K.

During Phases II and III, subjects will be breathing in a confined space with an expected increase in atmospheric CO_2, leading to a potential for CO_2 rebreathing. For this reason, a test termination criterion has been established as a function of in-mask change in CO_2 concentration from atmospheric levels. If the in-mask CO_2 concentration is greater than 6% of the atmospheric levels, for a period greater than one minute, the test will be terminated.

Using the information from the NIOSH Criteria for a Recommended Standard: Occupational Exposure to Heat and Hot Environments (Chapter 8) (Jacklitch *et al*., 2016) and the OSHA-NIOSH Heat Safety Tool App (CDC, 2018), the activities in the protocol at room/chamber temperature (72 degrees-F) and humidity (80% for summer months) poses a minimal risk of overheating. Monitoring body temperature is not recommended. Recording uncontrolled room/chamber conditions (temperature and humidity) with exercise at pre-test and post-test would useful to confirm. Chamber conditions are controlled and also tracked by a humidity/temperature sensor (section 3.3 Test Chamber).

<u>Adverse Event Management</u>

The Pittsburgh Campus NPPTL physiology laboratory and B40 laboratory emergency resuscitation equipment includes two cardiac defibrillators (standard and Automated External Defibrillator), and first aid items as is standard for non-hospital research facilities conducting human subjects research in the United States. Study activities will include monitoring by a certified registered nurse practitioner designated by NPPTL. All study team members are trained in Cardiopulmonary Resuscitation (CPR) and Automated External Defibrillator (AED) use. Additionally, NPPTL completes periodic simulated onsite emergency and/or resuscitation scenarios approximately every 4-6 months on campus. In the (unlikely) event that a subject would experience excessive body warmth generated by the study exercise, fans, a private shower, and cold liquids are available in the Physiology Laboratory/B40 laboratory for cooling purposes. An emergency response system is in place by dialing “O” or “911” on site to notify security personnel who initiate the emergency response plan and emergency services. Emergency transport by local Emergency Medical Services personnel would be to the nearest hospital facility as routed by emergency services.

7.5 Risks and Benefits

Risks

Exercise Induced Cardiovascular Event. According to data provided by the American College of Sports Medicine (2014), the risk of complications with vigorous exercise are rare and reported in 6 out of 10,000 people (including MI, ventricular fibrillation, hospitalization, and death). Note* this statistic includes general population sample with varying levels of health. Subjects without known underlying chronic health conditions will be used for this study per screening inclusion/exclusion (Section 4.0) reducing this rare risk even further. Screening medical evaluations and maximal graded exercise test baseline monitoring including EKG, will provide significantly reduced risk for this rare adverse event.

Exercise Induced Injury. Fatigue, nausea, dehydration, excessive warmth, and or a body injury from a fall, in rare events may occur during exercise.

Corn Oil Aerosol Irritation. Irritation caused by corn oil exposure is rare. Corn oil has an American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 10 mg/m^3 and an OSHA PEL of 15 mg/m^3. The respirator will reduce exposure to well below this level, but there may be some exposure at higher work rates and lower flow rates. OSHA finds that vegetable oil aerosols present the same safety and health hazards as do all physical irritants, including interference with vision, eye tearing, and skin (OSHA, 1988). Corn oil is a widely used foodstuff, and no impact is anticipated on the infants of nursing mothers. If the subject requests to stop the test at any point due to physical irritation caused by corn oil exposure, the test will be terminated. Corn oil may also soil clothes, shoes, and personal items it is exposed to so the volunteer will be reminded to wear old clothes and shoes and also to cover up with the provided personal protective equipment.

Equipment Induced Irritation. Irritation caused by respirator or equipment use is rare and may include:

- *Difficulty Breathing*: Associated with user error, device malfunction, or device modifications (lower flow) most typically and is rare, however may occur in a minority of participants. Participants will be instructed to remove their device and inform study personnel if this occurs
- *CO_2 rebreathing:* If in the rare event the in-mask CO_2 concentration is greater than 6% of the atmospheric levels, for a period greater than one minute, the test will be stopped for safety. This could be caused by the confined spaces of the respirator and/or reduced airflow respirator modification.
- *Contact Dermatitis:* The respirator or monitoring equipment may cause a sensitivity reaction in a minority of participants. Participants will be instructed to inform study personnel if they develop or suspect redness or irritation on their body, face, scalp, and/or neck
- *Claustrophobia:* Attributed to equipment wear, is rare and may occur in a minority of participants. Participants will be instructed to remove their device inform study personnel if this occurs. This could be caused by the confined spaces of the respirator and/or reduced airflow respirator modification.

Risk of Breach of Confidentiality. In very rare cases, people not associated with this research study may inadvertently see subject's identifiable research results. This could result in

psychosocial discomforts or difficulties. The researchers will try to prevent this from happening by keeping all research records in locked buildings and within secured server software systems accessible only by Personal Identification Verification badges.

Economic Risk. It is possible that subjects may experience financial costs, in the form of treatment-related expenses, as a result of injury or harm during study participation.

Refrainment Risks

Possible discomforts or risks associated with not using caffeine include headache, fatigue, decreased concentration, tremors, and irritability.

Possible discomforts or risks associated with not using tobacco include headache, cough, fatigue, and irritability.

Benefits

The benefit of this research is to gain data that may be used to improve PAPRs used by healthcare workers, which will ultimately aid patient care and worker safety for the U.S. population. Specifically, studying flow rates and work rates will aid the development of PAPRs as a class of respiratory protection and the standards that regulate them. In terms of standards development, this research will provide knowledge required to create an alternative PAPR standard geared toward industries such as healthcare, thus allowing for the next generation of PAPRs with smaller, quieter, more lightweight designs. This research will also evaluate the SWPF test method for assessing PAPR performance, which could ultimately become a standardized test method.

In the event of a filtering facepiece respirator (FFR) shortage, PAPRs will be an alternative source of respiratory protection, so it is important to learn about the capabilities, limitations, and usability of these devices. This is an important reason to increase the availability and usability of PAPRs, which this research will do through standards development and information dissemination. This benefit will not only be seen in every day occupational health, but during emergency situations as well.

This research may also benefit the subject personally in the form of respirator knowledge that could be applied in their own workplaces. Subjects will learn the correct procedures of donning, doffing, and operating PAPRs. They will learn the conditions and degrees to which they are protected in the workplace, how well the different devices fit them, and their level of comfortability performing various tasks. Lastly, subjects will have a sense of fulfillment that they are a part of research that is improving the state of both occupational health and healthcare in the United States.

7.6 Subject Follow-Up

Upon completion of Phase III, no follow up is required. The results of testing will be confidential, as provided under the Privacy Act. The participants will not receive study results and will be informed that the de-identified data results may be publicly disseminated by submission to peer-reviewed journals and through presentation at scientific meetings.

7.7 Retention of Records

Records pertaining to this study will be kept in accordance with CDC/NPPTL guidelines and for a period of no less than three years after study termination. Confidentiality methods will include:

limiting personal information recorded to only include what is essential to the research; substituting code numbers for identifiable information; limiting the individuals with access; storing paper data in secured access locations on the CDC/NIOSH campus in a locked area; and using computers which require a secure personal identity verification (PIV) badge. Study personnel at CDC/NPPTL conduct research confidentiality according to the Privacy Act, and any breach of confidentiality will be reported to the IRB within 48 hours of event knowledge. Individual results will not be provided to the subject and de-identified results from this study may instead be released to the public in peer reviewed journals, presentations, and/or conferences at undetermined time points.

7.8 Confidentiality

Certificate of Confidentiality

Section 301(d) of the Public Health Service (PHS) Act, states that the Secretary shall issue Certificates of Confidentiality (CoCs) to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected, as defined by Section 301(d), is deemed issued a CoC and therefore researchers are required to protect the privacy of individuals who are subjects of such research in accordance with Section 301(d) of the PHSA.

Consistent with Section 301(d), a CoC applies to this research because of the following:

1. The activity constitutes biomedical, behavioral, clinical, or other research
2. The research involves Human Subjects as defined by 45 CFR Part 46
3. The research is collecting or using biospecimens that are identifiable to individual as part of the research
4. The research involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act

Therefore, NPPTL and any of its collaborators, contractors, grantees, investigators or collaborating institutions that receive “identifiable, sensitive Information” as defined by subsection 301(d) of the Public Health Service Act shall not:

• Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or

• Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

• Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;

• Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

• Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

• Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

NPPTL and its collaborators and contractors conducting this research will establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the research is managed in compliance with subsection 301(d) of the Public Health Service Act. As per institutional policy, NPPTL will require: 1) that any investigator or institution not funded by CDC/NIOSH/NPPTL who receives a copy of identifiable, sensitive information protected by this Certificate, understands that it is also subject to the requirements of subsection 301(d) of the PHS Act; and 2) that any subrecipient that receives CDC funds to carry out part of this research involving a copy of identifiable, sensitive information protected by a Certificate understands that it is subject to subsection 301(d) of the PHS Act. Therefore, all study staff will receive training on the importance of protecting the confidentiality of human research subjects and of personal information acquired, including the collection of biological specimens.

NPPTL and its contractors shall inform research participants of the protections and the limits to protections provided by this Certificate. Therefore, all staff who are consenting individuals will receive training on how the Certificate protects the information collected and the limitations of the Certificate's protections.

System of Records Notices (SORN)

HHS System of Records Notices (SORNs) are required for studies in which the Privacy Act is applicable. As required by The Privacy Act, HHS publishes SORNs to provide public notice of the records it maintains about individuals, which are retrieved by personal identifiers. Each SORN describes the types of information contained in the records, the legal authority for collecting and maintaining the records, how the records are used within HHS, and the purposes (referred to as "routine uses") for which HHS may disclose the records to non-HHS parties without the individual record subject's consent.

09-20-0159 Records of Subjects in Certification, Testing, Studies of Personal Protective Devices, and Accident Investigations. **Categories of Individuals Covered by the System:** Individuals exposed to hazardous work environments and individuals selected as control groups are covered by this system. Additionally, the system pertains to individuals selected to test the interaction between people, personal protection or safety equipment, users of such equipment, and a hazardous environment. Some examples include individuals involved in investigated accidents and persons selected to perform respirator facepiece fit tests, perform lifting and manual

materials handling studies, perform work tests while wearing protective equipment, perform strength test studies, and perform hand speed tests.

7.9 Quality and Assurance

This protocol, source data, and all corresponding regulatory documents are subject to monitoring, trial-related audits, IRB reviews, and regulatory inspection(s). Electronic data capture will include data entry into a secured server software at the CDC, with access only enabled by an employee PIV badge. The project team will review the trial at monthly meetings and report any safety findings as applicable to necessary regulatory bodies. Quality assurance personnel designated by NIOSH/NPPTL will audit the trial as requested by the PI, IRB, and/or NPPTL Research Branch Chief. IRB review/renewal will occur annually at minimum.

7.10 Biomonitoring

A biological sample is any material from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or the assessment of the health of human beings, including material derived from the human body intended primarily for exposure assessment. All NIOSH intramural activities that include the collection of biological monitoring samples are subject to NIOSH Biomonitoring policy. NIOSH is given the authority to collect biological monitoring samples through the following regulations; Health Hazard Evaluations are conducted pursuant to 42 CFR Part 85, Occupational Safety and Health Investigations of Places of Employment are conducted pursuant to 42 CFR Part 85a, regulations by NIOSH under sections 20 and 8 of the Occupational Safety and Health Act of 1970, and sections 501 and 103 of the Federal Mine Safety and Health Act of 1977. The principal investigator for each NIOSH activity involving the collection of the biological monitoring samples is responsible for the creation of the biomonitoring plan. The Laboratory where the Principal Investigator is located is responsible for reviewing and approving and monitoring the implementation of the final Notification Plan.

This study will collect point of care urine pregnancy test results, as well as urine pregnancy test results before each visit, to evaluate a subject's general health. These results will be collected using CLIA waivers already on file at NPPTL, point of care over the counter devices, and standard operating procedures noted in section 5. Tests that are waived by CLIA may be performed at a site with a certificate of waiver and individual results provided to participants. Copies of the CLIA waivers will be kept by the Principal Investigator in the studies regulatory files. Results of these test results will be communicated to the participant on the same day of testing, by the medical monitor certified registered nurse practitioner during an in person discussion. A copy of these results will be offered to the subject with instruction to also notify their Primary Care Provider (PCP) in accordance with Appendix G, which they may choose to decline or accept. No other test results during this study will be provided to the subjects during the course of this study. For example, EKG results during Maximal Graded Exercise Testing during screening will be for research study interventions termination criteria purposes only because this is a continuous EKG completed during the Bruce protocol maximal exercise graded test as per Bruce protocol, The purpose of this continuous EKG is to monitor the exercise physiology during testing and though it will be considered for termination criteria in the event of abnormality. The continuous EKG it is not for diagnostic purposes due to potential for artifact. Because it is continuous and during exercise, and because exercise and movement can affect EKG quality creating artifact, it will not be provided to the subject.

8.0 STATISTICAL METHODS

8.1 Phase I Statistical Methods

For Phase I, mean VO_2 and HR values with 95% confidence interval will be calculated for each exercise. In this study phase, the data will be analyzed after all 25 subjects complete the first of three replicates so that each exercise will have 25 values calculated. If, after the first 25 subjects, the lower and upper bounds of the 95% confidence interval for the estimated population parameters are within the theoretically categorized work rates, then second and third replicates will not be needed.

8.2 Phase II Statistical Methods

For Phase **II** SWPF values will be calculated as the ratio of time-weighted average C_{out}/C_{in} for the summation particles across the size range measured, for each exercise. Overall SWPF for each attempt of a subject wearing each respirator model will be determined by taking the harmonic mean of the SWPF for all individual SWPF exercises. The performance of the respirators across the size range measured will be determined using the 5^{th} percentile and geometric mean (GM) SWPF values. The 5^{th} percentile SWPF value will be calculated from the formula $GM/GSD^{1.645}$, where GSD is geometric standard deviation. A log transformation of the data will be done to adjust for a skewed distribution and extreme outliers as described previously (OSHA 2006). For Phase **II**, a normality test will be conducted for the log transformed dependent variable (i.e. SWPF value for each test) first. If the normality holds, a three-way repeated measures ANOVA will be performed with subject number, respirator model, and work rate/exercise regime and flow rate of the respirator as independent variables, otherwise a Generalized Estimating Equation (GEE) model will be fit using the same set of independent variables. A full factorial design, which includes the main effects of work rate and flow rate, and their interaction, will be used. In this study phase, the data will be analyzed after all 25 subjects complete the first of three replicates with each PAPR and all three flow rates to estimate statistical effects and conduct a power analysis.

8.3 Phase III Statistical Methods

For Phase **III**, the same analysis approach as in Phase **II** will be used to test the effect of work rate, except excluding the effect of flow rate, since all the PAPRs will be set at the NIOSH minimum approved flow rate. In this study phase, the data will be analyzed after all 25 subjects complete the first of three replicates with each PAPR to estimate statistical effects and conduct a power analysis.

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APPENDIX A. STUDY CALENDARS

1. Phase I Study Calendar

Visit #1 (~3 hours)	Visit #2 (~3 hours)
Informed Consent[1]	Pregnancy Test[4]
NIOSH Bivariate Panel Measurements[2]	Daily Pre Visit Medical Evaluation[7]
OSHA/NPPTL Medical Evaluation Form[3]	Exercise Regimen (Table 3): Replicate 2[6]
NPPTL Screening Medical Evaluation[3]	Exercise Regimen (Table 3): Replicate 3[6]
Subject Data Form	Daily Post Visit Medical Evaluation[8]
NPPTL Photo Release Documentation[10]	Data Analysis
Pregnancy Test[4]	
QNFT[5]	
Maximal Graded Exercise Test	
Registration	
Daily Pre Visit Medical Evaluation[7]	
Exercise Regimen (Table 3): Replicate 1[6]	
Daily Post Visit Medical Evaluation[8]	
Data Analysis[9]	

1 Written informed consent (Appendix C.) must be completed prior to all screening and study interventions. All screening items must be completed prior to study registration. Replicate 1 study interventions may occur on the same day as screening study interventions, however if this occurs subject must complete all screening items, be assessed as eligible, and be registered for study prior to Replicate 1 study interventions. Additionally, if screening and Replicate 1 are completed same day subjects must be given a minimum of a ten minute break after Maximal Graded Exercises and also their vital signs must be assessed and return to baseline prior to attempt 1 exercise regimen.

