Supplementary Online Content

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Trial protocol

This supplementary material has been provided by the authors to give readers additional information about their work.

TITLE: **J**ust-in-time **E**lastomeric **T**raining and **Fi**t **T**esting **(JET FIT)**

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STUDY TERMS AND ABBREVIATIONS

TERM	ABBREVIATION
Adverse Events	AE
Centers for Disease Control and Prevention	CDC
Data Collection Form	DCF
Elastomeric Half Mask Respirator	EHMR
Filtering Face Piece respirator	FFR
Food and Drug Administration	FDA
Healthcare Personnel	HCP
Institutional Review Board	IRB
International Conference of Harmonisation Good Clinical Practice	ICH GCP
National Center for Immunization and Respiratory Diseases	NCIRD
National Institute for Occupational Safety and Health	NIOSH
National Personal Protective Technology Laboratory	NPPTL
Occupational Safety and Health Administration	OSHA
Office of Public Health Preparedness and Response	OPHPR
Powered Air Purifying Respirator	PAPR
Personal Protective Equipment	PPE
Principal Investigator	PI
Respiratory Protection Device	RPD
Respiratory Protection Program	RPP
Qualitative Fit Test	QLFT
Quantitative Fit Test	QNFT
Serious Adverse Events	SAE
Site Initiation Visit	SIV
Statement of Work	SOW
Unanticipated Problem	UAP
User Seal Check	USC

PROTOCOL SUMMARY

This is a national multicenter pragmatic demonstrative clinical trial to evaluate feasibility of a just in time elastomeric half mask respirator (EHMR) fit test and competency training for healthcare personnel (HCP) during a simulated public health emergency. This study will assess participant and institution ability to rapidly convert and demonstrate proficiency using **reusable respirators** in the healthcare field to provide a stopgap for respiratory protection program guidelines in times of **disposable respirator** supply shortages. This protocol is the first in a series of three studies included in the *Assessment of Elastomeric Respirators in Healthcare Delivery Settings* project sponsored by the National Institute for Occupational Safety and Health (NIOSH) at the Centers for Disease Control and Prevention (CDC). This project is funded in kind by the National Personal Protective Technology Laboratory (NPPTL), the Office of Public Health Preparedness and Response (OPHPR), and the National Center for Immunization and Respiratory Diseases (NCIRD). The first of three protocols, this will be followed by laboratory and field studies assessing disinfection methods and routine use EHMR. Three (3) United States (US) healthcare delivery organizations will be included as study sites in the base protocol, individually accruing a participant sample size up to 100 HCP, with a minimum of 50 **evaluable** participants per site. A total sample size of 150 to 300 evaluable participants are expected to be accrued nationally. The purpose of this Base protocol is to assess feasibility of reusable EHMRs in healthcare for a just in time adaptation during respiratory infectious disease outbreaks, epidemics, pandemics, and/or disposable respirator supply shortages.

1.0 BACKGROUND AND SIGNIFICANCE

Healthcare delivery system collaboration with federal, state, and local public health agencies during a contagious pandemic is an important component of preparedness, response, resiliency and recovery. The number of disposable respiratory protection devices (RPDs) needed to protect HCP may exceed national availability during a pandemic.[1] Limited resource availability may affect global economics as well as supply and demand for medical devices.[1] Capabilities requiring groundwork to optimize efficiency, effectiveness and safety amid a contagious respiratory infectious disease outbreak, include: a mature respiratory protection program, stockpiling of respiratory protective supplies, and actionable plans for HCP to rapidly modify practices to meet evolving needs posed by the outbreak.

1.1 Devices and Standards

Respiratory Protection Programs

In some settings, HCP may have a higher risk of exposure to infections than the public.[2] Once infected, HCP may spread infection to others, including patients, staff, and other community members, and help amplify a contagious outbreak. [2] Respiratory protection programs (RPPs) are required for all organizations in which respirators are necessary to protect employee health and/or are mandated by an employer.[2] The Occupational Safety and Health Administration (OSHA), in part, regulates usage of personal protective equipment (PPE) in US workplaces, while guidance and/or recommendations from the CDC and other public health agencies, professional societies, and other organizations help to promote adherence to the OSHA RPP Standard (29 CFR 1910.134).[2]

Face Masks

A face mask, also known as a surgical mask, is a disposable physical barrier covering the nose and mouth intended to contain wearer secretions from transfer, as well as to block large particle droplets and contaminants from reaching the users oral and nasal cavities.[3] A surgical mask does not ensure prevention of small particulate airborne transmission of pathogens. Surgical masks should be submitted for pre-market consideration to the U.S. Food and Drug Administration (FDA) and are not approved by NIOSH as a form of respiratory protection.[3]

Respirators

A *respirator* is a device that HCP should wear when interacting with patients who have suspected or confirmed airborne transmissible pathogens.[4] Respirators are certified by NIOSH prior to manufacture/use and reduce the risk of inhaling hazardous infectious agents. [3] To ensure safety and efficacy, passing OSHA accepted fit-testing is required for employees who wear tight-fitting respirators.[3] In most healthcare delivery settings, the mainstay for protection against infectious airborne particulate exposure for HCP is the *disposable N95 filtering face piece respirator (N95 FFR)*, however, EHMRs are used in some settings.[5-10] EHMRs may be more widely considered in the future, especially during periods when N95s are in short supply.

Fit Testing

OSHA requires employers to utilize an approved Quantitative fit test (QNFT) or qualitative fit test (QLFT) protocol for N95s and EHMRs to ensure safety and inward leak prevention.[21] QNFT includes use of a non-hazardous "test aerosol" generated in a chamber or by tubing connected to a user's EHMR with instruments to quantify the fit, which can be a costly method if the healthcare facility does not currently have the required equipment on site.[21] QLFT allows for an affordable approach, based on a pass or fail measure that utilizes the participant's palate and/or olfactory sensations to detect leakage of airborne particles into the respirator facepiece. Presently four methods are accepted by OSHA standards for QLFT including: isoamyl acetate, sodium saccharin, bitrex, and irritant smoke.[21] Irritant smoke is not feasible for the healthcare field setting and isoamyl acetate protocol is not appropriate to use with particulate respirators unless equipped with an organic vapor filter. Bitrex and saccharin sodium are the primary QLFT methods considered for healthcare settings. Bitrex however is a bitter tasting agent that has higher alpha and beta errors than saccharin sodium.[22] For the purposes of this study, sites will utilize sodium saccharin aerosol solution (a sweet tasting agent) QLFT method approved by OSHA for fit test confirmation. [23]

1.2 Literary Review

Respirator Supply and Demand

Studies show that the demand for RPDs may exceed domestic supplies during a wide scale contagious pandemic caused by a respiratory pathogen.[11] For instance, US local and regional shortages of N95 occurred during the Severe Acute Respiratory Syndrome (SARS) in 2003 and H1N1 influenza pandemic in 2009.[11] For example, Fraser Health Authority (a healthcare institution), typically utilizes an average of 1,440 N95 FFRs per week, however during the 2009 H1N1 pandemic, it required over 19,000 weekly.[12] In 2009 it was also determined that facilities ordering N95 respirators and facemasks in large quantities to meet pandemic requirements created a multiyear backlog leading to market shortages.[6, 13] CDC estimates 1.7 to 7.3 billion RPDs would be required in the US to meet the demand during a severe influenza pandemic.[14]

HCP who care for ill patients are at increased risk of infection in some instances. Recent outbreaks of novel viral disease, such as SARS and Middle Eastern Respiratory Syndrome

(MERS), led to a disproportionate number of infections among HCP compared to the general population. A recent systematic review concluded a statistically significant increase in the probability of influenza A (H1N1) transmitted to HCP during the 2009 pandemic as compared to controls/comparisons.[33] If HCP are to be in position to care effectively for their patients during a public health emergency, they need to be adequately protected from occupationally acquired infections.