2 NIOSH/NPPTL Bivariate Panel will be completed during screening. Subjects must have facial measurements that meet an open cell category in the Bivariate Panel to be included in this study. Cell category allocation should be the first screening procedure completed after informed consent to determine if the subject fits into an open cell category for inclusion. If the subject does not fit into an unfilled cell category, they will be considered screen failed and paid $40 for one hour.

3To be completed by the subject and reviewed by U.S. licensed health professional designated by the PI (Appendices D. & E.)

4 Women of child bearing potential are required to complete a pregnancy test prior to each visit study interventions, which will be reviewed by a U.S. licensed health professional . Only one pregnancy test per 7 calendar days is required and study visits within the same 7 calendar days may waive additional pregnancy tests after first visit in that 7-day period.

5QNFT will be completed for each of the two tight-fitting PAPR models to be later used in Phase II, to confirm cell category allocation.

6Replicates 1, 2, & 3 each include one 30-minute exercise regimen completed by the subject while monitored with a metabolic cart.

7Prior to each study visits exercise regimen test, subjects and a U.S. licensed health professional must complete the NPPTL Pre Visit Medical Evaluation form (Appendix L)

8After the subject completes the exercise regimen, they must be given a minimum of a ten-minute break before post visit medical evaluation (Appendix O) and a U.S. licensed health professional must review their pre and post test medical evaluations (Appendices M. & P) and approve discharge before they are dismissed from the visit.

9After 25 evaluable subjects complete replicate 1 study interventions, an interim data analysis will be completed. If additional attempts for all subjects are found to be warranted for (replicate 2 and/or 3), subjects may return and complete replicate 2 and replicate 3 during the same visit. If this occurs then subjects must be given a minimum of a ten-minute break in between attempts, and their vital signs must be assessed and returned to baseline values prior to initiating third attempt.

10Documentation of General Photo release agreement or decline must be recorded for each subject (Appendix U)

2. Phase II Study Calendar

Visit #1[1,4] (3 hours)	Visit #2[4] (3 hours)	Visit #3[4] (3 hours)
Pregnancy Test[2]	Pregnancy Test[2]	Pregnancy Test[2]
NPPTL Pre Visit Medical Evaluation[3]	NPPTL Pre Visit Medical Evaluation[3]	NPPTL Pre Visit Medical Evaluation[3]
Model 1: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 1	Model 3: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 1	Model 5: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 1
Phase II Survey	Phase II Survey	Phase II Survey
Model 2: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 1	Model 4: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 1	Model 6: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 1
Phase II Survey	Phase II Survey	Phase II Survey
NPPTL Post Visit Medical Evaluation[5]	NPPTL Post Visit Medical Evaluation[5]	NPPTL Post Visit Medical Evaluation[5]

Visit #4[4] (3 hours)	Visit #5[6] (3 hours)	Visit #6[6] (3 hours)
Pregnancy Test[2]	Pregnancy Test[2]	Pregnancy Test[2]
NPPTL Pre Visit Medical Evaluation[3]	NPPTL Pre Visit Medical Evaluation[3]	NPPTL Pre Visit Medical Evaluation[3]
Model 7: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 1	Model 1: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 2	Model 3: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 2
Phase II Survey	Phase II Survey	Phase II Survey
Model 8: Flow Rate 1 & 2	Model 2: Flow Rate 1 & 2	Model 4: Flow Rate 1 & 2
Phase II Survey	Phase II Survey	Phase II Survey
NPPTL Post Visit Medical Evaluation[5]	NPPTL Post Visit Medical Evaluation[5]	NPPTL Post Visit Medical Evaluation[5]
Interim Data Analysis		

Visit #7[6] (3 hours)	Visit #8[6] (3 hours)
Pregnancy Test[2]	Pregnancy Test[2]
NPPTL Pre Visit Medical Evaluation[3]	NPPTL Pre Visit Medical Evaluation[3]
Model 5: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 2[12]	Model 7: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 2[12]
Phase II Survey[10]	Phase II Survey[10]
Model 6: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 2[12]	Model 8: Flow Rate 1 & 2 Exercise Regimen (Table 3): Replicate 2[12]
Phase II Survey[10]	Phase II Survey[10]
NPPTL Post Visit Medical Evaluation[5]	NPPTL Post Visit Medical Evaluation[5]
	Data Analysis

[1] Subjects that participated in Phase I must complete consent and screening for Phase II prior to registration if it has been more than a year since their Phase I registration. Rescreening may also be completed within one year, if changes to subject's health and body measurements noted during a study visit (see section 3.1).

[2] Women of child bearing potential are required to complete a pregnancy test prior to each visit study interventions, which will be reviewed by a U.S. licensed health professional . Only one pregnancy test per 7 calendar days is required and study visits within the same 7 calendar days may waive additional pregnancy tests after first visit in that 7-day period.

[3] Prior to beginning study interventions at each study visit (for each of 8 total visits), subjects and a U.S. licensed health professional must complete the NPPTL Pre Visit Medical Evaluation form (Appendix L)

[4] Replicate 1 study interventions should be completed in 4 visits. Each visit, the subject will complete the 30-minute exercise regimen for two PAPR models and two flow rates, for a total of four 30-min tests. They must also complete a Phase II survey (Appendix M) for flow

rate comparisons and model comfort upon test end for each model. After each 30-minute exercise regimen completed subjects must be given a minimum of a 10-minute break and vitals must be assessed and returned to baseline prior to initiating next exercise regimen, even if for the same model.

5Subjects must be given a minimum of a ten-minute break before NPPTL Post Visit Medical Evaluation (Appendix O) completed and a U.S. licensed health professional must review both pre and post test medical evaluations (Appendices L & O) before they are dismissed.

6Replicate 2 study interventions should be completed in 4 additional visits. Each visit, the subject will complete the 30-minute exercise regimen for two PAPR models and 2 flow rates, for a total of 4 30-min tests. They must also complete a Phase II survey (Appendix M) for flow rate comparisons and model comfort upon test end for each model. After each 30-minute exercise regimen completed subjects must be given a minimum of a 10-minute break and vitals must be assessed and returned to baseline prior to initiating next exercise regimen, even if for the same model.

3. Phase III Study Calendar

Visit #1[1,4] (3 hours)	Visit #2[4] (3 hours)
Pregnancy Test[2]	Pregnancy Test[2]
NPPTL Pre Visit Medical Evaluation[3]	NPPTL Pre Visit Medical Evaluation[3]
Model 1: Exercise Regimen A & B (Table 6) - Replicate 1	Model 5: Exercise Regimen A & B (Table 6) - Replicate 1
Phase III Survey	Phase III Survey
Model 2: Exercise Regimen A & B (Table 6) - Replicate 1	Model 6: Exercise Regimen A & B (Table 6) - Replicate 1
Phase III Survey	Phase III Survey
Model 3: Exercise Regimen A & B (Table 6) - Replicate 1	Model 7: Exercise Regimen A & B (Table 6) - Replicate 1
Phase III Survey	Phase III Survey
Model 4: Exercise Regimen A & B (Table 6) - Replicate 1	Model 8: Exercise Regimen A & B (Table 6) - Replicate 1
Phase III Survey	Phase III Survey
NPPTL Post Visit Medical Evaluation[5]	NPPTL Post Visit Medical Evaluation[5]
	Interim Data Analysis

Visit #3[1,4] (3 hours)	Visit #4[4](3 hours)
Pregnancy Test[2]	Pregnancy Test[2]
NPPTL Pre Visit Medical Evaluation[3]	NPPTL Pre Visit Medical Evaluation[3]
Model 1: Exercise Regimen A & B (Table 6) - Replicate 2	Model 5: Exercise Regimen A & B (Table 6) - Replicate 2
Phase III Survey	Phase III Survey
Model 2: Exercise Regimen A & B (Table 6) - Replicate 2	Model 6: Exercise Regimen A & B (Table 6) - Replicate 2
Phase III Survey	Phase III Survey
Model 3: Exercise Regimen A & B (Table 6) - Replicate 2	Model 7: Exercise Regimen A & B (Table 6) - Replicate 2
Phase III Survey	Phase III Survey
Model 4: Exercise Regimen A & B (Table 6) - Replicate 2	Model 8: Exercise Regimen A & B (Table 6) - Replicate 2
Phase III Survey	Phase III Survey
NPPTL Post Visit Medical Evaluation[5]	NPPTL Post Visit Medical Evaluation[5]

[1]Subjects that participated in Phase I must complete consent and screening for Phase II prior to registration if it has been more than a year since their Phase I registration. Rescreening may also be completed within one year, if changes to subject's health and body measurements noted during a study visit (see section 3.1).

[2] Women of child bearing potential are required to complete a pregnancy test prior to each visit study interventions, which will be reviewed by a U.S. licensed health professional . Only one pregnancy test per 7 calendar days is required and study visits within the same 7 calendar days may waive additional pregnancy tests after first visit in that 7-day period.

[3]Prior to beginning study interventions at each study visit, subjects and a U.S. licensed health professional must complete the Pre Visit Medical Evaluation form (Appendix L)

[4]Subjects will complete exercise regimens A & B for 4 PAPR models per visit (~3 hours), for a total of four 30-min tests. After the subject completes exercise regimen A, they must receive a minimum of a ten-minute break and vitals must be assessed and have returned to baseline prior to initiating Exercise Regimen B. Subjects must also be provided a minimum of a ten-minute break and vitals must be assessed and have returned to baseline prior to initiating the next models exercise regimen A & B test. Additionally a Phase III Survey (Appendix N) must be completed by the subject at the end of each model tested (four per visit).

[5]Subjects must be given a minimum of a ten-minute break before post visit medical evaluation completed and a U.S. licensed health professional must review their pre and post test medical evaluations (Appendices M & P) before they are dismissed from the visit.

APPENDIX B. RECRUITMENT FLYER

Volunteers Needed in Research Study

Superior Powered Air-purifying Respirator Tests and New Technologies (SPARTAN)

Powered Air-purifying Respirator

The National Institute for Occupational Safety and Health (NIOSH) is asking for study volunteers to participate in research to help improve respirators for use by healthcare workers. This study will be conducted by the National Personal Protective Technology Laboratory (NPPTL) at NIOSH.

Participants in the study will be reimbursed at the rate of $40 per hour. The study interventions will include routine body movements and exercises with and without Powered Air-purifying Respirators for 30 minute periods at a time. The study will be conducted in the laboratory under controlled conditions monitored by a licensed healthcare professional for safety. Scheduled sessions for study participants can be arranged over the phone or in person with a study researcher. Each visit may may take about 3 hours and participants can volunteer for anywhere between 2 to 14 visits, scheduled at their leisure. Adults that enjoy exercising, and would like to help improve respirators for the safety of healthcare workers may want to volunteer. Adults that do not enjoy exercising, or have medical conditions that may increase their risk for exercising or wearing a respirator, should not volunteer.

Location

NIOSH NPPTL
626 Cochrans Mills Road
Pittsburgh, PA 15236

Phone: 412-386-4055

E-mail: zaz3@cdc.gov

To participate in this study you:

- Must be an adult between the ages of 18 and 55
- Cannot have cardiac or respiratory conditions
- Cannot be pregnant
- Must not have facial hair, piercings, or injuries that will affect respirator wear
- Cannot take medications that may interfere with exercise
- Cannot have any other medical conditions that may interfere with exercise testing or respirator use (a certified registered nurse practitioner/registered nurse will review your medical history and complete a medical evaluation for determination)

What is a respirator?

A respirator is a device that is worn in order to keep a person from breathing in particles, like dust or fumes, that are in the air.

What is NIOSH?

NIOSH is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC).

For more information, call Ziqing Zhuang, General Engineer, NIOSH NPPTL, at 412-386-4055

CDC Workplace Safety and Health NIOSH

NPPTL National Personal Protective Technology Laboratory

APPENDIX C. INFORMED CONSENT FORM

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: **Superior Powered Air-purifying Respirator Tests and New Technologies (SPARTAN)**

PRINCIPAL INVESTIGATOR:
Ziqing Zhuang, Ph.D.
412-386-4055
zaz3@cdc.gov
NIOSH/NPPTL, Bruceton Research Center
626 Cochrans Mill Rd., Bldg. 13
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STUDY STAFF:
Harold Boyles, B.S.N., R.N., MSHCA, MLT
Michael Bergman, M.S.
Adam Hornbeck, M.S.N., A.P.R.N., FNP-BC, FNP-C
Matthew Horvatin, B.S.
Jeffrey Powell, M.S.
Tyler Quinn, M.S.
Evanly Vo, Ph.D
Brooke Vollmer, B.S.
Andrew Wilson, B.S.

Source of Support:
National Personal Protective Technology Laboratory (NPPTL), NIOSH, CDC

Consent Version 4: 7/1/2021

Consent to be in a Research Study

TITLE: **Superior Powered Air-purifying Respirator Tests and New Technologies**

You are being asked if you would like to volunteer for a research study. This document gives you information about the study. A member of the research team will review this study with you. They will answer all your questions. Please read the information below. Ask questions about anything you do not understand before deciding if you want to volunteer.

KEY INFO	This study will be done to help improve powered air-purifying respirators' (PAPRs) design, safety, testing, and effectiveness. This study focuses on the use of PAPRs in healthcare settings. This study will be completed at the Bruceton Research Center located at 626 Cochrans Mill Rd., Pittsburgh, PA 15236. Volunteers for this study will come to this location for about 3 hours each visit, for about 14 visits. Volunteers will complete screening tests to check their current health and ability to participate. In order to join this study, you will need to agree to refrain from smoking 1 hour prior to and during testing and caffeine consumption 12 hours prior to and during testing. One of these is a treadmill test in which your oxygen uptake and heart rate will be monitored while the treadmill speed and grade increases in steps. On each of the visits, participants will do several exercises. These will last for up to 30 minutes at a time. Participants that enjoy exercising and are interested in helping us to improve respirator comfort, safety, and effectiveness for the nation's occupational health programs, may be interested in participating. Participants that have preexisting medical conditions that could be worsened by exercise, or do not like to exercise, may not want to participate. During the screening and study process, we will need to collect information such as the following: medical history (e.g. medications), bodily measurements (e.g. oxygen uptake) vital signs (blood pressure, heart rate, etc.).

1. Who is conducting the study?	The National Personal Protective Technology Laboratory (NPPTL) is a federal government laboratory. NPPTL studies personal protective equipment (respirators, gloves, etc.) worn by workers during their jobs. We are part of the National Institute for Occupational Safety and Health (NIOSH), which is a part of the Centers for Disease Control and Prevention (CDC).
2. What is the purpose of this study?	The purpose of this study is for researchers at NPPTL to learn more about PAPRs. PAPRs are respirators that use a motorized fan and filter to provide the wearer with clean breathing air. Many workers rely on PAPRs to protect their health. This study will look at different things about PAPRs that might affect the protection it provides someone. This includes design, amount of airflow, and fit to the face.

3. How many people are needed for this study?	Up to 75 healthy adult volunteers from Western Pennsylvania and surrounding areas will be offered participation in this study. There are no exclusions due to race, ethnic background, or social class status.
4. What are the requirements to join this study?	In order to join this study, you must review this informed consent form with the study team. To participate you must also agree to truthfully release your current and past health information. Females that are pregnant or may become pregnant will be required to take over the counter urine pregnancy tests in a private bathroom in the testing lab to be sure they are not pregnant, for safety to the fetus. Volunteers must also complete a medical and physical evaluation. This includes facial measurements, and complete screening exercise tests and health monitoring such as an EKG, while walking on a treadmill. There is also an optional photo release form. You will not be included in this study if you have known respiratory or heart illness. You will not be included if you have any medical condition that may cause you to be at risk for exercising or wearing a respirator during this study. You will not be included in this study if you have facial hair, jewelry that can't be removed, or head and neck injury, which may affect wearing a PAPR properly. You will not be included in the study if you are taking any medications or supplements that may interfere with study activities or cause safety concerns. You will not be included in this study if you do not agree to refrain from smoking tobacco 60 minutes before and consuming caffeine 12 hours before study activities. Tobacco products we ask you to refrain from include cigarettes, cigars, and electronic cigarettes.
5. What will I do for the study if I volunteer?	If you decide to volunteer for this study, you will be scheduled for about 14 test visits to the Pittsburgh NPPTL campus. You must provide your own transportation to and from the site. On the first visit, if you decide to volunteer, you will complete written informed consent and "screening" tests. These tests make sure it is safe for you to participate. You will have two facial measurements taken to see if you meet study requirements. We need people with different face shapes. To take part in the study, you must pass a medical screening and assessment. A U.S. licensed health professional will then assess your medical history and status. This will determine if it is safe for you to participate. If you are a female, you will be asked if you are pregnant or may become pregnant. You must complete a urine pregnancy test provided by NPPTL during screening and at the beginning of each study visit. This will happen no more than once every 7 days, during the study in order to participate. You must also have a clean-shaven face on the days of testing. Lastly, you will be monitored while walking on a treadmill in a test called a Maximal Graded Exercise Test. During this test, the treadmill slowly increases in grade and speed in 3 minute steps. The treadmill will reach a top grade of 18% and top speed of about 5 to 6 miles per hour. You will wear a heart rate monitor and a mask that measures your exhaled air. This will see how much oxygen you are breathing. You will be asked complete as many steps as you are able to. The purpose of this test is to measure your heart rate and oxygen uptake at maximum exercise intensity. This test

will be completed once per year. Depending on the timing of the study, you may need to complete this multiple times.

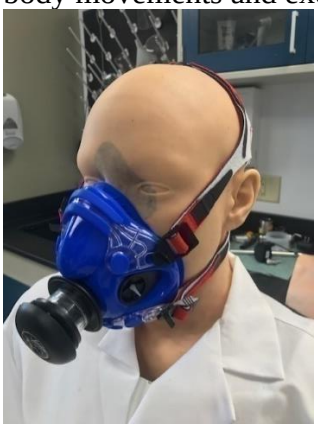
If you meet all study requirements, you will be scheduled for the remaining visits to test body movements, exercises, and respirators.

Study Visits

This study will include three different groups of tests, called phases. If you are interested in participating, you may be asked to be at the campus for about 14 visits that may each be about 3 hours long. The day of the week, frequency, number of total visits, and amount of time each visit takes, will be scheduled based on your ability to participate and scheduling needs.

In the first group of tests, known as Phase I, you will not need to wear a respirator. You will be asked to complete 10 every day body movements and exercises. This will last for about 30 minutes, plus a couple of short breaks after the hard exercises. You will wear face and body monitors to assess your breathing and heart. The exercise intensity will begin at low levels and will become harder in stages. We may stop the tests at any time because of signs of exhaustion or changes in your vital signs that will be monitored. Please refer to the body movements and exercises you will be asked to do in this phase that follow below.

In the second group of tests, called Phase II, you will try out eight different types of approved respirators. You will complete the same 10 everyday body movements and exercises from Phase I \ while wearing the different respirators. Also, we will try different respirator airflow rates during the tests. One of the flow rates is within approved NIOSH standard limits. The other one is below the approved minimum standard. However, it has been used in Europe safely and routinely. Please see the body movements and exercises you will be asked to do in this phase on the next page.



Mask worn in exercise tests

PAPR worn during corn oil tests

Photo Credit: NIOSH NPPTL

Phase I and II Exercises

Exercise	Minutes
Normal breathing: normal breathing while standing	3
Reading: reading the rainbow passage* while standing	3
Moving head side-to-side: moving head side-to-side at approximately 10 times per minute while standing.	3
Moving head up and down: moving head up and down at approximately 10 times per minute while standing.	3
Twisting at waist with weight: Twisting at waist to the left while holding with both hands a 10 pound bag with a handle, raising and lowering arms and then repeat this to the right, at a rate of 12-15 sets per minute.	3
Reaching up and stepping out (Modified jumping jack): bending the left knee slightly while reaching up both arms overhead & looking up and stepping the right leg out to the side, then repeat with the other leg, at a rate of 10-12 sets per minute.	3
Walk on a treadmill: walking upright on a treadmill at a speed of 3 miles per hour without movement of the head, and without speaking.	3
Bending and Picking up weight: bending to pick up two weighted bags with a handle (5 pound bag in each hand) and carrying them from side-to-side of the testing chamber at a moderate walking pace, then bending to put down weights. Repeat for 3 minutes.	
Perform CPR/AED: perform CPR on a training manikin by compressing chest cavity 1.5 to 2 inches at a rate of 80 to 100 compressions per minute. 2 minutes of CPR then 1 minute of AED use.	3
Stair climbing: stair climbing (using a 3-step ladder) climb rate ~ 10 to 12 cycles per minute (one cycle = up 3 steps and back down 3 steps).	3

*****When the sunlight strikes raindrops in the air, they act like a prism and form a rainbow. The rainbow is a division of white light into many beautiful colors. These take the shape of a long round arch, with its path high above, and its two ends apparently beyond the horizon. There is, according to legend, a boiling pot of gold at one end. People look but no one ever finds it. When a man looks for something beyond his reach, his friends say he is looking for the pot of gold at the end of the rainbow.

In the third group of tests, called Phase III, you will try out the same eight respirators that were also used during Phase II. This time you will complete three everyday healthcare activity exercises for 15 minutes straight. Then, you will have a 10-minute break. Finally, you will complete 3 more exercises for 15 minutes straight. Please see the body movements and exercises you will be asked to do for Phase III that follow below. Exercises were chosen from Phase I and Phase II. The exercises will now be in a different order and for 5 minutes long.

Phase III Exercises

Exercise	Minutes
Reading: read the rainbow passage* while standing	5
Walking with weight: bending to pick up two weighted bags equipped with a handle (5 pound bag/each hand) and carrying it from side-to-side of the testing chamber at a moderate walking pace.	5
Perform CPR: perform CPR on a training manikin by compressing chest cavity ~1.5 - 2 inches at a rate of 80 to 100 compressions per minute.	5
A minimum of a ten-minute break provided	
Nurse Routine activities: Hang an IV bag, connect tubing, and insert plastic syringe into IV bag. Repeat as needed for 3 minutes.	5
Reaching up and down: Reaching up and down (reaching arms up above head & looking up; then reaching arms down to floor & looking down at a rate of approximately one completed motion every 10 seconds).	5
Stair climbing: Stair climbing (using a 3-step ladder) climb rate ~ 10 to 12 cycles/min (one cycle = up 3 steps and back down 3 steps).	5

Some things you will do during these tests:
You will wear a fingertip-pulse oximeter (reader) to take oxygen saturation information. You will be told how to communicate with the test operator whenever you feel unable to continue. The PAPR will be removed immediately.

- You will wear a Tyvek® suit or lab coat to cover normal clothes before wearing the PAPR device for this study
- You will wear a fingertip-pulse oximeter (reader) to take oxygen saturation information. You will be told how to communicate with the test operator whenever you feel unable to continue. The PAPR will be removed immediately

	• You will do many of the tests in Phase II and Phase III in a large test chamber that has windows and a door. You will perform exercises while two machines will be used at the same time to measure vapor outside the PAPR and inside the PAPR. • After completing testing with each PAPR, you will exit the test chamber and staff will help you remove the PAPR. Notes: There are no other alternative procedures or courses of treatment. It is possible that you could be observed by non-study personnel when completing the testing.
6. Are there any risks?	**NPPTL has attempted to reduce risk and use safety measures during every part of this study to prevent risk to participants. However, rare risks may include:** • **Exercise Induced Cardiovascular Events:** This is reported in 6 out of 10,000 people (including heart attack, abnormal heartbeats, hospitalization, and death). *Note* This statistic represents the general population. For participants that exercise regularly and are without chronic health conditions, this risk is likely lower.* • **Exercise Induced Injury:** Fatigue, nausea, dehydration, above normal body temperature, and/or a body injury from a fall, in rare cases may occur during exercise. Every effort will be made by the study team to help participants before beginning study testing each visit, during study testing, and at the end of the study visit. The safety efforts during study testing includes anti-slip tread on the stairs used for stair climbing, handrails along the stairs, gradually building intensity of exercises, a gradual walking down of the treadmill during the treadmill test, and the positioning of study staff near the test participants to provide immediate first aid and/or contact emergency services. • **Corn Oil Vapor Irritation:** Irritation caused by corn oil exposure is rare. Corn oil has an American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV) of 10 mg/m3 and an Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit (PEL) of 15 mg/m3. The respirator will reduce exposure to well below this level. However, there may be some exposure at higher work rates and lower flow rates. OSHA finds that vegetable oil aerosols have the same safety and health hazards as do all physical irritants. These include hindering vision, eye tearing, and skin (OSHA, 1988). Corn oil is a widely used foodstuff. No impact is expected on the newborns of nursing mothers. If the participant asks to stop the test at any point due to physical irritation caused by corn oil, the test will be ended. Corn oil may also stain clothes, shoes, and personal items. The participant will be reminded to wear old clothes and shoes. The participant will also be told to cover up with the provided personal protective equipment. • **Equipment Induced Irritation:** Irritation caused by respirator or equipment use is rare. It may include:

- *Difficulty Breathing*: Caused by user or device error most typically and is rare. However, it may occur in a small number of participants. Participants will be instructed to remove their device and inform study staff if this occurs
- *Carbon dioxide rebreathing:* If in the rare case the in-mask carbon dioxide level is greater than 6% of the atmospheric levels, for a period longer than one minute, the test will be stopped for safety.
- *Contact Dermatitis:* The respirator or monitoring equipment may cause a reaction to the skin in a small number of participants. Participants will be asked to inform study staff if they develop or suspect redness or irritation on their body, face, scalp, and/or neck.
- *Claustrophobia:* Caused by equipment wear, is rare and may occur in a small number of participants. Participants will be told to remove their device and inform study staff if this occurs.

- **Risk of Breach of Confidentiality.** In very rare cases, people not connected with this research study may accidently see your identifiable research results. This could result in emotional and mental discomforts or difficulties. For example, some people may feel embarrassed that someone knows your medical history. The researchers will try very hard to prevent this from happening. They will keep all research records in locked buildings and within secured server software systems accessible only by Personal Identification Verification badges.
- **Unforeseeable Risks.** The study may involve risks that are currently unforeseeable.
- **Economic Risk.** It is possible that you may experience financial costs, in the form of treatment-related expenses, resulting from injury or harm during study participation.
- **Refrainment Risks.** Possible discomforts or risks associated with not using caffeine include headache, fatigue, decreased concentration, tremors, and irritability. Possible discomforts or risks associated with not using tobacco include headache, cough, fatigue, and irritability.

All study staff and U.S. licensed health professionals will have Basic Life Support, Automated External Defibrillators (AED), and first aid training and certification. An AED and first aid kit will be located directly outside the chamber during testing. The study's certified registered nurse practitioner will be present during all exercises. The certified registered nurse practitioner is not licensed in the state of Pennsylvania and will not have physician oversight as required by Pennsylvania's scope of practice law. In the case of a medical emergency, the U.S. licensed health professional will remain with the participant at all times. They will provide basic life support and/or first aid. They will direct additional trained and certified study staff to help as needed. In the rare event a serious medical emergency, study staff will immediately use the Emergency system in place. The participant will be transported by emergency responders to the nearest medical facility.

7. **Is my participation voluntary?**	The study is voluntary. You may choose to be in the study or not. You may choose to answer any or all questions. You may drop out any time for any reason without consequences to you and without losing any benefits to which you are otherwise entitled.
8. **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. However, 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 Health and Human Services (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.
9. **For how long will I be needed?**	Before being accepted into the study, you must complete screening forms and tests. This can be done in just one visit and will take about 3 hours. If you are selected to participate after screening above, you will return for about: 2 visits for Phase I (including first screening visit) over 3 to6 months (July 2019 to December 2019). 8 visits for Phase II over 6 to 9 months (November 2019 to July 2020). 4 visits for Phase III over 3 to 6 months (April 2020- to September 2020). This is about 14 visits over the course of 14 to 15 months. If you complete approximately 14 visits for 3 hours each (for 42 total hours) at $40/hour, your total possible reimbursement is about $1,680.
10. **Will I be reimbursed or paid?**	You will be paid at $40/hour during each visit. You will be paid$10 per quarter hour (15 minutes) if the visit lasts longer than 3 hours, rounded up to the nearest quarter hour. If you complete about 14 visits for 3 hours each (for 42 total hours) at $40/hour, your total possible payment is about $1,680.
11. **Are there any benefits?**	The benefit of this research is to gain data that may be used to improve PAPRs used by healthcare workers, which will ultimately aid patient care and worker safety for the U.S. population. Specifically, studying flow rates and work rates will aid the development of PAPRs as a class of respiratory protection and the standards that

	regulate them. In terms of standards development, this research will provide knowledge required to create an alternative PAPR standard geared toward industries such as healthcare, thus allowing for the next generation of PAPRs with smaller, quieter, more lightweight designs. This research will also evaluate the SWPF test method for assessing PAPR performance, which could ultimately become a standardized test method. In the event of a filtering facepiece respirator (FFR) shortage, PAPRs will be an alternative source of respiratory protection, so it is important to learn about the capabilities, limitations, and usability of these devices. This is an important reason to increase the availability and usability of PAPRs, which this research will do through standards development and information dissemination. This benefit will not only be seen in every day occupational health, but during emergency situations as well. This research may also benefit you personally in the form of respirator knowledge that could be applied in your own workplace. You will learn the correct procedures of donning, doffing, and operating PAPRs. You will learn the conditions and degrees to which you are protected in the workplace, how well the different devices fit you, and your level of comfortability performing various tasks. Lastly, you will have a sense of fulfillment that you are a part of research that is improving the state of both occupational health and healthcare in the United States. If you agree to volunteer, your information will only be used for research. It will not be sold for profit. The research completed with your information may help to develop new products, tests, and/or processes in the future. Any money or other rewards that may result from the development of new products, tests, and/or processes will not be shared with you.
12. Will my personal information be kept private?	This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The researchers with this Certificate may not share or use information, documents, or bodily samples that may identify you in any capacity. This includes, for example, if there is a court subpoena, unless you have agreed to this use. Information, documents, or bodily samples protected by this Certificate cannot be given to anyone else who is not connected with the research. The only exceptions is if there is a federal, state, or local law that requires it. If you have consented to the release, including for your medical treatment or if it is used for other scientific research, as allowed by federal guidelines protecting research participants. The Certificate cannot be used to refuse a request for information from staff of the United States federal or state government agency sponsoring the project. This includes information that is needed for auditing or program evaluation by the CDC, which is funding this project. Further, information must be given in order to meet the requirements of the federal Food and Drug Administration (FDA). The Certificate of Confidentiality does not stop you from choosing to release information about yourself or your involvement in this research. If you want your research information given to an insurer, medical care provider, or any other person not connected with the research,

	you must give consent to allow the researchers to release it. HHS System of Records Notices (SORNs) are required for studies in which the Privacy Act is relevant. As required by The Privacy Act, HHS publishes SORNs to give public notice of the records it keeps. These are found by personal identifiers. Each SORN describes the types of information contained in the records, the legal right for collecting and keeping the records, and how the records are used within HHS. It also contains the purposes (referred to as "routine uses") for which HHS may share the records to non-HHS parties without the participant's consent. 09-20-0159 Records of Participants in Certification, Testing, Studies of Personal Protective Devices, and Accident Investigations. **Categories of Individuals Covered by the System:** Individuals working in unsafe environments and individuals selected as control groups are covered by this system. Also, the system concerns individuals selected to test the interaction between people, personal protection or safety equipment, users of such equipment, and an unsafe environment. NPPTL is allowed to collect your personal information. NPPTL will protect it to the degree allowed by law. There are conditions under the Privacy Act where your information may be given to partners or contractors, health departments or disease registries, to the Departments of Justice or Labor, or to Congressional offices. This research study will result in identifiable information that will be placed in a locked location on a secured NPPTL campus. Only study information without identifying information will be used in the research data reports and publications. All information published or released publicly will be without participant identity. This information could also be used for future research studies or given to another investigator for future research studies. This does not require additional informed consent from you or a legal representative. NPPTL's ability to collect and keep your information is protected by three federal laws. These laws are: Health Service Act (42 U.S.C. 241) Occupational Safety and Health Act (29 U.S.C. 669) The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)
13. Who will know about my participation in this study?	The results of the study will be recorded in a journal article or a National Personal Protective Technology Laboratory research report. At your request, copies will be provided to you upon publication. Please contact Ziqing Zhuang, Ph.D., General Engineer, at the NIOSH National Personal Protective Technology Laboratory, (412) 384-4055. Your individual results will not be given to you. However, female participants will be provided a copy of urine pregnancy test results. We encourage you to share this with your doctor or medical provider. The urine samples will not be used for commercial profit. It is possible that you will be advised to follow up with your medical provider at the discretion of the U.S. licensed health professional . Circumstances could include abnormal vital sign measurements or abnormal physical examination results. Depending on the degree of abnormality/change from prior status, the U.S. licensed health professional will make this advisory.