Stockpile Considerations

To better understand US preparedness in 2012, the Association of State and Territorial Health Officials (ASTHO) assessed PPE availability in 23% of US hospitals, accounting for N95s, surgical masks, and powered air purifying respirators (PAPRs).[18] Supplies varied considerably among geographic regions and from one health facility to another, however the authors concluded that *"sufficient quantities to meet the need of a pandemic may not currently be available in most hospitals".*[18] A cost model developed by the U.S. Department of Veterans Affairs in 2015 suggested that health systems may save money if they stockpile EHMRs for public health emergencies.[11]

1.3 Current State of Knowledge

A qualitative clinical demonstration study was recently conducted with 1,152 healthcare personnel and published January of 2019, which assessed worker perception of EHMRs as compared to the currently used N95 FFRs in this feild.[35] The results concluded that N95 FFRs are more favorable for comfort and communication ($P < .001$), however EHMRs were more favorable for sense of protection ($P < .001$).[35] Overall, reusable respirators such as EHMRs and PAPRs were significantly preferred over N95 FFRs in high-risk situations such as a public health emergency.[35] This data supports the need to review rapid conversion feasibility for high risk situations as well as to study methods for improved design features and RPP standards which may aid in transition to EHMRs in healthcare during a public health emergency.

A consensus report with the purpose of reviewing EMHR use in healthcare was published in December of 2018 by the National Academies of Sciences, Engineering, & Medicine. A 16 member expert committee concluded EHMRs would be beneficial for use in healthcare, particularly during a public health emergency in which disposable respirator demand exceeds national stockpile supply.[6,34] The consensus report states that during a world wide pandemic:

> "*a significant proportion of the respiratory protective device supply chain is produced offshore and may not be available to the U.S. market during a public health response because of export restrictions to the United States or the nationalization of manufacturing facilities, which may favor in-country rather than foreign demands*".[6,34]

Current limitations to EHMR use in healthcare, based on this consensus report include: comfort; storage space; disinfection capability and timeliness; fit testing capability, user competency considerations; procurement and stockpile logistics; perceptions of patients and staff; and policies/regulations for use.[34] This protocol is the first of three of the Elastomeric project and will assess the feasibility of rapid conversion fit testing and user competency during a simulated public health emergency. Two additional protocols in this series will study novel methods for EHMR disinfection, storage, comfort, and staff/patient perceptions.

2.0 OBJECTIVES AND SPECIFIC AIMS

2.1 Primary Objectives:

A. To determine EHMR fit test feasibility for HCP, as measured by participant pass/fail OSHA approved sodium saccharin aerosol protocol QLFT, and evaluation of individual and institutional time thresholds
B. To determine HCP proficiency post EHMR education during a simulated public health emergency, as measured by per participant assessment, competency, and task evaluations repeated in triplicate

2.2 Secondary Objectives:

A. To determine user seal check (USC) predictive value for OSHA approved sodium saccharin aerosol protocol QLFT fit testing with EHMRs in healthcare
B. To determine NIOSH/NPPTL Bivariate Panel percentage of accuracy for correct size correlation to passing qualitative fit tests, in a population of HCP
C. To determine control time threshold and pass rate for N95 FFR fit testing in a subset of the sampled population

3.0 STUDY DESIGN AND METHODS

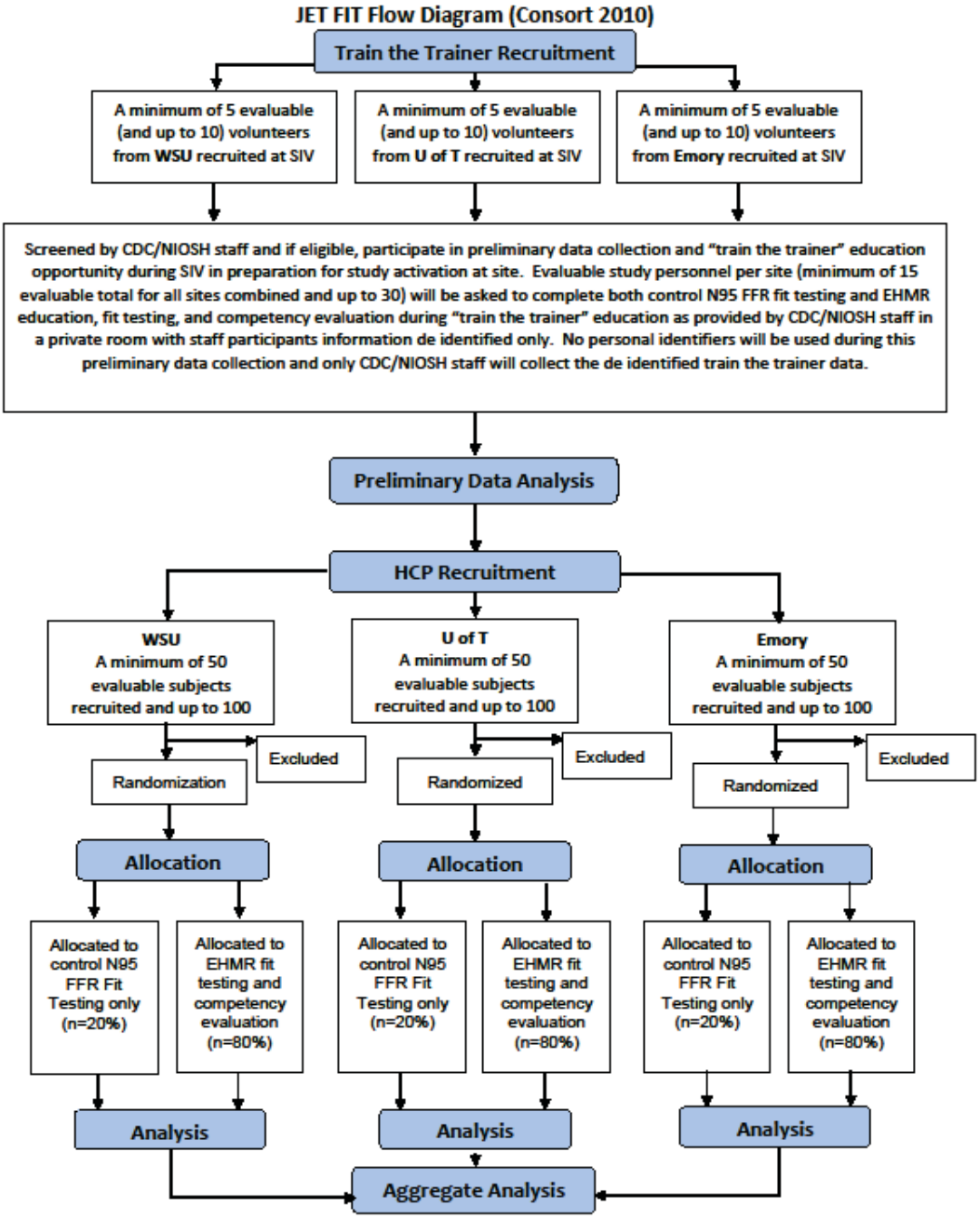
3.1 Study Design

This will be a demonstrative clinical study of elastomeric respirator introduction at three healthcare institutions for a "just in time" simulated public health emergency. This study will assess feasibility for rapid conversion to EHMRs in healthcare by evaluating fit testing capability, competency, and time thresholds to build on NIOSH research, and aid in development of US RPPs in healthcare for preparation of a large-scale infectious disease pandemic. Maximum time threshold and pass rate control fit testing will be conducted with N95 FFRs. Participation will be offered to healthy, consented HCP volunteers in units and/or departments requiring respiratory protection such as intensive care, respiratory therapy, emergency medicine, serious communicable disease units, etc. as determined by the project managers and/or principal investigators (PIs) at each site and approved by NIOSH.

The study will include preliminary analysis of evaluation tool validity by completing "train the trainer" data collection by CDC/NIOSH staff with a minimum of 5 study personnel and up to 10 per site during site initiation visits (SIVs). During train the trainer data collection study personnel will complete both N95 FFR fit testing as well as EHMR education, fit testing, and competency evaluation in triplicate provided by CDC/NIOSH staff. Once SIV is completed and a site is activated, consenting and screening HCP for eligibility to participate must occur within 60 days of Day 1 study interventions. Active study interventions with 50 to 100 evaluable participants within a seven-day period at each site and participants will be randomized to one of two cohorts using a random number generator. Approximately 80% of participants will be allocated to the EHMR education, fit testing, and competency evaluation cohort and 20% to the N95 FFR education and fit testing control cohort.

On day of study intervention, all eligible participants in each cohort will be provided an infographic and demonstration checklist as well as watch a demonstration video describing how to conduct user seal checks (USCs) and what to expect during fit testing. Next subjects will be provided 15 minutes (+15 minutes window to prevent deviations) for aptitude practice. Post practice session subjects will complete USCs and fit testing for their device. Lastly, EHMR cohort participants will be evaluated in triplicate on six EHMR competencies. Interventions from this study will help inform healthcare RPP policy and practice revisions. A study design flowchart can be seen in Figure 1 below.

Figure 1. JET FIT Protocol Flow Chart (Consort 2010)



3.2 Base Statement of Work

This protocol is part of a competitive contract funded in kind by the CDC. The statement of work (SOW) depicts the steps and timeline of events for NIOSH and sites. NIOSH will provide EHMRs, filter sets, protocol, consent, data collection forms (DCFs), demonstration video, laptop, and collaboration support for site completion of eight base tasks during the life of the study (Table 1.). Upon contract award, the protocol will be provided to each site for review and

modifications based on local IRB and site-specific requirements. NIOSH must approve all modifications made, prior to site IRB approval.

A CDC/NIOSH staff member will coordinate the SIV for "train the trainer" with each sites study team after IRB approval. IRB approval and SIV completion are required prior to site activation for HCP recruitment initiation. The SIV meeting will be provided by CDC/NIOSH staff and include a tabletop discussion, protocol review, site study personnel training including preliminary evaluation tool analysis, and data management overview. Preliminary analysis will include a minimum of 5 study personnel and up to 10, that participating in "train the trainer" and validation of the competency evaluation tool, with de identified data collection and storage on CDC secured software by CDC/NIOSH study personnel only.

Upon site activation, NIOSH will provide elastomeric respirators, filter sets, and demonstration videos. Each site is contracted to complete study interventions with 50 to 100 eligible and evaluable HCP. Data collection must be completed utilizing the paper DCFs during the study interventions (Appendices D, F, G, I, & K.). Data entry of the DCFs into REDCap software on a NIOSH issued laptop provided to each site will also be required. Data lock requirements and timelines for DCF submissions to NIOSH will be scheduled based on SIV date(s). While each study site may choose to publish a portion of their own data in co-authorship with NIOSH (e.g., scientific meeting abstract(s), an additional manuscript(s) inclusive of data from all sites will be coordinated by NIOSH at the end of the study (e.g., peer-reviewed publication). Post manuscript submission, sites will complete an educational NIOSH coordinated Webinar for the public in collaboration with NIOSH.

Table 1. Base Statement of Work

EVENT	NIOSH	SITE
Base 0 *Development of a Project Plan*	NIOSH will provide: protocol, consent, data capture forms, and educational materials to site(s)	Site will review contract and SOW to initiate site specific plan for project completion
Base 1 *Adapting the Draft NIOSH Protocol*	NIOSH final review and approval of site(s) final protocol and consent edits	Site specific modifications to protocol and consent
Base 2 *Adapting the Draft Educational Materials*	NIOSH final review and approval of site(s) final protocol appendices edits	Site should review DCFs and educational demonstration checklist (protocol appendices) for site and IRB specific edits
Base 3 *Feasibility Assessment*	NIOSH study staff visit during feasibility assessment to monitor study and meet with study team members	Site will complete study interventions with 50 to100 evaluable HCP participants per site. Study personnel to complete DCFs during feasibility assessment as per protocol
Base 4 *Education Material Effectiveness Assessment*	NIOSH will host a Skype meeting with site(s) to determine effectiveness of educational video and materials provided by NIOSH	Site study team meeting to review data analysis and observational statistics. Meeting report to be submitted to NIOSH regarding perceived effectiveness
Base 5 *Feasibility Reports*	NIOSH will collaborate with site(s) to schedule three meetings to include SIV, Feasibility Assessment Active Study, and End of Study	Site(s) will schedule with NIOSH three meetings to include SIV, Feasibility Assessment Active Study, and End of Study. Site(s) must complete a report to submit to NIOSH
Base 6 *Webinar Presentation*	NIOSH will Coordinate a free public Webinar	Site(s) in collaboration with NIOSH will design a webinar for the public based on publications and study findings
Base 7 *Manuscript*	NIOSH approved manuscript submission. NIOSH will serve as a co-author on the manuscript in accordance with CDC authorship guidelines	Site(s) will draft at least one peer-reviewed manuscript to document the study results, lessons learned, and considerations for further development

3.3 Study Specific Respirators

EHMR

For the purposes of this study, CDC/NIOSH will provide participants with NIOSH approved Honeywell North RU8500 Series EHMR (sizes small medium, large) and 7580P100 filter sets (Figure 2.). This model was chosen due to its design having been tailored for healthcare settings: (a) relatively small, (b) relatively lightweight, (c) a speech diaphragm to facilitate verbal communication, and (d) an exhalation cover diverter to direct exhaled breath and potentially infectious particulates away from the wearer's immediate surroundings (e.g., a sterile field) [19]

Figure 2. Honeywell North RU8500 Elastomeric Respirator *A. Front B. Back*

A. 

B. 

N95 FFR

Each site will be permitted to select the N95 FFR used by their institution for the control cohort, upon review and approval by CDC/NIOSH to be sure it meets NPPTL standards.

3.4 Screening Design

Recruitment of subjects will include a convenience sample of healthcare workers at each site. Sites are encouraged to offer participation to a diverse population of ages, gender, occupations and respirator experience levels. Once IRB approval and the SIV is completed, NIOSH will review regulatory documents and confirm site activation. Once activated, site research personnel will identify and offer study participation to HCP in the site selected unit(s), prior to and within 60 days of planned participant educational demonstrations, QLFT, and competency evaluation date(s). HCP interested in participating must complete written informed consent (Appendix B.) with a study team member whom is NOT their direct supervisor, and whom is on the site delegation log. Next, if consent is complete, screening eligibility requirements include: OSHA/NPPTL Medical Evaluation Form (Appendix C.), NIOSH/NPPTL Bivariate Panel DCF (Appendix D.), optional NIOSH Photo Release form (Appendix E.), Taste Threshold Test DCF (Appendix F.), and the eligibility checklist (Appendix G.).