	By signing the optional photo release form during screening, the investigators and/or NIOSH has the right to publish your photo in a public study or report or use it in presentations. We will not publish a photo of you unless you agree to the optional photo release. We will not publish your name or other personal identifiers with your photo. The draw feature on a photo editor program will be used to obstruct view of participants' eyes and faces to lessen the risk of a participant being identified in a photo. In rare cases, the researchers may be required to release identifiable information related to this research study for safety. If the researchers learn that you, someone close to you, or the public is in danger of potential harm, they will need to alert, the proper agency, as required by law.
14. Who can I talk to if I have more questions?	If an injury should happen during the study, you should also contact: Ziqing Zhuang, Ph.D., General Engineer, National Personal Protective Technology Laboratory, (412) 386-4055. 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.
15. How long is information used?	Identifiers might be removed from the private information. After such removal, the information could be used for future research studies. It may also be given to another researcher for future research studies without additional informed consent from the participant or the legally authorized representative.
16. Can I stop participating if I no longer want to?	You may change your mind at any time and no longer take part in this research. This is often called withdrawing consent for participation. Any information recorded about you before your withdrawal date may be used. To withdraw your consent, you should contact the study team on the first page of this document.
17. Can I be removed from the study?	It is possible that you could be removed from the study. This could be for safety reasons. Also, you may be removed from study if you are resistant or unable to perform the study visits or tests. If you experience discomforts from the study sessions, you may also need to stop participating. If you are removed from the research study, the study team will explain to you the reason for your removal. For example, if at any point you decide not to refrain from smoking 1 hour prior to and during testing or consuming caffeine 12 hours prior to or during testing, you may be removed from the study. Also, if you take certain supplements the U.S. licensed health professional believes may interfere with testing or increase your risk for participation, you may be removed from the study.
18. What are my	If you decide to participate, you must truthfully share any information you have about your health or previous health conditions after signing the consent. You also must

respons-ibilities?	agree to immediately report changes to your health, any unusual feelings, and/or discomforts experienced during or after the study tests. This is for your safety.
19. Voluntary Informed Consent	**VOLUNTARY INFORMED CONSENT:** This study was explained to me. All my questions have been answered. I agree to participate in this study. _____ _____ Signature of **Participant** **Date** _____ Printed Name of **Participant** **CERTIFICATION OF INFORMED CONSENT:** I declare that I have explained the method and purpose of this research study to the above-named individual. I have discussed the possible benefits and risks of study participation. Any questions the individual had about this study have been answered. The study team will be available to answer future questions as they come up. I confirm that no part of this protocol was started until after this consent form was signed. _____ _____ Signature of **Study Representative** Date _____ Printed Name of **Study Representative**

20. Future Contact Consent	**FUTURE CONTACT CONSENT:** NPPTL may offer future research studies and opportunities. If you agree, we would like to add you to our secure NPPTL Future Contact Registry list. We can discuss with you possible future study participation opportunities. Information we will keep include your name, contact information, facial measurements, and medical history. Benefits of Future Contact The benefit of future contact includes learning about research study participation opportunities. Risks of Future Contact The greatest risk to you is the release of personal information. We will do our best to make sure that your personal information remains private. The chance of information being accessed by an unapproved person is very small. See the "*Who can I talk to if I have more questions?*" section for your rights if this happens. Storage of Data for Future Contact The information we collect will be kept in a secure location at NPPTL. It may be stored for the foreseeable future. If you agree now and later change your mind, you can contact us and say that you no longer want to be in the NPPTL Future Contact Registry. At that point, you will be removed from the registry, and you will no longer be contacted about study participation opportunities. Please read the sentence below. After reading it, check "Yes" or "No". Your choice will not affect your participation in this study. You can include me in the NPPTL Future Contact Registry ____ Yes, I agree ____ No, I do not agree Participant Initials ____ Date_____

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APPENDIX D. OSHA/NPPTL MEDICAL EVALUATION FORM

OSHA/NPPTL Mandatory Medical Evaluation: ***Full Facepiece & SCBA Long Form*** Version: February 01, 2019		
Your name ***(Last, First, Middle Initial)*** **:**		
Part A.	**Your Answer**	
1. Today's date ***(MM/DD/YYYY)*** :	/ /	
2. Birth Date ***(MM/DD/YYYY)*** :	/ /	
3. Biological Sex:	☐ Male	☐ Female
4. Your height:	ft.	in.
5. Your weight:		lbs.
6. Your occupation:		
7. Your phone number	( ) -	
8. The best time to phone you ***(morning, afternoon, evening, any)***		
9. Have your received contact information for the study team?	☐ Yes	☐ No
10.Have you worn a respirator previously	☐ Yes	☐ No
If "Yes", how many years of experience wearing respirators?		Years
If "Yes", what types of respirators have you worn/used?		
Part B.	**Your Answer**	
1. Do you ***currently*** smoke tobacco, or have you smoked tobacco in the last month:	☐ Yes	☐ No
2. Have you ***ever had*** any of the following conditions?		
a. Seizures:	☐ Yes	☐ No
b. Diabetes or chronic kidney disease:	☐ Yes	☐ No
c. Allergic reactions that interfere with your breathing:	☐ Yes	☐ No
d. Claustrophobia (fear of closed-in places):	☐ Yes	☐ No
e. Trouble smelling odors:	☐ Yes	☐ No
3. Have you ever had any of the following pulmonary or lung problems?		
a. Asbestosis:	☐ Yes	☐ No
b. Asthma:	☐ Yes	☐ No
c. Chronic bronchitis:	☐ Yes	☐ No
d. Emphysema:	☐ Yes	☐ No
e. Pneumonia:	☐ Yes	☐ No
f. Tuberculosis:	☐ Yes	☐ No
g. Silicosis:	☐ Yes	☐ No
h. Pneumothorax (collapsed lung):	☐ Yes	☐ No
i. Lung cancer:	☐ Yes	☐ No
j. Broken ribs:	☐ Yes	☐ No
k. Any chest injuries or surgeries:	☐ Yes	☐ No
l. Any other lung problem that you've been told about:	☐ Yes	☐ No
4. Do you currently have any of the following symptoms of pulmonary or lung illness?		
a. Shortness of breath (SOB):	☐ Yes	☐ No
b. SOB when walking fast on level ground or walking up a slight hill:	☐ Yes	☐ No
c. SOB when walking at an ordinary pace on level ground:	☐ Yes	☐ No
d. Have to stop for breath when walking on level ground:	☐ Yes	☐ No

e. SOB when washing or dressing yourself:	☐ Yes	☐ No
f. SOB that interferes with your job:	☐ Yes	☐ No
g. Coughing that produces phlegm (thick sputum):	☐ Yes	☐ No
h. Coughing that wakes you early in the morning:	☐ Yes	☐ No
i. Coughing that occurs mostly when you are lying down:	☐ Yes	☐ No
j. Coughing up blood in the last month:	☐ Yes	☐ No
k. Wheezing:	☐ Yes	☐ No
l. Wheezing that interferes with your job:	☐ Yes	☐ No
m. Chest pain when you breathe deeply:	☐ Yes	☐ No
n. Any other symptoms that you think may be related to lung problems:	☐ Yes	☐ No
5. Have you *ever had* any of the following cardiovascular or heart problems?		
a. Heart attack:	☐ Yes	☐ No
b. Stroke:	☐ Yes	☐ No
c. Angina:	☐ Yes	☐ No
d. Heart failure:	☐ Yes	☐ No
e. Swelling in your legs or feet (not caused by walking):	☐ Yes	☐ No
f. Heart arrhythmia (heart beating irregularly):	☐ Yes	☐ No
g. High blood pressure:	☐ Yes	☐ No
h. Any other heart problem that you've been told about:	☐ Yes	☐ No
6. Do you *currently have* any of the following cardiovascular or heart symptoms?		
a. Frequent pain or tightness in your chest:	☐ Yes	☐ No
b. Pain or tightness in your chest during physical activity:	☐ Yes	☐ No
c. Pain or tightness in your chest that interferes with your job:	☐ Yes	☐ No
d. In the past 2 years, has your heart skipped or missed a beat:	☐ Yes	☐ No
e. Heartburn or indigestion that is not related to eating:	☐ Yes	☐ No
f. Any symptoms you think may be related to heart or circulation problems:	☐ Yes	☐ No
7. Do you *currently* take medication for any of the following problems?		
a. Breathing or lung problems:	☐ Yes	☐ No
b. Cardiovascular or Heart trouble:	☐ Yes	☐ No
c. Blood pressure:	☐ Yes	☐ No
d. Seizures:	☐ Yes	☐ No
8. If you've used a respirator, have you *ever had* any of the following? (If you've never used a respirator, select no and go to # 9)	☐ Yes	☐ No
a. Eye irritation:	☐ Yes	☐ No
b. Skin allergies or rashes:	☐ Yes	☐ No
c. Anxiety:	☐ Yes	☐ No
d. General weakness or fatigue:	☐ Yes	☐ No
e. Any other problem that interferes with your use of a respirator:	☐ Yes	☐ No
9. Would you like to talk to the medical professional?	☐ Yes	☐ No

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10. Have you *ever lost* vision in either eye (temporarily or permanently):	☐ Yes	☐ No
11. Do you currently have any of the following vision problems?	☐ Yes	☐ No
a. Wear contact lenses:	☐ Yes	☐ No
b. Wear glasses:	☐ Yes	☐ No
c. Color blind:	☐ Yes	☐ No
d. Any other eye or vision problem:	☐ Yes	☐ No
12. Have you ever had an injury to your ears, including a broken ear drum:	☐ Yes	☐ No
13. Do you currently have any of the following hearing problems?	☐ Yes	☐ No
a. Difficulty hearing:	☐ Yes	☐ No
b. Wear a hearing aid:	☐ Yes	☐ No
c. Any other hearing or ear problem:	☐ Yes	☐ No
14. Have you *ever had* a back injury:	☐ Yes	☐ No
15. Do you currently have any of the following musculoskeletal problems?	☐ Yes	☐ No
a. Weakness in any of your arms, hands, legs, or feet:	☐ Yes	☐ No
b. Back pain:	☐ Yes	☐ No
c. Difficulty fully moving your arms and legs:	☐ Yes	☐ No
d. Pain or stiffness when you lean forward or backward at the waist:	☐ Yes	☐ No
e. Difficulty fully moving your head up or down:	☐ Yes	☐ No
f. Difficulty fully moving your head side to side:	☐ Yes	☐ No
g. Difficulty bending at your knees:	☐ Yes	☐ No
h. Difficulty squatting to the ground:	☐ Yes	☐ No
i. Climbing a flight of stairs or a ladder carrying more than 25 lbs:	☐ Yes	☐ No
j. Any muscle or skeletal problem that interferes with using a respirator:	☐ Yes	☐ No
PARTICIPANT STOP HERE		

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Licensed Medical Professional:
In accordance with good clinical practice, all abnormal answers to clinical signs or symptoms in the clinical history form should be followed up with additional questions to clearly document the clinical significance of the reported abnormal condition. While in many cases adequate information may be obtained with simple follow-up probes, in other cases (such as any chest pain) a rather detailed history may be necessary. The licensed medical professional is expected to use good clinical judgment in this process.

Evaluation notes (address abnormal findings):

☐ No exclusions identified ☐ Further evaluation necessary ☐ Excluded from participation

Licensed Medical Professional Printed Name: _____

Licensed Medical Professional Signature: _____

Date (MM/DD/YYYY): _____

APPENDIX E. NPPTL SCREENING MEDICAL EVALUATION

NPPTL SCREENING MEDICAL EVALUATION

Protocol: **Superior Powered Air-Purifying Respirator Tests and Technologies (SPARTAN)**

_____

Last Name, First Name, Middle Initial Date (MM/ DD/ YYYY)

_____

Emergency Contact Name, Emergency Contact Phone

.....

1. What is your general sense of health ☐ Excellent ☐ Good ☐ Fair ☐ Poor

2. Have you had a cold, flu, or illness recently? ☐ Yes ☐ No
   - If yes, what was the illness? _____
   - How long has it been since you fully recovered? _____ Days

3. Do you currently use tobacco?
   - If you answered yes, what types? _____
   - How frequently? _____
   - When was the last time you used the product(s)? _____

4. Do you currently use alcohol?
   - If you answered yes, how frequently? _____
   - When was the last time you used the product(s)? _____

5. Do you currently use illicit drugs?
   - If you answered yes, what types? _____
   - How frequently? _____
   - When was the last time you used the product(s)? _____

6. **Known Allergies**

Allergy	Medicine or Environmental	Reaction

7. **Current Medications (prescribed and over the counter)**

Medication	Indication (reason you take it)	Is it prescribed?

8. **Current Supplements** (e.g. Caffeine, Energy Drinks, Nicotine, Ma huang, Yohimbine, Ginseng, Ephedra, Khat, Licorice root, Bitter orange, Goldenseal, or any other supplement that could affect your heart rate or blood pressure?)