The NIOSH Bivariate Panel facial measurement classification, an efficient two step method utilizing anthropometer and spreading calipers, will be conducted during screening to calculate in millimeters the individual participant face length (from menton to sellion) and face width (distance between zygomatic arches).[20] This method is time effective and studies show accuracy for approximately 96.7% male and 98.7% female national work force based on facial dimension limits of 98.5 to 138.5 mm for face length and 120.5 to 158.5 mm for face width.[20] Greater than or equal to 50% of the current national US workforce is anticipated to require medium sized EHMRs based on data collected from 3994 subjects representing 95% of the national population.[20] During this study, data will be captured by study personnel for secondary endpoint NIOSH bivariate panel allocations in a complete population of HCP to assist in healthcare institution supply recommendations, as seen in section 2.2, secondary objective B.

3.5 Fit Test Assessment

On the day of the scheduled simulated public health emergency study interventions, participants will be provided with their EHMR and filter set or N95 FFR that meets the sizing results from the screening bivariate panel facial measurements. Participants will also be provided an infographic (Appendix H.) and an educational handout based on cohort allocation

(Appendix I. or Appendix J.). The infographic includes an overview of respirators and the educational handouts include education for the device in their cohort. Next, EHMR cohort participants will watch the EHMR NIOSH Demonstration Video for education on proper inspection, donning, positive USC, negative USC, doffing, cleaning/disinfection and fit testing. N95 FFR cohort participants will watch the N95 FFR NIOSH demonstration video on donning, positive pressure USC, negative pressure USC and fit testing. Once the video concludes participants will be instructed to practice what they have learned for 15 minutes (+ 15 minutes window to prevent deviation).

Fit testing will be initiated after participant practice session concludes. First participants will don their respirator and adjust it accordingly for best-perceived fit; next, they will complete USCs while evaluated by study staff. Lastly, they will complete QLFT fit test administered and evaluated by study staff. If upon USC the participant feels the respirator size is incorrect based on leaks and/or comfort, the participant will still complete the USCs and QLFT with their original NPPTL/NIOSH Bivariate Panel cell category allocated respirator size. If the subject fails the QLFT, the DCFs (Appendix K.) will be kept for analysis and the participant will complete a second USC and QLFT with an alternative size as appropriate. A second DCF (Appendix K.) will be captured for participants that fail their first QLFT and all records kept from each size and assessment.

3.6 Competency Evaluation

Post QLFT, study personnel will evaluate HCP EHMR use proficiency with the six competencies containing 26 tasks identified from OSHA standards. The evaluation attempts will be completed in triplicate utilizing the NIOSH approved Competency Evaluation DCF (Appendix M.). During competency evaluation study staff will Inform participants of each competency title (in sequential order). Study staff will not provide task information unless participant misses/incorrectly completes a task. If this occurs study staff will first verbally assist the participant. If participant is still unable to complete the task/competency, next study staff will physically assist. Scores per attempt will reflect this process. Note: cumulative task scores per competency and cumulative competency scores per attempt must be totaled once the stop watch and attempt is over. Only individual task scores should be written during the times attempt. Five of the tasks in the competency evaluation document are labeled “if needed”. If it isn't needed by the participant, ask them to state what they would do if it was. This is not considered verbal assist unless they are unsure of what to do.

3.7 Competency Evaluation Tool (Appendix M.)

The Competency Evaluation tool is designed to measure performance in terms of knowledge, skills, and proficiency for EHMR use in healthcare. The assessment tool was developed based on OSHA standards and guidelines.[21, 25, 26] The tool was designed and reviewed by nine members of the CDC/NIOSH project team, and additionally peer reviewed by five CDC/NIOSH leaders with expertise relevant to this field. Through an integrative process of developing the tool, six core competencies and 26 tasks emerged as the most critical performance metrics associated with current EHMR use OSHA standards.[21,25,26] Attempts completed three times (in triplicate) will be conducted to determine if repeated task execution or “practice” improves subject performance and evaluation time.

3.7.1 Evaluation Tasks: The 26 task scores will be individually determined by the study personnel, based on if the participant requires no assistance (3), verbal assistance (2), or

physical assistance (1). Study personnel will only provide the competency one-word title to each participant during evaluation, and will not provide task information, unless a task is missed and/or completed incorrectly. If a participant misses or incorrectly performs a task, study personnel will first verbalize assistance to the participant. If the participant is still unable to complete it correctly with verbal assistance, the study personnel will next physically assist. Scores allotted will reflect this process.

3.7.2 Evaluation Competencies: The first five competencies each contain four tasks, with individual competency scores of 4-12 points possible. The sixth competency contains six tasks with 6-18 points possible. Study personnel will use the competency evaluation instrument to uniformly assess each participant and collect corresponding data. Study personnel will begin the evaluation by initiating a stop clock (for time analysis per attempt) and next immediately inform participant of the first competency title (in sequential order). A total of

3.7.3 Evaluation Attempts: A total of 26 to 78 points are possible for overall score, per attempt. Attempt scores will be calculated by summing the assigned score (1, 2, or 3) for each task aligned within each core competency. The higher the score, the greater the level of proficiency. Once a participant completes the first attempt of all six competencies and 26 tasks, the stopwatch will be stopped and time for the attempt will be recorded in seconds. Next study personnel and participant will repeat this process for the second attempt and lastly the third attempt. Each attempt will be individually timed. The competency total scores and the attempt total scores will be tallied once the participant completes each attempt and stop watch is stopped so that calculation time is not included in participant attempt time recorded.

4.0 HEALTHY HUMAN PARTICIPANTS

Subject selection will demonstrate the racial, gender, and ethnic characteristics and population demographics of HCP from three healthcare institutions in the United States: University of Texas in Houston Texas, Emory University in Atlanta Georgia, and Wayne State University in Detroit Michigan. The study accrual goal is 150 to 300 **evaluable** participants nationally, with 50 to 100 evaluable HCP per site. No exclusion criteria will be based on race, gender, or ethnicity.

4.1 Inclusion Criteria:

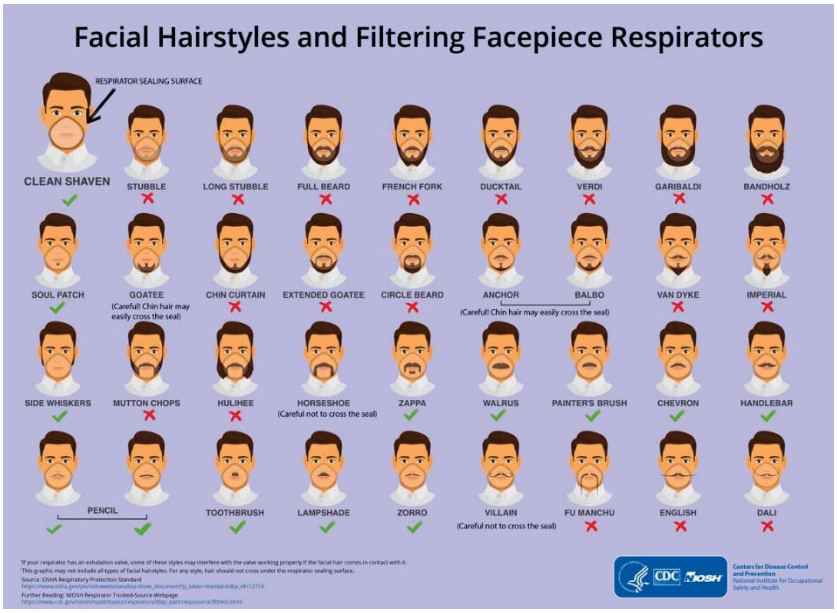
- Ability to understand, the willingness to participate, and the completion of a written informed consent document (Appendix B.)
- Understands spoken and written English language as required for consent, demonstration videos, demonstration checklist, and evaluation measures
- Age $\geq$ 18 years old
- OSHA/NIOSH Medical Evaluation Form completed by the participant and reviewed/signed by a licensed medical professional such as a registered nurse, nurse practitioner, physician assistant, or physician (Appendix C.)
- If a subject reports “yes” to any medical condition listed on the OSHA/NPPTL Medical Evaluation Form (Appendix C.) in Part B Questions 2, 5, 6, and/or 7, a Physician must review the subject’s current and past medical history and provide documented clearance for them to participate.