Supplement	Indication (reason you take it)	

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NPPTL SCREENING MEDICAL EVALUATION

Protocol: **Superior Powered Air-Purifying Respirator Tests and Technologies (SPARTAN)**

9. Medical History

Please list all medical conditions past or present in this box:

_____
_____
_____
_____
_____

10. Surgical History

Please list all past and scheduled surgical procedures in this box:

_____
_____
_____
_____
_____

PARTICIPANT STOP HERE

Resting Vital Signs *(subject should sit for a minimum of 10 minutes prior to obtaining vital signs)*

Date (MM/DD/YYYY):_____ **Time:** _____ **AM / PM**

VITAL SIGN	LOCATION	RESULT
Temperature		
O_2 Saturation		
Respirations/minute		
Heart Rate/minute		
Blood Pressure		

PROTOCOL SPECIFIC SCREENING TESTS:

☐ Urine Pregnancy Test Result: _____

☐ Maximal oxygen uptake (VO_{2max}) Result: _____

☐ Maximal Heart Rate (HR_{max}) Result: _____

☐ EKG Results: _____

CDC NIOSH NPPTL National Personal Protective Technology Laboratory

NPPTL SCREENING MEDICAL EVALUATION

Protocol: **Superior Powered Air-Purifying Respirator Tests and Technologies (SPARTAN)**

PHYSICAL EXAMINATION:

BODY SYSTEM	WNL	ABN	NA	COMMENTS
HEENT				
Respiratory				
Cardiovascular				
Gastrointestinal				
Urogenital				
Musculoskeletal				
Neurological				
Psychiatric				
Dermatological				
Hematologic				
Endocrine				
Other				

WNL: Within normal limits, ABN: Abnormal, NA: Not assessed

Note to Licensed Medical Professional:
In accordance with good clinical practice, all abnormal answers to clinical signs or symptoms in the clinical history form should be followed up with additional questions to clearly document the clinical significance of the reported abnormal condition.

I certify that I have examined the subject and completed the screening medical evaluation:

¯ No exclusions identified _ Further evaluation necessary _ Excluded from participation

Licensed Medical Professional Printed Name: _____

Licensed Medical Professional Signature: _____

Date (MM/DD/YYYY): _____

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CDC Workplace Safety and Health NIOSH NPPTL National Personal Protective Technology Laboratory

APPENDIX F. SUBJECT DATA FORM

1) Today's Date: _____

2) Name _____ Date of Birth: _____

3) Gender (circle one): Male Female

4) Race (circle one):

White (non-Hispanic) African American (non-Hispanic)

Asian Hispanic

Other (specify): _____

5) Do you currently smoke tobacco products? Yes _____ No _____
If "Yes", are you willing to refrain from smoking for at least one hour prior to and during a 4-hour lab test session? Yes _____ No _____

6) (Males only) Are you willing to appear for visits with a clean-shaven face?
Yes _____ No _____

7) Are you aware that you are allergic to any of the following substances found in baby powder or corn oil (e.g., corn starch, tricalcium phosphate, aloe barbadensis, vitamin E, fragrances)?
Yes _____ No _____

8) (Females only) Are you pregnant? Yes _____ No _____

9) (Females Only) Are you of child bearing potential?
If "No", please complete at least one of the following:
Date of Menopause: _____
Date of surgical sterilization and procedure: _____

10) Do you regularly exercise (about 30 minutes at moderate intensity on at least 3 days per week for the past 3 months)?
Yes _____ No _____

11) Do you currently consume caffeine? Yes _____ No _____
If "Yes", are you willing to refrain from consuming caffeine for at least 12 hours prior to and during a 4-hour lab test session? Yes _____ No _____

Study personnel to review this form and complete the below

Subject # _____

Technician Name: _____ ***Date Reviewed (MM/DD/YYYY):*** _____

1604

1605 **APPENDIX G. POINT OF CARE TESTING FORM**

Point of Care Testing Form

Participant: please provide your copy to your Primary Care Provider

_____

Last Name, First Name, Middle Initial Date (MM/DD/YYYY)

Urine Pregnancy Test Results:

	Urine Pregnancy Test
Reference Range	
Subject Result	

.....

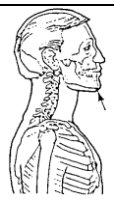
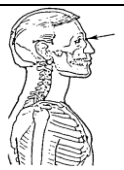
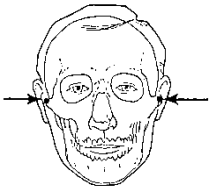
Licensed medical professional printed name: _____

Signature: _____ Date (MM/DD/YYYY): _____

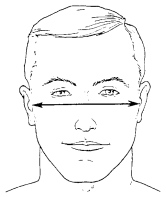
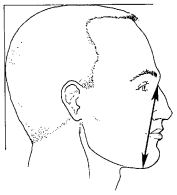
Phone number of NIOSH medical professional: _____

1606
1607
1608
1609

APPENDIX H. DESCRIPTION, DEFINITION, AND DIAGRAM OF LANDMARKS

Description	Definition	Diagram
Menton	The inferior point of the mandible in the midsagittal plane (bottom of the chin).	
Sellion	The point of the deepest depression of the nasal bones at the top of the nose.	
Zygion, right and left	The most lateral point on the zygomatic arch. (unmarked). When unmarked, this is located by movement of the tips of the spreading caliper during measurement.	

APPENDIX I. DESCRIPTION, DEFINITION, AND DIAGRAM OR MEASUREMENTS

Description	Definition	Diagram
Bizygomatic Breadth	Maximum horizontal breadth of the face as measured with a spreading caliper between the zygomatic arches.	
Menton-Sellion Length	Distance as measured with a sliding caliper in the midsagittal plane between the menton landmark and the sellion landmark.	

APPENDIX J. TRADITIONAL ANTHROPOMETRIC DATA FORM

Subject No. _____ Date _____

Dimension	Measurement (mm)
Bizygomatic Breadth (face width)	
Menton-Sellion Length (face length)	

APPENDIX K. MAXIMAL GRADED EXERCISE TEST (GXT)

This screening test will be conducted according to the Bruce protocol (table below). Subjects will begin by walking on a treadmill at 1.7 mph at 0%, 5%, and 10% grade for 3 minutes at each grade. Then, the treadmill speed will be increased by 0.8 mph and the grade by 2% every 3 minutes until the speed reaches 5.0 mph and the grade reaches 18%. The speed will continue to increase by 0.5 mph every 3 minutes, but the grade will remain the same for the remainder of the test. Subjects will complete as many stages until volitional fatigue.

Bruce Protocol

Stage	Duration (min)	Treadmill Speed (mph)	Treadmill Grade (%)
1	3	1.7	0
2	3	1.7	5
3	3	1.7	10
4	3	2.5	12
5	3	3.4	14
6	3	4.2	16
7	3	5.0	18
8	3	5.5	18
9	3	6.0	18

Subjects will be equipped with a heart rate (HR) monitor and silicone-rubber oronasal facemask from the metabolic cart (K5 Wearable Metabolic Technology) (Cosmed, Rome, Italy) during the Maximal Graded Exercise Test. The metabolic cart, authorized for use by NPPTL physiology lab personnel, is device that measures expired air for oxygen uptake (VO_2), minute ventilation (V_e), and carbon dioxide (VCO_2).

Subjects will be placed into the one of the categories described in Table 4 following this test. Subjects who achieve a maximal oxygen consumption above “Poor” category (e.g. Fair to Excellent categories) based on American College of Sports Medicine Fitness Categories for Maximal Aerobic Power (treadmill test) maybe included in the study.

Subjects will be equipped with an EKG during this test to detect and potential abnormal responses to exercise (e.g., life-threatening dysrhythmias, ventricular tachycardia, ST-T waves changes, or any evidence of ischemia). The reason for the EKG being taken during the test is to identify potential abnormal cardiovascular conditions that otherwise may not be visible on an EKG taken at rest.

Subjects’ blood pressure will be monitored once during each stage of this protocol. Any abnormal blood pressure response to exercise (e.g. hypotensive response) will result in test termination.

The termination of this test will be carried out with a gradual walking down of the treadmill grade and speed, as to avoid injuries to the subjects. Following GXT, subject will be given water as much they want.

This screening test will take place at the NPPTL physiology lab or NPPTL Building 40 environmental test chamber and high bay area under the supervision of trained physiologists, medical monitor certified registered nurse practitioner, and study investigators. It will be conducted in a thermoneutral environment (23°C and 45%RH).

APPENDIX L. NPPTL DAILY PRE-TEST EVALUATION

NPPTL PRE TEST EVALUATION

Protocol: **Superior Powered Air-Purifying Respirator Tests and Technologies (SPARTAN)**

Last Name, *First Name,* *Middle Initial* *Date (MM/ DD/ YYYY)*

Emergency Contact Name, *Emergency Contact Phone*

1. What is your general sense of health ☐ Excellent ☐ Good ☐ Fair ☐ Poor
2. Have you had a cold, flu, or illness since your last visit here? ☐ Yes ☐ No
   - If yes, what was the illness? _____
   - How long has it been since you fully recovered? _____ Days
3. Have you smoked tobacco products within the last 60 minutes? ☐ Yes ☐ No
4. Did you eat or drink anything other than water in the last 30 minutes? ☐ Yes ☐ No
5. Any reason why body movements and exercises today may be unsafe for you? ☐ Yes ☐ No
6. Have you been to the hospital or seen a doctor since last visit here? ☐ Yes ☐ No
7. Any new medical or surgical conditions since your last visit here? ☐ Yes ☐ No
8. Any new allergies since your last visit here? ☐ Yes ☐ No
9. Any new medications since your last visit here? ☐ Yes ☐ No
10. Have you consumed caffeine in the past 12 hours? ☐ Yes ☐ No

PARTICIPANT STOP HERE

Resting Vital Signs *(subject must sit for a minimum of 10 minutes prior to obtaining vital signs)*

Date (MM/DD/YYYY):_____ **Time:** _____ **AM / PM**

VITAL SIGN	LOCATION	RESULT
Temperature		
O_2 Saturation		
Respirations/minute		
Heart Rate/minute		
Blood Pressure		

CDC NIOSH NPPTL National Personal Protective Technology Laboratory

CDC Workplace Safety and Health NIOSH NPPTL National Personal Protective Technology Laboratory

NPPTL PRE TEST EVALUATION

Protocol: **Superior Powered Air-Purifying Respirator Tests and Technologies (SPARTAN)**

PROTOCOL SPECIFIC DAILY SAFETY TESTS:

☐ Urine Pregnancy Test Result: _____

FOCUSED PHYSICAL EXAMINATION:

BODY SYSTEM	WNL	ABN	NA	COMMENTS
Respiratory				
Cardiovascular				
Musculoskeletal				
Neurological				
Dermatological				

WNL: Within normal limits, ABN: Abnormal, NA: Not assessed

PRE TEST CHECKLIST:

☐ Informed Consent completed and available
☐ NPPTL Screening Medical Evaluation form referred to for baseline medical history
☐ NPPTL Pre Test Evaluation forms previously completed referred to for baseline changes
☐ AED and first aid kit locations in test lab and known by licensed medical professional monitor
☐ Subjects screening Maximal Oxygen Uptake (VO_{2max}) safety parameter: _____
☐ Subjects screening Maximal Heart Rate (HR_{max}) safety parameter: _____

.....

Note to Licensed Medical Professional:
In accordance with good clinical practice, all abnormal answers to clinical signs or symptoms in the clinical history form should be followed up with additional questions to clearly document the clinical significance of the reported abnormal condition.

I certify that I have examined the subject and completed the Pre Test Evaluation:

☐ No exclusions identified ☐ Further evaluation necessary ☐ Excluded from participation

Licensed Healthcare Professional Printed Name: _____

Signature: _____

Date (MM/DD/YYYY): _____ Time:_____ AM / PM

CDC NIOSH NPPTL National Personal Protective Technology Laboratory

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APPENDIX M. PHASE II QUESTIONNAIRE: ASSESSING PAPR FLOW RATE EFFECT

Subject ID _____ Date _____
PAPR Model name and facepiece type (Tight/Loose) _____
Airflow rate setting (Low, NIOSH Standard (115 or 170), High)_____

1. In general, how easy was it to don and doff this PAPR model?
   (1 = easy, 2 = acceptable, 3 = not easy). Circle one number.

   1 2 3

2. How do you rate the weight of this PAPR?
   (1 = light, 2 = comfortable but slightly heavy, 3 = heavy). Circle one number.

   1 2 3

3. Relating to the airflow, rate the comfort, perceived fit, and feeling of airflow?
   (1 = very poor, 2 = poor, 3 = acceptable, 4 = good, 5 = very good). Circle one number.

   1 2 3 4 5

4. How do you rank the noise inside the PAPR hood or mask?
   (1 = very loud, 2 = loud, 3 = acceptable, 4 = quiet). Circle one number.

   1 2 3 4

5. How do you rank this PAPR for your visibility?
   (1 = very poor visibility, 2 = poor visibility, 3 = acceptable, 4 = good visibility, 5 = very good visibility). Circle one number.

   1 2 3 4 5

6. Considering all aspects of the PAPR, rate your experience wearing this PAPR?
   (1 = very poor, 2 = poor, 3 = acceptable, 4 = good, 5 = very good). Circle one number.

   1 2 3 4 5

APPENDIX N. PHASE III QUESTIONNAIRE: ASSESSING USER WORK RATE EFFECT

Subject ID _____ Date _____
PAPR Model name and facepiece type (Tight/Loose) _____
Exercise regime (A, B) _____

1. In general, how easy was it to don and doff this PAPR model?
(1 = easy, 2 = acceptable, 3 = not easy). Circle one number.

1 2 3

2. How do you rate the weight of this PAPR?
(1 = light, 2 = comfortable but slightly heavy, 3 = heavy). Circle one number.

1 2 3

3. Relating to the airflow, rate the comfort, perceived fit, and feeling of airflow?
(1 = very poor, 2 = poor, 3 = acceptable, 4 = good, 5 = very good). Circle one number.

1 2 3 4 5

4. How do you rank the noise inside the PAPR hood or mask?
(1 = very loud, 2 = loud, 3 = acceptable, 4 = quiet). Circle one number.

1 2 3 4

5. How do you rank this PAPR for your visibility?
(1 = very poor visibility, 2 = poor visibility, 3 = acceptable, 4 = good visibility, 5 = very good visibility). Circle one number.

1 2 3 4 5

6. Considering all aspects of the PAPR, rate your experience wearing this PAPR?
(1 = very poor, 2 = poor, 3 = acceptable, 4 = good, 5 = very good). Circle one number.

1 2 3 4 5

APPENDIX O. NPPTL DAILY POST-TEST EVALUATION

NPPTL POST TEST EVALUATION

Protocol: **Superior Powered Air-Purifying Respirator Tests and Technologies (SPARTAN)**

_____

Subject Full Name (last, first, middle initial) *Date (MM/DD/YYYY)*

1. Does the subject report pain, illness, or discomfort after completing the test(s) today ☐ Yes* ☐ No
   *If the answer above is "yes" provide the below assessment:
   - Onset: _____
   - Location: _____
   - Duration: _____
   - Characteristics: _____
   - Aggravating/relieving factors: _____
   - Related 2º symptoms: _____
   - Treatments: _____

Resting Vital Signs *(subject must sit for a minimum of 10 minutes prior to obtaining vital signs)*

Date (MM/DD/YYYY):_____ **Time:** _____ **AM / PM**

VITAL SIGN	LOCATION	RESULT
Temperature		
O_2 Saturation		
Respirations/minute		
Heart Rate/minute		
Blood Pressure		

Vitals signs are within baseline limits (compare to Pre Test Evaluation)? ☐ Yes ☐ No

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NPPTL POST TEST EVALUATION

Protocol: **Superior Powered Air-Purifying Respirator Tests and Technologies (SPARTAN)**

Document any Adverse Events identified if applicable (CTCAE Version 5.0)[1]

ADVERSE EVENT	GRADE (1-5)[2]	RELATION[3]
.		