- HCP requiring OSHA's respiratory protection requirement, included in the hospital's Respiratory Protection Program and able to provide estimated number of years using respirators
- NIOSH Bivariate Panel facial measurements and completed DCF (Appendix D.)
- Review of the NIOSH General Photo Release Form (Appendix E.). This allows photos and/or videos taken during study participation to be utilized in presentations and publications or the post study webinars contracted (photos/videos will not contain participant personal identifiers). Participants may decline completing this form (and if they decline, they may not be included in any photos or videos). Documented verification of agreement or decline must be addressed before registration to study
- Passed the Taste Threshold test with a score recorded of 10, 20, or 30, indicating participant can taste the sodium saccharin challenge agent for the QLFT) (Appendix F, Page 3).
- Eligibility Checklist (Appendix G.)

4.2 Exclusion Criteria:

- Inability to adhere to study and/or follow up procedures
- Facial hair or piercings, which may interfere with the facial seal region of the elastomeric respirator (Figure 3.)
- Individuals with facial deformities/injuries that may prevent seal and/or passing a fit test
- Known hypoguesia or ageusia (decreased ability to taste certain types of foods or the absence of taste entirely which precludes QLFT)
- Inability to ensure availability for the study intervention date(s) selected by site personnel
- 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 C.)
- Prior problems using a respirator as reported in Part B. question 8 of the OSHA/NPPTL Medical Evaluation Form (Appendix C.)

Figure 3. NIOSH Respirator Seal and Facial Hair Reference Chart[24]



5.0 PROCEDURES AND EVALUATIONS

Participant protocol interventions will include: consent, screening, randomization, educational demonstration, practice session, and USC and fit testing. In addition, the EHMR cohort will also complete competency evaluation at the end of the visit. Please note that each EHMR cohort participant will complete the study interventions outlined in 5.8 through 5.13 below, in triplicate, during competency evaluation. See also the study calendar (Appendix A.)

5.1 Screening

Within 60 days of the scheduled active study feasibility assessment, healthy HCP candidates will be identified in unit(s) selected by each site to represent the sample population and provided written informed consent form (Appendix B.) to review. Written informed consent will be discussed with participants by study personnel, allowing time for participants to ask questions, and receive answers for adequate consent process. Explanation of the study purpose and potential risks and benefits will be presented to each interested HCP. HCP will be allowed to take the informed consent form home to further review and/or seek advice from their own physicians and lawyers outside of this study if desired. HCP will have the opportunity to ask questions at any time during the consent process and study. If the potential participant agrees to participate, he or she will then sign the informed consent form and a study team member on the delegation log will sign it after the participant. A copy of the signed consent form or a second signed consent form will be provided to the participant for their records. The study team will keep the original copy of the consent form (wet ink version). If a potential participant declines to sign the informed consent form, no study interventions or screening assessments will be completed. No coercion or undue influence from investigators or hospital management will be used to obtain informed consent and/or study participation of HCP. Participation in this study is voluntary and HCP may withdraw their participation from the study at any time. Study staff will make it clear to HCP that participation is their choice and they should report perceived coercion to the local Institutional Review Board (IRB) listed on their informed consent form.

Study related screening and interventions will NOT be completed until the participant has provided written informed consent. Upon completion of informed consent, participants will be provided a copy of the OSHA/NPPTL Medical Evaluation form (Appendix C.) required for safety review and eligibility. During screening, participants will also complete the NIOSH/NPPTL Bivariate Panel DCF (Appendix D.), Taste Threshold Test DCF (Appendix F.), and review of the optional General Photo Release form (Appendix E.) with study personnel. Delegated study personnel will complete an eligibility checklist (Appendix G.) and informed consent process note (on page 3 of the eligibility checklist) for each participant. Once screening items are complete and eligibility is confirmed, eligible participants will be randomized to one of two cohorts (section 5.4).

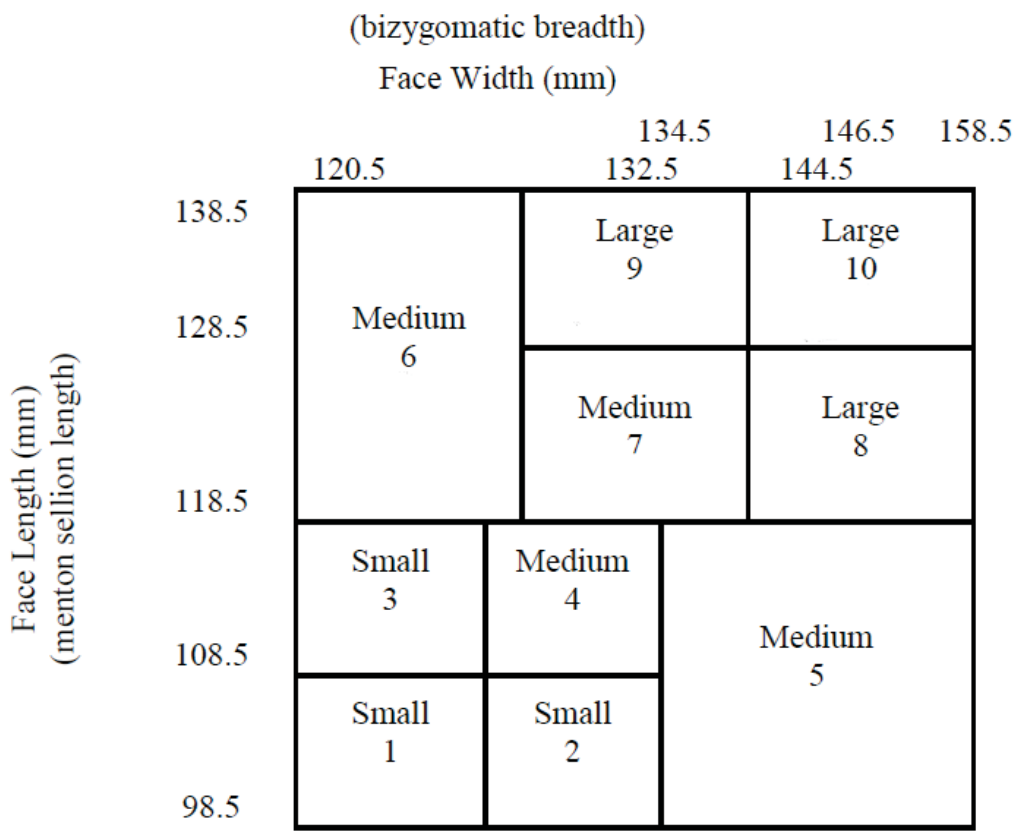
5.2 NIOSH/NPPTL Bivariate Panel (Appendix D.)