[1]Adverse events (AEs) refer to any untoward medical occurrences, whether considered study intervention-related or not. Serious adverse events (SAEs) refer to anything that causes death, life-threatening event, requires hospitalization, leads to incapacity, is a substantial disruption of a subject's quality of life, or causes a congenital anomaly/birth defect. All AEs or SAEs encountered during the study will be evaluated on an ongoing basis according to the NCI Common Toxicity Criteria Adverse Events (CTCAE) version 5.0. SAEs must be reported to the IRB within 48 hours from notification of the incident onset.
[2]Grade according to Common Terminology Criteria for Adverse Events (CTCAE) Version 5.0
[3]Study Intervention Relations (select one): Not Related, Unlikely Related, Possibly Related, Likely Related, Definitely Related

PROTOCOL SPECIFIC TERMINATION CRITERIA SAFETY PARAMETERS:

1. Was subjects Maximal Oxygen Uptake (VO_{2max}) reached today during test(s)? ☐ Yes ☐ No
2. Did subject reach 90% of their Maximal Heart Rate (HR_{max}) today during test(s)? ☐ Yes ☐ No
3. Did subjects resting vitals in between exercise regimens fail to return WNL? ☐ Yes ☐ No

Note to Licensed Medical Professional:
In accordance with good clinical practice, all abnormal answers to clinical signs or symptoms in the clinical history form should be followed up with additional questions to clearly document the clinical significance of the reported abnormal condition.

I certify that I have examined the subject and completed the Post Test Evaluation:

☐ No adverse events identified, subject may be discharged ☐ Further evaluation necessary

Licensed Healthcare Professional Printed Name: _____

Signature: _____

Date (MM/DD/YYYY): _____ Time:_____ AM / PM

CDC NIOSH NPPTL National Personal Protective Technology Laboratory

APPENDIX P. EMERGENCY DECISION MAKING PROTOCOL

Emergency Procedures for NIOSH Pittsburgh

1. Dial 11 - Employee calls, all calls will be received by the Telephone Operator/Security Guard (B-100).
2. The Telephone Operator/Security Guard will answer "What is the Emergency?"
3. Caller - Stay on the line to answer these questions:
    a. The location of the emergency (Building, Floor, and Room)
    b. Number of persons who are injured and the nature of injury
    c. Your name and telephone number
4. **Do not attempt to move or assist an injured person unless you have had the proper training.** If possible, provide comfort by talking to the injured person until further help arrives.
5. At this point, Telephone Operator/Security Guard will activate the NIOSH-Pittsburgh Emergency Response Team, with an announcement over the NIOSH-Pittsburgh 2-way radio system.
6. Telephone Operator/Security Guard will call for the outside emergency response assistance (i.e., Fire, Police, and Ambulance Services) and forward all information to the NIOSH-Pittsburgh Emergency Response Team.
7. During an incident involving a subject in the lab, the study staff will provide emergency triage. In addition, we require all study staff to be CPR/AED certified. The study staff will assess the subject until further outside assistance (ambulance) arrives to transport to outside medical facility (hospital). The emergency numbers are prominently displayed in the lab so that any of the lab staff can activate the emergency system.
8. If the emergency occurs in the fit test chamber, depending on the situation, the study staff will remove or cut away the mask or hood if safe to do so, turn off any challenge agents, flush the area with clean air, etc as appropriate while waiting for emergency response.

APPENDIX Q. STUDY INVESTIGATORS

Ziqing Zhuang, Ph.D. – Dr. Zhuang is currently the team leader for Team 1in the Research Branch (RB) at NIOSH/NPPTL. He provides technical guidance for this study and will be responsible for high quality data collection, data analyses, and dissemination of study results. His major areas of expertise are occupational health and safety engineering and industrial engineering. Dr. Zhuang joined NIOSH in 1996 and joined the National Personal Protective Technology Laboratory (NPPTL) when NPPTL was established. He has more than 20 years of research experience in respiratory protection. Dr. Zhuang conducted a series of workplace protection factor studies at foundry, paint-spraying, and steel-manufacturing operations. He was involved in various studies to compare fit factors of six quantitative fit test methods with exposure dose of Freon-113, to measure laboratory performance of N95 respirators, and to determine the adequacy of Bitrex, Saccharin, ambient aerosol (PORTACOUNT), PORTACOUNT with N95 Companion, and generated aerosol fit test methods. He conducted a head-and-face anthropometric survey of U.S. respirator users, and various studies to develop respirator fit test panels representative of today's U.S. workforce, and standard headforms for testing respirators, safety glass, and helmets. He serves on the ISO TC94 SC15 respiratory protective device standards, WG1 (working group 1) and WG2. He is the Editor for the Journal of the International Society for Respiratory Protection. He has authored or co-authored more than 80 peer reviewed publications on respirator fit testing, selection, and use. Of these publications, two papers were selected by the Institute (i.e., NIOSH) as Outstanding Scientific Paper and Charles C. Shepard Award Nominee in 2004 & 2006. Seven papers were Division nominees for Charles C. Shepard Award in 2000, 2002, 2003, 2004, 2005, 2006, and 2014. One paper received the Honorable Mention award for the 2014 Alice Hamilton Award in the Engineering and Controls Category. Four posters presented at the American Industrial Hygiene Conference and Exposition in 2000, 2002, 2004, and 2010 were selected for the Best of Session Award. Two papers were part of a large scale research project to reduce back injury in nursing homes and the project was selected for the 2003 NORA Partnership Award. Five papers were selected by the Respiratory Protection Committee of the American Industrial Hygiene Association for the John M. White Best Paper Awards in 1996, 1999, 2000, 2015 and 2016, respectively. Results from his research projects have, to date, substantially impacted US and international policies, procedures, and standards for respiratory protective devices. Manufacturers and academicians have used respirator fit test panels and 3D digital headforms resulted from his research as tools in fit test research and in designing, sizing and testing new personal protective devices.

Evanly Vo, Ph.D. – He earned DDS degree in 1987. He also obtained a Ph.D. degree in organic chemistry and biological chemistry at the University of Houston in 1997. He will provide technical assistance in data collection and analysis for this project. Evanly joined the UC Biotechnology Research System in California, where he involved in studies on the UC Berkeley funded project: "Characterization of the Physical and Functional Properties of Plant Dehydration-Associated Proteins" as a postdoctoral scientist from 1997-1998. In 1998, he started as a research chemist with National Institute for Occupational Safety (NIOSH, Morgantown, WV). Evanly joined with National Personal Protective Technology Laboratory (NPPTL, Pittsburgh, PA) in 2003 and has been working as a physical scientist with NPPTL and since that time has been working to evaluate filtration performance of respirators for particles with unique properties such as viruses or nanoparticles. He is expertise in organic and peptide synthesis, colorimetric indicator synthesis, chemical and biological analysis, and aerosol technology and its application. He is the first author of over 20 publications, including some top scientific journals such as Journal of American Chemical Society, Inorganic Biochemistry, Analyst, Applied Analytical Chemistry, Plant Physiology, Applied & Environmental Microbiology, Aerosol Sciences, and Aerosol Science & Technology.

Michael S. Bergman, M.S. – Michael Bergman is an Associate Service Fellow at NIOSH/NPPTL/RB and serves as co-investigator on the project. He is a task leader for this project and is responsible for high quality human subject data collection, data analyses, and dissemination of study results. Mr. Bergman has 10 years of experience in the fields of respirator use, policy, and research. He previously worked for NIOSH as a laboratory technician where he assisted with research on respirator filtration efficiency. He has authored or co-authored 20 peer reviewed publications on respirator fit testing and filtration.

Matthew Horvatin, B.S. – Matthew Horvatin is a chemist employed as a Federal Contractor at NIOSH/NPPTL/RB and serves as a co-investigator on the project. He will be responsible for recruiting, collecting human subject test data, data analyses, and dissemination of study results. He received his B.S. in Chemistry from The Pennsylvania State University in 2006. He has been supporting NPPTL for 7 years (2010) and has supported several projects including Respirator Protection against Nanoparticles (RPAN), Ebola related glove studies and surgical gown rapid elbow lean tests (RELTs), Carbon Nanotubes research (CNTs) as well as Chemical Permeation through PPE. So far, he has co-authored six peer reviewed publications on his work in these fields.

Harold Boyles, B.S.N., R.N., MSHCA, MLT. - Harold Boyles, RN, MHCA, MLT received a Medical Laboratory Technology degree from George Washington University, he received his Bachelor of Science in Nursing from Alderson-Broaddus College, and finally he obtained his Masters in Healthcare Administration from Independence University. Harold is a six year United States Navy Veteran where he begin his medical career as a Hospital Corpsman, he then transitioned to the United States Army in the West Virginia National Guard as a Combat Medic for three years. Finally, Harold accepted a Commission in the United States Public Health Service where he has been detailed to the Federal Bureau of Prisons and Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health for the last 15 years. He is currently the Deputy, Research Branch at the National Personal Protective Technology Laboratory. Harold has practiced Registered Nursing for 17 years and has provided medical monitoring for human subject research/respirator approval program testing protocols at CDC/NIOSH/NPPTL for the past 5 years.

Tyler Quinn, M.S. - Tyler Quinn, MS is a doctoral candidate of exercise physiology at the University of Pittsburgh (Pittsburgh, US) where he researches occupational health promotion and cardiovascular health with an expected graduation of January 2020. He is currently working as a ORISE fellow at the U.S. Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health (CDC/NIOSH) where he has accumulated 5 years of research experience. Tyler has worked as a physiologist and data scientist on more than 6 major projects and has published over 15 peer reviewed publications in the areas of human thermal physiology, workplace health promotion, occupational sedentary behavior, and cardiovascular health. Most notably, he has published multiple peer reviewed publications regarding healthcare worker safety and countermeasures to physiological strain during the Ebola response efforts in West Africa of 2014-16. He will be responsible for developing the test protocol to determine work load and breathing rates for the project. He will also provide assistance with the data collection for physiological measurements and data analyses.

Jeffrey Powell, M.S. - Mr. Jeffrey Powell, MS is a Biologist at NIOSH/NPPTL. He received M.S in Exercise Physiology from the University of Pittsburgh and is a Certified Health and Fitness Instructor (American College of Sports Medicine). He has over 15 years' experience in human subject research including experimental physiology, occupational physiology, and exercise testing. He will be

responsible for developing the test protocol to determine work load and breathing rates for the project. He will also provide assistance with the data collection for physiological measurements and data analyses.

Adam Hornbeck, M.S.N., A.P.R.N., FNP-BC, FNP-C - Adam Hornbeck serves as a Board Certified Family Nurse Practitioner. Adam is licensed as an Advanced Registered Nurse Practitioner in Iowa which is an independent practice state. Iowa (similar to numerous other states in the United States) allows a Nurse Practitioner to practice medicine independently without supervision from a Physician. He serves as the medical monitor in the Research Branch of the National Personal Protective Technology Laboratory within the National Institute of Occupation Safety and Health and Centers for Disease Control and Prevention. Since March 2020, he has served as the medical monitor for the Evaluation and Testing Branch (ETB) at NPPTL. His work as medical monitor for ETB includes screening participants for inclusion/exclusion criteria, providing physical examinations, and monitoring activities such as graded exercise testing and rigorous self-contained breathing apparatus man tests. He joined the United States Public Health Service Commissioned Corps in 2010 as a Nurse Officer and has been a Registered Nurse since 2006. He obtained his Bachelor of Science in Nursing from Fairmont State University, and his Master of Science in Nursing from Simmons University in Boston, Massachusetts. Research methodology was included in his education and training and was a part of his Family Nurse Practitioner Exam. Adam also has vast clinical experience, both on and off federal premises, working as an R.N. in the Davis Memorial Hospital (Elkins, WV) Emergency Department from 2006-2008 and the West Virginia University Hospital (Morgantown, WV) Adult Medical and Surgical Intensive Care Units from 2008-2010. He served as an R.N. and A.P.R.N. in the Federal Correctional Complex (Hazelton, WV) from 2009-2013 and in the Federal Medical Center (Lexington, KY) from 2013-2020. His work in corrections at the U.S. Federal Bureau of Prisons Medical Center also included providing Occupational Health to all staff related to Infection Prevention and Control. He was also in charge of annual training for approximately 500 staff in the area of Blood-borne Pathogens and Infectious Disease.

Brooke Vollmer, B.S. – Brooke Vollmer is a Regular Fellow at NIOSH/NPPTL/RB and serves as a co-investigator for this project. She will be responsible for recruiting, collecting human subject test data, data analyses, and dissemination of study results. She received her B.S. in Biology from the University of Pittsburgh in 2020. She worked as a Research Intern in summer 2019, where she aided in aerosol filtration research on NIOSH-certified powered air-purifying respirator high efficiency filters. Her most recent research contributions involve manikin headform fit performance and analysis of decontaminated N95 filtering facepiece respirators.

Andrew V. Wilson, B.S. – Andrew (Vlad) Wilson, is a Regular Research Fellow within the Research Branch of NIOSH/NPPTL/RB. He will be responsible for recruiting, collecting human subject test data, data analyses, and dissemination of study results. He obtained his B.S. in Chemical Engineering and Chemistry from Geneva College in 2020. He worked as a Research Intern in summer 2018 at NIOSH Pittsburgh, where he investigated PAPR (Powered Air Purifying Respirator) Performance at variable PAPR flow rates using a new robotic head form. He worked as a Research Intern in summer 2019 at NIOSH Morgantown, where he compared compare Carbon Tetrachloride to Cyclohexane and set up and reconfigure a gas and vapor test box that was intended to be used for audit testing. He currently works on the Evaluation of Decontaminated N95 Respirators project.

APPENDIX R. DELEGATION OF AUTHORITY LOG

Delegation of Authorities (DoA) Log for Superior Powered Air-Purifying Respirator Tests and New Technologies (SPARTAN)

Start Date on the DoA must be on or before the first date that any study activities were completed by the staff member. The start date indicates that the PI has determined the staff member to be delegated and trained for their responsibilities listed. Maintain this roster with study essential documents and update as staffing changes occur. This log serves as a legal delegation of trial responsibilities; however delegation assignment does not absolve the site PI of any regulatory or contractual responsibilities for protocol management and oversight.

Principal Investigator: Ziqing Zhuang, PhD

Protocol Version 4 Date: 3-2-2021

Role Codes[1]:

PI	Principal Investigator	LT	Lab Technician	BS	Biostatistician
MD	Medical Doctor	RA	Research Assistant	TA	Technical Advisor
DM	Data Manager	EP	Exercise Physiologist	CoI	Co Investigator
RN	Registered Nurse	NP	Nurse Practitioner		

Responsibility Codes[2]:

1	Informed Consent	11	Regulatory Management	21	Accrual activities
2	Determination of Eligibility	12	PII (access to personal identifiers)	22	Participant Retention Oversight/Tracking
3	Evaluation of Trial Lab Results	13	Data Capture Forms (DCF)	23	Exercise Testing Administration/Education
4	Assess Adverse Events	14	QA/QC	24	Metabolic cart set up and management
5	Assess & Reporting of SAEs	15	Data management	25	PAPR education and application for subjects
6	Trial Related Medical Decisions	16	Protocol/Consent IRB submissions/mods	26	Physiological Data Collection/interpretation
7	Perform Physical Exams	17	Surveys	27	Data Analysis
8	Obtain Medical/Medication History	18	Document Protocol Deviations	28	Fit Testing
9	Randomization	19	Collects Specimens		
10	Medical monitoring	20	Processes/Ships Specimens		

The individuals listed on this log are properly qualified and have received appropriate training including NIOSH power point review and study protocol review related to their respective tasks for this protocol. I assert that these duties were performed under my direct supervision.