The study team will complete the NIOSH/NPPTL Bivariate Panel measurements with participants for bi-dimensional head measurements in millimeters utilizing an anthropometer and a spreading caliper, to determine small, medium, or large EHMR sizing (Figure 3.). The NIOSH/NPPTL Bivariate Panel includes two facial measurements for EHMR fit sizing, including the distance between the zygomatic arches (facial width) and distance from the menton to the sellion (facial length). Study staff will complete the associated NIOSH/NPPTL Bivariate Panel measurements DCF for each participant during this activity (Appendix D.) Once facial length and width are determined, the NIOSH/NPPTL Bivariate Test Panel algorithm (Figure 5.) will be reviewed by the study team to provide EHMR size cell category for each participant utilizing the three-size system accounting for small, medium, and large respirator sizes.

Figure 4. Bivariate Panel Measurements [20]

Bizygomatic Breadth: Maximum horizontal breadth of the face measured utilizing a spreading caliper between the zygomatic arches.	
Menton-Sellion Length: Distance measured utilizing a sliding caliper in the midsagittal plane between the menton and sellion landmarks	

Figure 5. NIOSH Bivariate Test Panel[20]



5.3 Taste Threshold Test (Appendix F.):

During the screening taste threshold test, participant must wear an OSHA approved fit test hood and breathe normally with a slightly open mouth and tongue extension in order to participate. The threshold check solution is prepared by putting the manufacture recommended amount of the fit test solution in 100 ml of distilled water. To produce the aerosol, the nebulizer bulb is firmly squeezed so that it collapses completely, then released and allowed to fully expand. Ten squeezes of the nebulizer bulb are repeated rapidly and then the test participant is asked whether the sodium saccharin sweet taste can be tasted. If the test participant reports tasting the sweet taste during the ten squeezes, the screening test is completed and score is recorded as ten. This test is always scored in tens, with the option of 10, 20 or 30 to be eligible to continue study participation. If the sweet taste is not recognized after the maximum 30 squeezes, the test subject is unable to taste sodium saccharin and may not perform the sodium saccharin QLFT. If this occurs, the PI/PM must be notified and the participant will be informed and removed from study as a screen fail. IMPORTANT: The nebulizer must be thoroughly rinsed in water, shaken dry, and refilled at least every four hours by study personnel to ensure accuracy of test results.

5.4 Randomization

Participants deemed eligible post screening requirements will be randomized to study using a random number generator. Approximately 20% of subjects will be allocated into the control N95 FFR cohort and 80% allocated to the EHMR cohort. Each participant will be assigned a site-specific identification number (ID) in sequential order that will include their two digit CDC/NIOSH pre assigned site number followed by their three digit local subject number (example: 01-001, 01-002, 01-003, etc.) Once randomized, participants in the control N95 FFR cohort will complete sections 5.5 to 5.7 study interventions on the pre-selected feasibility assessment date. Participants randomized to the EHMR cohort will complete sections 5.5 to 5.13 study interventions during the pre-selected feasibility assessment date. Subjects that screen fail will be removed from the study after being informed of the rationale for ineligibility. Screen failed subject's data will be stored and provided to NIOSH de-identified. Rationale for a screen fail must be indicated on the eligibility checklist. Participants that screen fail will be provided a screen fail ID number including the alpha characters SF, site number, and screen fail subject number beginning with the double digit 01 and continuing in sequential order (example: SF-01-01, SF-01-02, SF-01-03, etc.).

5.5 Educational Demonstration

Participants will be provided the NIOSH approved Infographic (Appendix H.) and Educational Handout (Appendix I. or J.) and next the NIOSH Demonstration Video. The EHMR cohort will be provided the EHMR NIOSH Demonstration Video which includes instruction on EHMR inspection, donning, positive pressure USC, negative pressure USC, doffing, and cleaning/disinfection. Finally, it concludes with an overview of what participants will expect during QLFT fit testing. The N95 FFR cohort will be provided the N95 NIOSH Demonstration Video which includes instruction on donning, positive pressure USC, and negative pressure USC. Finally, it concludes with an overview of what participants will expect during QLFT fit testing.

5.6 Practice Session

Participants will be provided 15 minutes (+15-minute window to prevent deviation) to practice what they have learned from their educational handouts and the NIOSH demonstration videos.

5.7 USCs and Sodium Saccharin QLFT (Appendix K.) [21-23]

Note: Subjects cannot eat or drink for at least 15 minutes prior to this test.

Staff designated to conduct this test must have completed SIV/training prior to site activation and re-review of training within seven days leading up to active study as provided by NIOSH. Data will be collected prior and during the QLFT by the study personnel on the provided DCF (Appendix I.), which includes measures for both USCs and the sodium saccharin QLFT. Immediately prior to the QLFT, study personnel will ask the participant complete the USCs to ensure respirator seal and provide secondary endpoint data (Appendix K, Pages 1 & 2).

The site PM/PI will ensure study personnel administering the QLFT are able to prepare test solutions, perform tests properly, recognize invalid tests, and ensure that test equipment is in proper working order. The USC evaluations will also provide the 5 minutes of OSHA required respirator wear immediately prior to fit testing.[15] The QLFT, for the purposes of this study, is the OSHA approved sodium saccharin aerosol solution protocol, which will be conducted immediately post the UCSs. This QLFT test data will be recorded on Appendix K, page 3.

USC and QLFT procedures will include the following:

5.7.1 Positive Pressure User Seal Check (Appendix K, Page 1.)

- Participant covers exhalation valve opening with thumb, fingers, or hand and exhales slowly for a count of 10 seconds (window of - 5 seconds if required)
- Participant determines if they notice leaks
- Participant readjusts head straps and device to properly seal leaks as needed
- Participant checks again for leaks and repeat all steps, if applicable, until free of leaks

5.7.2 Negative Pressure User Seal Check (Appendix K, Page 2.)

- Participant with EHMRs remove filter covers and place both palms over filters. Participants with N95 FFR cover entire facepiece of respirator.
- Participant inhales slowly for a count of 10 seconds (window of - 5 seconds if required)
- Participant determines if they notice slight collapse of facepiece
- Participant readjusts head straps and device to properly seal if slight collapse does not occur
- Participant checks again for slight collapse and repeats all steps, if applicable, until slight collapse of facepiece during

5.7.3 Sodium Saccharin Aerosol Protocol QLFT (Appendix K, Page 3.)

1) Participant will first don a fit test hood while wearing their assigned respirator. They should breathe normally with a slightly open mouth and tongue extension
2) A DeVilbiss Model 40 Inhalation Medication Nebulizer or equivalent is used to spray the fit test solution into the enclosure and is prepared by adding the manufacture recommended amount of solution to 100 ml of warm water
3) The nebulizer is inserted into the opening in the front of the hood enclosure and an initial concentration of sodium saccharin fit test solution is sprayed in inside the hood using the same number of squeezes (either 10, 20 or 30 squeezes) that were required to elicit a taste response during the participants screening taste threshold test. A minimum of 10 squeezes is required.
4) Test Exercises: Each test exercise will be performed for approximately one minute and the respirator cannot not be adjusted once the exercises begin until all exercises are completed, or the test is void. If this occurs, participants must start over from the beginning of the DCF tool using a second DCF copy, with the USCs (Appendix K.). During each exercise, the aerosol concentration shall be sprayed every 30 seconds using one-half the original number of squeezes it took to elicit the taste during the screening taste threshold test (i.e. 5, 10 or 15 squeezes).
5) Test Exercises include participants instructed to complete:
    a. Normal breathing - In a normal standing position
    b. Deep breathing - In a normal standing position
    c. Turning their head from side to side - Standing in place, while inhaling at each side
    d. Moving their head up and down - Standing in place, while inhaling when head is in the up position

e. Talking (Rainbow Passage: Appendix L.) - The participant shall talk loud and slowly using the rainbow passage paragraph provided by study personnel and be able to be heard clearly by the test conductor
f. Bending over – Instructed to bend at the waist within participant comfort and safety limitations
g. Normal breathing - In a normal standing position