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Delegation of Authorities Log for SPARTAN

Name (please print)	Project Role[1] (Please list all that apply; refer to Cover Sheet for codes list)	Responsibilities[2] (Please list all that apply; refer to Cover Sheet for codes list)	Contractor or Federal Employee	Position Title
Adam Hornbeck	NP	2,3,4,5,6,7,8,10,12, 19,20,26	Federal Employee	Medical Monitor
Harold Boyles	RN	7,8,12,19,20,26	Federal Employee	Branch Chief and Nurse Consultant
Ziqing Zhuang	PI	1,2,4,5,9,11,12,13,14, 15,16,17,18,21,22,23, 25,26,27,28	Federal Employee	General Engineer and Team Lead
Michael Bergman	DM, TA, Col	1,2,4,5,9,11,12,13,14, 15,16,17,18,21,22,23, 25,26,27,28	Federal Employee	Biologist
Matthew Horvatin	LT, Col	1,2,4,5,9,11,12,13,14, 15,16,17,18,21,22,23, 25,26,27,28	Contractor	Lab Technician
Brooke Vollmer	RA, Col	1,2,4,5,9,11,12,13,14, 15,16,17,18,21,22,23, 25,26,27,28	Contractor	Regular Fellow
Yongsuk Seo	RA, EP	4,5,12,13,14,15,17,18, 21,22,23,24,26	Contractor	ORISE Fellow
Kevin Strickland	RA, Col	1,2,4,5,9,11,12,13,14, 15,16,17,18,21,22,23, 25,26,27,28	Contractor	ORISE Fellow
Evanly Vo	DM, TA, Col	1,2,4,5,9,11,12,13,14, 15,16,17,18,21,22,23, 25,26,27,28	Federal Employee	Physical Scientist
Andrew Wilson	RA, Col	1,2,4,5,9,11,12,13,14, 15,16,17,18,21,22,23, 25,26,27,28	Contractor	Regular Fellow
Patrick Yorio	BS	27	Federal Employee	Statistician
Tyler Quinn	RA, EP	4,5,12,13,14,15,17,18, 21,22,23,24,26	Contractor	ORISE Fellow
Jeffrey Powell	RA, EP	4,5,12,13,14,15,17,18, 21,22,23,24,26	Federal Employee	Biologist

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APPENDIX S. IRS FORM W-9

Form **W-9**
(Rev. October 2018)
Department of the Treasury
Internal Revenue Service

Request for Taxpayer Identification Number and Certification

▶ Go to *www.irs.gov/FormW9* for instructions and the latest information.

Give Form to the requester. Do not send to the IRS.

Print or type. See Specific Instructions on page 3.

1 Name (as shown on your income tax return). Name is required on this line; do not leave this line blank.

2 Business name/disregarded entity name, if different from above

3 Check appropriate box for federal tax classification of the person whose name is entered on line 1. Check only one of the following seven boxes.

☐ Individual/sole proprietor or single-member LLC ☐ C Corporation ☐ S Corporation ☐ Partnership ☐ Trust/estate

☐ Limited liability company. Enter the tax classification (C=C corporation, S=S corporation, P=Partnership) ▶ _____

Note: Check the appropriate box in the line above for the tax classification of the single-member owner. Do not check LLC if the LLC is classified as a single-member LLC that is disregarded from the owner unless the owner of the LLC is another LLC that is not disregarded from the owner for U.S. federal tax purposes. Otherwise, a single-member LLC that is disregarded from the owner should check the appropriate box for the tax classification of its owner.

☐ Other (see instructions) ▶

4 Exemptions (codes apply only to certain entities, not individuals; see instructions on page 3):

Exempt payee code (if any) _____

Exemption from FATCA reporting code (if any) _____

(Applies to accounts maintained outside the U.S.)

5 Address (number, street, and apt. or suite no.) See instructions.

Requester's name and address (optional)

6 City, state, and ZIP code

7 List account number(s) here (optional)

Part I Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. The TIN provided must match the name given on line 1 to avoid backup withholding. For individuals, this is generally your social security number (SSN). However, for a resident alien, sole proprietor, or disregarded entity, see the instructions for Part I, later. For other entities, it is your employer identification number (EIN). If you do not have a number, see *How to get a TIN*, later.

Note: If the account is in more than one name, see the instructions for line 1. Also see *What Name and Number To Give the Requester* for guidelines on whose number to enter.

Social security number

___ – ___ – ____

or

Employer identification number

__ – _____

Part II Certification

Under penalties of perjury, I certify that:

1. The number shown on this form is my correct taxpayer identification number (or I am waiting for a number to be issued to me); and
2. I am not subject to backup withholding because: (a) I am exempt from backup withholding, or (b) I have not been notified by the Internal Revenue Service (IRS) that I am subject to backup withholding as a result of a failure to report all interest or dividends, or (c) the IRS has notified me that I am no longer subject to backup withholding; and
3. I am a U.S. citizen or other U.S. person (defined below); and
4. The FATCA code(s) entered on this form (if any) indicating that I am exempt from FATCA reporting is correct.

Certification instructions. You must cross out item 2 above if you have been notified by the IRS that you are currently subject to backup withholding because you have failed to report all interest and dividends on your tax return. For real estate transactions, item 2 does not apply. For mortgage interest paid, acquisition or abandonment of secured property, cancellation of debt, contributions to an individual retirement arrangement (IRA), and generally, payments other than interest and dividends, you are not required to sign the certification, but you must provide your correct TIN. See the instructions for Part II, later.

Sign Here Signature of U.S. person ▶ Date ▶

General Instructions

Section references are to the Internal Revenue Code unless otherwise noted.

Future developments. For the latest information about developments related to Form W-9 and its instructions, such as legislation enacted after they were published, go to *www.irs.gov/FormW9*.

Purpose of Form

An individual or entity (Form W-9 requester) who is required to file an information return with the IRS must obtain your correct taxpayer identification number (TIN) which may be your social security number (SSN), individual taxpayer identification number (ITIN), adoption taxpayer identification number (ATIN), or employer identification number (EIN), to report on an information return the amount paid to you, or other amount reportable on an information return. Examples of information returns include, but are not limited to, the following.

- Form 1099-INT (interest earned or paid)
- Form 1099-DIV (dividends, including those from stocks or mutual funds)
- Form 1099-MISC (various types of income, prizes, awards, or gross proceeds)
- Form 1099-B (stock or mutual fund sales and certain other transactions by brokers)
- Form 1099-S (proceeds from real estate transactions)
- Form 1099-K (merchant card and third party network transactions)
- Form 1098 (home mortgage interest), 1098-E (student loan interest), 1098-T (tuition)
- Form 1099-C (canceled debt)
- Form 1099-A (acquisition or abandonment of secured property)

Use Form W-9 only if you are a U.S. person (including a resident alien), to provide your correct TIN.

If you do not return Form W-9 to the requester with a TIN, you might be subject to backup withholding. See What is backup withholding, *later.*

Cat. No. 10231X Form **W-9** (Rev. 10-2018)

By signing the filled-out form, you:

1. Certify that the TIN you are giving is correct (or you are waiting for a number to be issued),

2. Certify that you are not subject to backup withholding, or

3. Claim exemption from backup withholding if you are a U.S. exempt payee. If applicable, you are also certifying that as a U.S. person, your allocable share of any partnership income from a U.S. trade or business is not subject to the withholding tax on foreign partners' share of effectively connected income, and

4. Certify that FATCA code(s) entered on this form (if any) indicating that you are exempt from the FATCA reporting, is correct. See *What is FATCA reporting*, later, for further information.

Note: If you are a U.S. person and a requester gives you a form other than Form W-9 to request your TIN, you must use the requester's form if it is substantially similar to this Form W-9.

Definition of a U.S. person. For federal tax purposes, you are considered a U.S. person if you are:

- An individual who is a U.S. citizen or U.S. resident alien;
- A partnership, corporation, company, or association created or organized in the United States or under the laws of the United States;
- An estate (other than a foreign estate); or
- A domestic trust (as defined in Regulations section 301.7701-7).

Special rules for partnerships. Partnerships that conduct a trade or business in the United States are generally required to pay a withholding tax under section 1446 on any foreign partners' share of effectively connected taxable income from such business. Further, in certain cases where a Form W-9 has not been received, the rules under section 1446 require a partnership to presume that a partner is a foreign person, and pay the section 1446 withholding tax. Therefore, if you are a U.S. person that is a partner in a partnership conducting a trade or business in the United States, provide Form W-9 to the partnership to establish your U.S. status and avoid section 1446 withholding on your share of partnership income.

In the cases below, the following person must give Form W-9 to the partnership for purposes of establishing its U.S. status and avoiding withholding on its allocable share of net income from the partnership conducting a trade or business in the United States.

- In the case of a disregarded entity with a U.S. owner, the U.S. owner of the disregarded entity and not the entity;
- In the case of a grantor trust with a U.S. grantor or other U.S. owner, generally, the U.S. grantor or other U.S. owner of the grantor trust and not the trust; and
- In the case of a U.S. trust (other than a grantor trust), the U.S. trust (other than a grantor trust) and not the beneficiaries of the trust.

Foreign person. If you are a foreign person or the U.S. branch of a foreign bank that has elected to be treated as a U.S. person, do not use Form W-9. Instead, use the appropriate Form W-8 or Form 8233 (see Pub. 515, Withholding of Tax on Nonresident Aliens and Foreign Entities).

Nonresident alien who becomes a resident alien. Generally, only a nonresident alien individual may use the terms of a tax treaty to reduce or eliminate U.S. tax on certain types of income. However, most tax treaties contain a provision known as a "saving clause." Exceptions specified in the saving clause may permit an exemption from tax to continue for certain types of income even after the payee has otherwise become a U.S. resident alien for tax purposes.

If you are a U.S. resident alien who is relying on an exception contained in the saving clause of a tax treaty to claim an exemption from U.S. tax on certain types of income, you must attach a statement to Form W-9 that specifies the following five items.

1. The treaty country. Generally, this must be the same treaty under which you claimed exemption from tax as a nonresident alien.

2. The treaty article addressing the income.

3. The article number (or location) in the tax treaty that contains the saving clause and its exceptions.

4. The type and amount of income that qualifies for the exemption from tax.

5. Sufficient facts to justify the exemption from tax under the terms of the treaty article.

Example. Article 20 of the U.S.-China income tax treaty allows an exemption from tax for scholarship income received by a Chinese student temporarily present in the United States. Under U.S. law, this student will become a resident alien for tax purposes if his or her stay in the United States exceeds 5 calendar years. However, paragraph 2 of the first Protocol to the U.S.-China treaty (dated April 30, 1984) allows the provisions of Article 20 to continue to apply even after the Chinese student becomes a resident alien of the United States. A Chinese student who qualifies for this exception (under paragraph 2 of the first protocol) and is relying on this exception to claim an exemption from tax on his or her scholarship or fellowship income would attach to Form W-9 a statement that includes the information described above to support that exemption.

If you are a nonresident alien or a foreign entity, give the requester the appropriate completed Form W-8 or Form 8233.

Backup Withholding

What is backup withholding? Persons making certain payments to you must under certain conditions withhold and pay to the IRS 24% of such payments. This is called "backup withholding." Payments that may be subject to backup withholding include interest, tax-exempt interest, dividends, broker and barter exchange transactions, rents, royalties, nonemployee pay, payments made in settlement of payment card and third party network transactions, and certain payments from fishing boat operators. Real estate transactions are not subject to backup withholding.

You will not be subject to backup withholding on payments you receive if you give the requester your correct TIN, make the proper certifications, and report all your taxable interest and dividends on your tax return.

Payments you receive will be subject to backup withholding if:

1. You do not furnish your TIN to the requester,

2. You do not certify your TIN when required (see the instructions for Part II for details),

3. The IRS tells the requester that you furnished an incorrect TIN,

4. The IRS tells you that you are subject to backup withholding because you did not report all your interest and dividends on your tax return (for reportable interest and dividends only), or

5. You do not certify to the requester that you are not subject to backup withholding under 4 above (for reportable interest and dividend accounts opened after 1983 only).

Certain payees and payments are exempt from backup withholding. See *Exempt payee code*, later, and the separate Instructions for the Requester of Form W-9 for more information.

Also see *Special rules for partnerships*, earlier.

What is FATCA Reporting?

The Foreign Account Tax Compliance Act (FATCA) requires a participating foreign financial institution to report all United States account holders that are specified United States persons. Certain payees are exempt from FATCA reporting. See *Exemption from FATCA reporting code*, later, and the Instructions for the Requester of Form W-9 for more information.

Updating Your Information

You must provide updated information to any person to whom you claimed to be an exempt payee if you are no longer an exempt payee and anticipate receiving reportable payments in the future from this person. For example, you may need to provide updated information if you are a C corporation that elects to be an S corporation, or if you no longer are tax exempt. In addition, you must furnish a new Form W-9 if the name or TIN changes for the account; for example, if the grantor of a grantor trust dies.

Penalties

Failure to furnish TIN. If you fail to furnish your correct TIN to a requester, you are subject to a penalty of $50 for each such failure unless your failure is due to reasonable cause and not to willful neglect.

Civil penalty for false information with respect to withholding. If you make a false statement with no reasonable basis that results in no backup withholding, you are subject to a $500 penalty.

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Criminal penalty for falsifying information. Willfully falsifying certifications or affirmations may subject you to criminal penalties including fines and/or imprisonment.

Misuse of TINs. If the requester discloses or uses TINs in violation of federal law, the requester may be subject to civil and criminal penalties.

Specific Instructions

Line 1

You must enter one of the following on this line; **do not** leave this line blank. The name should match the name on your tax return.

If this Form W-9 is for a joint account (other than an account maintained by a foreign financial institution (FFI)), list first, and then circle, the name of the person or entity whose number you entered in Part I of Form W-9. If you are providing Form W-9 to an FFI to document a joint account, each holder of the account that is a U.S. person must provide a Form W-9.

a. **Individual.** Generally, enter the name shown on your tax return. If you have changed your last name without informing the Social Security Administration (SSA) of the name change, enter your first name, the last name as shown on your social security card, and your new last name.

Note: ITIN applicant: Enter your individual name as it was entered on your Form W-7 application, line 1a. This should also be the same as the name you entered on the Form 1040/1040A/1040EZ you filed with your application.

b. **Sole proprietor or single-member LLC.** Enter your individual name as shown on your 1040/1040A/1040EZ on line 1. You may enter your business, trade, or "doing business as" (DBA) name on line 2.

c. **Partnership, LLC that is not a single-member LLC, C corporation, or S corporation.** Enter the entity's name as shown on the entity's tax return on line 1 and any business, trade, or DBA name on line 2.

d. **Other entities.** Enter your name as shown on required U.S. federal tax documents on line 1. This name should match the name shown on the charter or other legal document creating the entity. You may enter any business, trade, or DBA name on line 2.

e. **Disregarded entity.** For U.S. federal tax purposes, an entity that is disregarded as an entity separate from its owner is treated as a "disregarded entity." See Regulations section 301.7701-2(c)(2)(iii). Enter the owner's name on line 1. The name of the entity entered on line 1 should never be a disregarded entity. The name on line 1 should be the name shown on the income tax return on which the income should be reported. For example, if a foreign LLC that is treated as a disregarded entity for U.S. federal tax purposes has a single owner that is a U.S. person, the U.S. owner's name is required to be provided on line 1. If the direct owner of the entity is also a disregarded entity, enter the first owner that is not disregarded for federal tax purposes. Enter the disregarded entity's name on line 2, "Business name/disregarded entity name." If the owner of the disregarded entity is a foreign person, the owner must complete an appropriate Form W-8 instead of a Form W-9. This is the case even if the foreign person has a U.S. TIN.

Line 2

If you have a business name, trade name, DBA name, or disregarded entity name, you may enter it on line 2.

Line 3

Check the appropriate box on line 3 for the U.S. federal tax classification of the person whose name is entered on line 1. Check only one box on line 3.

IF the entity/person on line 1 is a(n) . . .	THEN check the box for . . .
• Corporation	Corporation
• Individual • Sole proprietorship, or • Single-member limited liability company (LLC) owned by an individual and disregarded for U.S. federal tax purposes.	Individual/sole proprietor or single-member LLC
• LLC treated as a partnership for U.S. federal tax purposes, • LLC that has filed Form 8832 or 2553 to be taxed as a corporation, or • LLC that is disregarded as an entity separate from its owner but the owner is another LLC that is not disregarded for U.S. federal tax purposes.	Limited liability company and enter the appropriate tax classification. (P= Partnership; C= C corporation; or S= S corporation)
• Partnership	Partnership
• Trust/estate	Trust/estate

Line 4, Exemptions

If you are exempt from backup withholding and/or FATCA reporting, enter in the appropriate space on line 4 any code(s) that may apply to you.