Note: The participant shall indicate to the study personnel test conductor if at any time during the sodium saccharin fit test the sweet taste is detected while wearing their respirator. If the test subject does not report tasting this agent, the test is passed. **If the sweet taste is detected, the fit is deemed unsatisfactory and the test is failed.** In the event a failure occurs, a different respirator size will be given to the participant if applicable and the entire test procedure including USCs prior to QLFT, will be repeated. Additionally, because the nebulizer may clog during repeated use, the test conductor must check function between each participant to ensure that it is not clogged. If clogging is found at the end of the test session, the test is invalid and must be repeated upon correction.

5.8 Inspection Evaluation[25] (Appendix M.)
Tasks for this competency will be completed by each participant and evaluated by study personnel utilizing the provided DCF (Appendix M.). The tasks for Inspection *Competency 1* include:

5.8.1 Participant will inspect face piece for damage
5.8.2 Participant will examine head straps for twists, loss of elasticity, etc.
5.8.3 Participant will remove exhalation valve cover and inspect exhalation valve
5.8.4 Participant will examine filters and attach to the mask

5.9 Donning Evaluation[25] (Appendix M.)
Tasks for this competency will be completed by each participant and evaluated by study personnel utilizing the provided DCF (Appendix M.). The tasks for donning *Competency 2* include:

5.9.1 Participant will position face piece under chin and over bridge of nose
5.9.2 Participant will position head harness above the ears and across crown of head
5.9.3 Participant will hook neck strap below ears/around neck
5.9.4 Participant will adjust straps to correct fit

5.10 Positive Pressure USC Evaluation[25] (Appendix M.)
OSHA regulations require anyone wearing a tight-fitting respirator to perform USCs for assurance that an adequate seal is achieved each time the EHMR is put on. Participants may first need to rotate the exhalation valve cover upwards towards their nose for ease of competency completion. Tasks for this competency will be completed by each participant and evaluated by study personnel utilizing the provided DCF (Appendix M.). The tasks for positive pressure user seal check *Competency 3* include:

5.10.1 Participant covers exhalation valve opening with thumb, fingers, or hand and exhales slowly for a count of 10 seconds (window of - 5 seconds if required)
5.10.2 Participant determines if they notice leaks
5.10.3 Participant readjusts head straps and device to properly seal leaks as needed

5.10.4 Participant checks again for leaks and repeat all steps, if applicable, until free of leaks

5.11 Negative Pressure USC Evaluation[25] (Appendix M.)
Tasks for this competency will be completed by each participant and evaluated by study personnel utilizing the provided DCF (Appendix M.). The tasks for negative pressure user seal check *Competency 4* include:

5.11.1 Participant removes filter covers and places both palms over filters and inhales slowly for a count of 10 seconds (window of - 5 seconds if required)
5.11.2 Participant determines if they notice slight collapse of facepiece
5.11.3 Participant readjusts head straps and device to properly seal if slight collapse does not occur
5.11.4 Participant checks again for slight collapse and repeats all steps, if applicable, until slight collapse of facepiece during

5.12 Doffing Evaluation[25] (Appendix M.)
Tasks for this competency will be completed by each participant and evaluated by study personnel utilizing the provided DCF (Appendix M.). The tasks for doffing *Competency 5* include:

5.12.1 Participant will perform hand hygiene and don gloves
5.12.2 Participant will unhook the neck strap
5.12.3 Participant will pull the head harness over the head, without touching respirator facepiece
5.12.4 Participant will place respirator on an appropriate surface such as a chux pad

5.13 Between Patient/Use Cleaning and Disinfection Evaluation[26] (Appendix M.)
In between patient/use cleaning and disinfectants for EHMRs should be completed with OSHA approved cleaning and disinfectant wipes or methods[26] For the purposes of this simulation health emergency, **simulated** cleaning and disinfection wipes may be used (such as paper towels or tissues) to reduce evaluation in triplicate down time which would be increased while waiting for kill times/drying devices between evaluation attempts. Tasks for this process will be completed by each participant and evaluated by study personnel utilizing the provided DCF (Appendix K.). The steps for between patient/use cleaning and disinfection *Competency 6* include:

5.13.1 Participant will prepare clean surface such as a chux pad before starting
5.13.2 Participant will complete hand hygiene and don new gloves
5.13.3 Participant will first hold the inside of the respirator, and wipe **outside** of EHMR face piece and head straps utilizing simulated cleaning & disinfectant wipes
5.13.4 Participant will place device face down on clean chux pad and complete hand hygiene and don new gloves
5.13.5 Participant will next wipe the **inside** of the respirator using cleaning & disinfectant wipes and place respirator in a clean area
5.13.6 When finished, participant will remove and discard gloves and perform hand hygiene

6.0 PARTICIPANT DISCONTINUATION
Participants may be removed from the study for the following reasons:

- New conditions that prevent the participant from wearing of the EHMR

- New conditions that prevent the participant from completion of the study interventions and/or evaluations
- EHMR or QLFT related adverse events experienced by the participant
- Participant decides to withdraw from the study
- Participant non-compliance with study requirements confirmed by the site PI/PM
- For any reason the PI/PM deems is necessary to protect the safety, data integrity, and/or confidentiality of the participant

7.0 SAFETY PLAN

Minimal risk is defined by 45 U.S. Code of Federal Regulations (CFR) 46.102 (i) 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." All devices and test procedures conducted with subjects are nationally accepted and/or commercially available. This protocol is classified under minimal risk and will be conducted according to all conditions of the protocol. This is including all statements regarding confidentiality, in accordance with applicable local legal and regulatory requirements, and applicable US Federal regulations including; International Conference of Harmonisation (ICH) Good Clinical Practice (GCP) E6 and the 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 site specific Health Insurance Portability and Accountability Act (HIPAA) training. Screening safety measures include informed consent, OSHA/NPPTL Medical Evaluation Form, and the eligibility checklist. Site study personnel and licensed medical professionals will monitor subjects for adverse events during each study visit. Site investigators and research personnel will review recruitment, adverse events, deviations, and unanticipated problems during monthly study meetings. Modifications necessary to ensure subject safety and decisions to continue or close the trial 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 Unanticipated Problem submission and the study may be terminated.

HCP interested in participating will first complete a written informed consent process discussed in section 5.1. Next participants will complete a screening process for safety and inclusion review, which includes the OSHA/NPPTL Medical Evaluation Form (Appendix C.) and Eligibility Checklist (Appendix G.). Participants will be monitored for EHMR and sodium saccharin QLFT related adverse events by site research staff from the time of participant registration until study termination. Site Investigator(s) and study personnel will review serious adverse events (SAEs), adverse events (AEs), participant safety, recruitment, accrual, deviations, unanticipated problems, and breaches of confidentiality as applicable at the sites study meetings. Any modifications necessary to ensure participant safety and decisions to continue, or close the trial, are also discussed at these meetings. If any 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 Unanticipated Problem submission and the study may be terminated.