Exempt payee code.

- Generally, individuals (including sole proprietors) are not exempt from backup withholding.
- Except as provided below, corporations are exempt from backup withholding for certain payments, including interest and dividends.
- Corporations are not exempt from backup withholding for payments made in settlement of payment card or third party network transactions.
- Corporations are not exempt from backup withholding with respect to attorneys' fees or gross proceeds paid to attorneys, and corporations that provide medical or health care services are not exempt with respect to payments reportable on Form 1099-MISC.

The following codes identify payees that are exempt from backup withholding. Enter the appropriate code in the space in line 4.

1—An organization exempt from tax under section 501(a), any IRA, or a custodial account under section 403(b)(7) if the account satisfies the requirements of section 401(f)(2)

2—The United States or any of its agencies or instrumentalities

3—A state, the District of Columbia, a U.S. commonwealth or possession, or any of their political subdivisions or instrumentalities

4—A foreign government or any of its political subdivisions, agencies, or instrumentalities

5—A corporation

6—A dealer in securities or commodities required to register in the United States, the District of Columbia, or a U.S. commonwealth or possession

7—A futures commission merchant registered with the Commodity Futures Trading Commission

8—A real estate investment trust

9—An entity registered at all times during the tax year under the Investment Company Act of 1940

10—A common trust fund operated by a bank under section 584(a)

11—A financial institution

12—A middleman known in the investment community as a nominee or custodian

13—A trust exempt from tax under section 664 or described in section 4947

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The following chart shows types of payments that may be exempt from backup withholding. The chart applies to the exempt payees listed above, 1 through 13.

IF the payment is for . . .	THEN the payment is exempt for . . .
Interest and dividend payments	All exempt payees except for 7
Broker transactions	Exempt payees 1 through 4 and 6 through 11 and all C corporations. S corporations must not enter an exempt payee code because they are exempt only for sales of noncovered securities acquired prior to 2012.
Barter exchange transactions and patronage dividends	Exempt payees 1 through 4
Payments over $600 required to be reported and direct sales over $5,000[1]	Generally, exempt payees 1 through 5[2]
Payments made in settlement of payment card or third party network transactions	Exempt payees 1 through 4

[1] See Form 1099-MISC, Miscellaneous Income, and its instructions.

[2] However, the following payments made to a corporation and reportable on Form 1099-MISC are not exempt from backup withholding: medical and health care payments, attorneys' fees, gross proceeds paid to an attorney reportable under section 6045(f), and payments for services paid by a federal executive agency.

Exemption from FATCA reporting code. The following codes identify payees that are exempt from reporting under FATCA. These codes apply to persons submitting this form for accounts maintained outside of the United States by certain foreign financial institutions. Therefore, if you are only submitting this form for an account you hold in the United States, you may leave this field blank. Consult with the person requesting this form if you are uncertain if the financial institution is subject to these requirements. A requester may indicate that a code is not required by providing you with a Form W-9 with "Not Applicable" (or any similar indication) written or printed on the line for a FATCA exemption code.

A—An organization exempt from tax under section 501(a) or any individual retirement plan as defined in section 7701(a)(37)

B—The United States or any of its agencies or instrumentalities

C—A state, the District of Columbia, a U.S. commonwealth or possession, or any of their political subdivisions or instrumentalities

D—A corporation the stock of which is regularly traded on one or more established securities markets, as described in Regulations section 1.1472-1(c)(1)(i)

E—A corporation that is a member of the same expanded affiliated group as a corporation described in Regulations section 1.1472-1(c)(1)(i)

F—A dealer in securities, commodities, or derivative financial instruments (including notional principal contracts, futures, forwards, and options) that is registered as such under the laws of the United States or any state

G—A real estate investment trust

H—A regulated investment company as defined in section 851 or an entity registered at all times during the tax year under the Investment Company Act of 1940

I—A common trust fund as defined in section 584(a)

J—A bank as defined in section 581

K—A broker

L—A trust exempt from tax under section 664 or described in section 4947(a)(1)

M—A tax exempt trust under a section 403(b) plan or section 457(g) plan

Note: You may wish to consult with the financial institution requesting this form to determine whether the FATCA code and/or exempt payee code should be completed.

Line 5

Enter your address (number, street, and apartment or suite number). This is where the requester of this Form W-9 will mail your information returns. If this address differs from the one the requester already has on file, write NEW at the top. If a new address is provided, there is still a chance the old address will be used until the payor changes your address in their records.

Line 6

Enter your city, state, and ZIP code.

Part I. Taxpayer Identification Number (TIN)

Enter your TIN in the appropriate box. If you are a resident alien and you do not have and are not eligible to get an SSN, your TIN is your IRS individual taxpayer identification number (ITIN). Enter it in the social security number box. If you do not have an ITIN, see *How to get a TIN* below.

If you are a sole proprietor and you have an EIN, you may enter either your SSN or EIN.

If you are a single-member LLC that is disregarded as an entity separate from its owner, enter the owner's SSN (or EIN, if the owner has one). Do not enter the disregarded entity's EIN. If the LLC is classified as a corporation or partnership, enter the entity's EIN.

Note: See *What Name and Number To Give the Requester*, later, for further clarification of name and TIN combinations.

How to get a TIN. If you do not have a TIN, apply for one immediately. To apply for an SSN, get Form SS-5, Application for a Social Security Card, from your local SSA office or get this form online at *www.SSA.gov*. You may also get this form by calling 1-800-772-1213. Use Form W-7, Application for IRS Individual Taxpayer Identification Number, to apply for an ITIN, or Form SS-4, Application for Employer Identification Number, to apply for an EIN. You can apply for an EIN online by accessing the IRS website at *www.irs.gov/Businesses* and clicking on Employer Identification Number (EIN) under Starting a Business. Go to *www.irs.gov/Forms* to view, download, or print Form W-7 and/or Form SS-4. Or, you can go to *www.irs.gov/OrderForms* to place an order and have Form W-7 and/or SS-4 mailed to you within 10 business days.

If you are asked to complete Form W-9 but do not have a TIN, apply for a TIN and write "Applied For" in the space for the TIN, sign and date the form, and give it to the requester. For interest and dividend payments, and certain payments made with respect to readily tradable instruments, generally you will have 60 days to get a TIN and give it to the requester before you are subject to backup withholding on payments. The 60-day rule does not apply to other types of payments. You will be subject to backup withholding on all such payments until you provide your TIN to the requester.

Note: Entering "Applied For" means that you have already applied for a TIN or that you intend to apply for one soon.

Caution: A disregarded U.S. entity that has a foreign owner must use the appropriate Form W-8.

Part II. Certification

To establish to the withholding agent that you are a U.S. person, or resident alien, sign Form W-9. You may be requested to sign by the withholding agent even if item 1, 4, or 5 below indicates otherwise.

For a joint account, only the person whose TIN is shown in Part I should sign (when required). In the case of a disregarded entity, the person identified on line 1 must sign. Exempt payees, see *Exempt payee code*, earlier.

Signature requirements. Complete the certification as indicated in items 1 through 5 below.

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1. Interest, dividend, and barter exchange accounts opened before 1984 and broker accounts considered active during 1983. You must give your correct TIN, but you do not have to sign the certification.

2. Interest, dividend, broker, and barter exchange accounts opened after 1983 and broker accounts considered inactive during 1983. You must sign the certification or backup withholding will apply. If you are subject to backup withholding and you are merely providing your correct TIN to the requester, you must cross out item 2 in the certification before signing the form.

3. Real estate transactions. You must sign the certification. You may cross out item 2 of the certification.

4. Other payments. You must give your correct TIN, but you do not have to sign the certification unless you have been notified that you have previously given an incorrect TIN. "Other payments" include payments made in the course of the requester's trade or business for rents, royalties, goods (other than bills for merchandise), medical and health care services (including payments to corporations), payments to a nonemployee for services, payments made in settlement of payment card and third party network transactions, payments to certain fishing boat crew members and fishermen, and gross proceeds paid to attorneys (including payments to corporations).

5. Mortgage interest paid by you, acquisition or abandonment of secured property, cancellation of debt, qualified tuition program payments (under section 529), ABLE accounts (under section 529A), IRA, Coverdell ESA, Archer MSA or HSA contributions or distributions, and pension distributions. You must give your correct TIN, but you do not have to sign the certification.

What Name and Number To Give the Requester

For this type of account:	Give name and SSN of:
1. Individual	The individual
2. Two or more individuals (joint account) other than an account maintained by an FFI	The actual owner of the account or, if combined funds, the first individual on the account[1]
3. Two or more U.S. persons (joint account maintained by an FFI)	Each holder of the account
4. Custodial account of a minor (Uniform Gift to Minors Act)	The minor[2]
5. a. The usual revocable savings trust (grantor is also trustee)	The grantor-trustee[1]
b. So-called trust account that is not a legal or valid trust under state law	The actual owner[1]
6. Sole proprietorship or disregarded entity owned by an individual	The owner[3]
7. Grantor trust filing under Optional Form 1099 Filing Method 1 (see Regulations section 1.671-4(b)(2)(i)(A))	The grantor*
For this type of account:	**Give name and EIN of:**
8. Disregarded entity not owned by an individual	The owner
9. A valid trust, estate, or pension trust	Legal entity[4]
10. Corporation or LLC electing corporate status on Form 8832 or Form 2553	The corporation
11. Association, club, religious, charitable, educational, or other tax-exempt organization	The organization
12. Partnership or multi-member LLC	The partnership
13. A broker or registered nominee	The broker or nominee
14. Account with the Department of Agriculture in the name of a public entity (such as a state or local government, school district, or prison) that receives agricultural program payments	The public entity
15. Grantor trust filing under the Form 1041 Filing Method or the Optional Form 1099 Filing Method 2 (see Regulations section 1.671-4(b)(2)(i)(B))	The trust

[1] List first and circle the name of the person whose number you furnish. If only one person on a joint account has an SSN, that person's number must be furnished.

[2] Circle the minor's name and furnish the minor's SSN.

[3] You must show your individual name and you may also enter your business or DBA name on the "Business name/disregarded entity" name line. You may use either your SSN or EIN (if you have one), but the IRS encourages you to use your SSN.

[4] List first and circle the name of the trust, estate, or pension trust. (Do not furnish the TIN of the personal representative or trustee unless the legal entity itself is not designated in the account title.) Also see *Special rules for partnerships*, earlier.

*__Note:__ The grantor also must provide a Form W-9 to trustee of trust.

Note: If no name is circled when more than one name is listed, the number will be considered to be that of the first name listed.

Secure Your Tax Records From Identity Theft

Identity theft occurs when someone uses your personal information such as your name, SSN, or other identifying information, without your permission, to commit fraud or other crimes. An identity thief may use your SSN to get a job or may file a tax return using your SSN to receive a refund.

To reduce your risk:

- Protect your SSN,
- Ensure your employer is protecting your SSN, and
- Be careful when choosing a tax preparer.

If your tax records are affected by identity theft and you receive a notice from the IRS, respond right away to the name and phone number printed on the IRS notice or letter.

If your tax records are not currently affected by identity theft but you think you are at risk due to a lost or stolen purse or wallet, questionable credit card activity or credit report, contact the IRS Identity Theft Hotline at 1-800-908-4490 or submit Form 14039.

For more information, see Pub. 5027, Identity Theft Information for Taxpayers.

Victims of identity theft who are experiencing economic harm or a systemic problem, or are seeking help in resolving tax problems that have not been resolved through normal channels, may be eligible for Taxpayer Advocate Service (TAS) assistance. You can reach TAS by calling the TAS toll-free case intake line at 1-877-777-4778 or TTY/TDD 1-800-829-4059.

Protect yourself from suspicious emails or phishing schemes. Phishing is the creation and use of email and websites designed to mimic legitimate business emails and websites. The most common act is sending an email to a user falsely claiming to be an established legitimate enterprise in an attempt to scam the user into surrendering private information that will be used for identity theft.

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The IRS does not initiate contacts with taxpayers via emails. Also, the IRS does not request personal detailed information through email or ask taxpayers for the PIN numbers, passwords, or similar secret access information for their credit card, bank, or other financial accounts.

If you receive an unsolicited email claiming to be from the IRS, forward this message to *phishing@irs.gov*. You may also report misuse of the IRS name, logo, or other IRS property to the Treasury Inspector General for Tax Administration (TIGTA) at 1-800-366-4484. You can forward suspicious emails to the Federal Trade Commission at *spam@uce.gov* or report them at *www.ftc.gov/complaint*. You can contact the FTC at *www.ftc.gov/idtheft* or 877-IDTHEFT (877-438-4338). If you have been the victim of identity theft, see *www.IdentityTheft.gov* and Pub. 5027.

Visit *www.irs.gov/IdentityTheft* to learn more about identity theft and how to reduce your risk.

Privacy Act Notice

Section 6109 of the Internal Revenue Code requires you to provide your correct TIN to persons (including federal agencies) who are required to file information returns with the IRS to report interest, dividends, or certain other income paid to you; mortgage interest you paid; the acquisition or abandonment of secured property; the cancellation of debt; or contributions you made to an IRA, Archer MSA, or HSA. The person collecting this form uses the information on the form to file information returns with the IRS, reporting the above information. Routine uses of this information include giving it to the Department of Justice for civil and criminal litigation and to cities, states, the District of Columbia, and U.S. commonwealths and possessions for use in administering their laws. The information also may be disclosed to other countries under a treaty, to federal and state agencies to enforce civil and criminal laws, or to federal law enforcement and intelligence agencies to combat terrorism. You must provide your TIN whether or not you are required to file a tax return. Under section 3406, payers must generally withhold a percentage of taxable interest, dividend, and certain other payments to a payee who does not give a TIN to the payer. Certain penalties may also apply for providing false or fraudulent information.

APPENDIX T. TEST SUBJECT PAYMENT FORM

Test Subject Payment Form at the National Personal Protective Technology Laboratory (NPPTL)

Record of Test Subject Participation
Project: Superior Powered Air-Purifying Respirator Tests and New Technologies (SPARTAN)
Charge #: 2545.CDC I.04.04906.000.0005
Account #: 500-22-105
CAN: 921043E

Subject Name (Print clearly):

Date:

Test	Hours Worked	Reimbursement per Hour	Reimbursement Total
For respirator testing (3 hour period), *test subject payment is $40.00/hr.*		X $40.00	$

Test	Number of 15 min periods worked	Reimbursement per 15 min period	Reimbursement Total
For respirator testing **over** 3 hours, *test subject payment is $10.00 for every 15 min period.*		X $10.00	$

Total Due: $

Participant Signature/Date

☐ Please check box if your address on File is correct

Technician or Investigator Signature/Date

APPENDIX U. NPPTL GENERAL PHOTO RELEASE

General Photo Release

I hereby agree to allow my photographic image to be used (without my name, both singly and in conjunction with other persons or objects) by the Centers for Disease Control and Prevention (CDC) of the U.S. Department of Health and Human Services.

CDC may use my photograph, at its discretion and consistent with its public health mission, in any publication and/or on an Internet web site or in any other format. I understand that other persons will be free to copy and/or print and/or distribute my photographic image.

I understand that this publication may be printed by the United States Government Printing Office and/or posted on the Internet or in any other format by CDC without copyright protection and may be distributed free or sold. I also understand that additional printings or web postings may be conducted by the United States Government Printing Office and CDC in the future.

I understand that for the use of my photographic image in this publication or Internet posting or any other format, I will receive no financial compensation or payment of any kind from the United States Government or from any agency of the Government.

Name Date of Birth

Signature Date

Address

City, State and Zip Code

Phone Number

IF A MINOR: Name of Parent or Legal Guardian

Signature of Parent or Legal Guardian