7.1 Recruitment Procedures

Site Study Personnel Participation

Study personnel at each site may complete protocol tests and procedures during a train the trainer SIV to ensure they comprehend fit testing and user competency evaluation procedures, if they first complete voluntary informed consent and meet screening safety requirements provided by CDC/NIOSH staff. Data collection for this preliminary analysis and training session will be collected de-identified only and by CDC/NIOSH staff only. Records for this preliminary

train the trainer and data collection will not be provided to the site to ensure protection of confidentiality. Study staff at each site will not receive additional monetary reimbursement for their participation in train the trainer SIV tests and will only be performing study tests to determine validity, if instrumentation is working properly, and/or to train and prepare for their role in conducting participant testing. The informed consent form (Appendix B.) additionally advises employees to contact the Institutional Review Board Chair if they believe in any way coercion to participate has occurred, or if their data has not been kept confidential.

Healthcare Participants

Potential HCP participant's will be identified by site study staff in healthcare units, departments, and/or sites designated to wear respiratory protection and complete annual fit testing. Sites selected will benefit from creating and/or contributing to their site-specific respiratory protection program and staff education. Informed consent must be obtained prior to all study interventions, and the certification of informed consent statement signed by the participant and an approved study personnel on the site delegation log. The EHMR and filter set will be provided at no cost to each participant during attendance at the feasibility assessment meeting(s). Participants may also keep their EHMR after they complete all study interventions. Participants will be provided a one-time reimbursement of $50 upon completion of all study interventions.

Informed Consent (Appendix B.)

Designated study personnel must provide and complete review of the written informed consent document (Appendix B.) with each participant recruited, and complete a consent note documentation on the eligibility checklist (Appendix G, Page 3.). Written informed consent must be obtained from all participants prior to participating in the study. The participants will be given adequate time to read the document and ask any questions pertaining to the study before participating. Participants will be informed they are able to voluntarily withdraw themselves from the study at any point without prejudice to themselves. All participants will be given a copy of the consent form. Written informed consent must be completed prior to the start of ANY study related interventions. The estimated reading associated grade level of the informed consent form is 12.4 utilizing Flesch-Kincaid scale which is appropriate for the population to be studied.

7.2 Management of Events

Medical Evaluations

In order to prevent underlying medical disorder exacerbation due to study activities, study participants will complete a medical evaluation form (Appendix C.), provided by a licensed health care professional during screening. In the event participants report an underlying medical disorder listed in Part B, questions 3, 4, and/or 8, they will be excluded from the study. In the event participants report an underlying medical disorder listed in Part B, questions 2, 5, 6, and/or 7, a physician will be required to complete a current and past medical history review and documentation of clearance for the participant to participate prior to continuing with testing and registration. Participants they will be excluded for any medical or physical conditions and any medications that would affect performance or preclude the safe performance of fit testing and user competency of EHMRs.

Unanticipated problems

Unanticipated problems are those not anticipated to have occurred and were not addressed as a potential risk during the initial review.

Adverse Events

Adverse events (AEs) refer to any untoward medical occurrences, whether considered study intervention-related or not. Serious adverse events (SAEs) include: death, life-threatening events, hospitalization, incapacity, substantial disruption of a subject's quality of life, or 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.[29] Serious adverse events must be reported to CDC/NIOSH and the sites IRB immediately and at minimum within 48 hours from notification of the incident onset. Other, non-serious incidents must be reported within five (5) business days. In the event of an SAE, the site PM/PI, CDC/NIOSH, and the Institutional Review Board will be notified utilizing the FDA 3500A MedWatch form, including section B - Product Problem.[30]

Expected Rare Adverse Events May Include:

7.2.1 *Difficulty Breathing*: Associated with user error or device malfunction 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

7.2.2 *Contact Dermatitis:* The EHMR is composed of flexible elastomer silicone, which 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 face and/or scalp

7.2.3 *Claustrophobia:* Attributed to 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

7.2.4 *Sodium Saccharin Solution Irritations:* OSHA approves sodium saccharin for QLFT. Irritation is rare, however may occur in a minority of participants.[28] Manufacture safety recommendations include:

7.2.4.1 Respiratory event: Participant will be instructed to remove device and/or hood and move to fresh air, seek medical advice if cough, shortness of breath, or other respiratory problems occur.[29]

7.2.4.2 Skin irritation: Participant will be instructed to rinse thoroughly with water, seek medical advice if redness, swelling, itching, or burning occurs.[29]

7.2.4.3 Eye irritation: Participant will be instructed to rinse immediately with water and obtain medical attention if irritation persists.[29]

7.2.4.4 Ingestion irritant: Participant will be instructed to seek advice of medical personnel if gastrointestinal symptoms occur.[29]

7.3 Participant Follow Up

No follow up is required for the purposes of this study with the exception of participants that experience unexpected and at least possibly related adverse events. All participants experiencing unexpected and at least possibly related adverse events will be followed monthly until resolution of the event and/or until study termination, whichever occurs first.

7.4 Retention of Records

Records pertaining to this study will be kept in accordance with site and CDC/NIOSH guidelines and for a period of no less than three years after study termination. The participant study data will be de identified by each site utilizing assigned ID numbers beginning with a two-digit site number and ending with a three-digit participant ID. All participant personal identifiers will be kept confidential by each site. Breach of confidentiality is the knowledge of a participant medical and/or research data, which could potentially affect future insurability, employability, have a negative impact on family relationships, and/or result in shame or embarrassment. Breach of confidentiality will be reported as an unanticipated study event, and site/IRB policy on participant notification must be employed. Training confirmation for the Health Insurance Portability and Accountability Act (HIPAA) is required by all study personnel members at each site, to assure compliance with the laws associated with disclosure of identifiable participant information.[31] CITI Program training confirmation or equivalent is also required for all study personnel at each site.[32] CITI Program training provides assurance of compliance with ethical research.[32] HIPAA training and CITI training for each study personnel on the delegation log must be provided to the CDC/NIOSH PM prior to site activation.

7.5 Data Management and Quality Assurance

This protocol, data captured for source, and all corresponding regulatory documents are subject to monitoring, trial-related audits, IRB reviews, and regulatory inspection(s). Data will first be collected on paper DCFs during study interventions. DCFs will be kept in a locked secured environment provided by each sites PI. De identified DCFs will be submitted to NIOSH for monitoring and quality assurance. Sites will next complete de identified electronic data capture from the DCFs for analysis in REDCap, a secured server software. CDC/NIOSH will manage and monitor REDCap data.

Each site will review the trial at monthly meetings and report any safety findings immediately as applicable to necessary regulatory bodies. Quality assurance personnel designated by CDC/NIOSH will audit the trial annually at minimum, or at more frequent intervals as requested by the site PI, NIOSH PI, and/or IRB. IRB review/renewal will occur annually at minimum.

8.0 STATISTICAL METHODS

This is a demonstration study providing groundwork for baseline feasibility data. For the purposes of the objectives, descriptive statistics derived from the sample will be used to estimate population parameters. DCF tools provided by NIOSH will be used at each site to ensure uniform assessment and scoring for each endpoint. Validity of scoring will be ensured by SIV training and site study personnel self-testing under the direction of CDC/NIOSH study team members. Data collection and management will first be completed utilizing the paper DCFs during study interventions, and next be entered electronically into the NIOSH provided laptop and REDCap program. Sites must provide CDC/NIOSH a copy of all DCFs, de-identified. The NIOSH PM will monitor the site DCFs and electronic REDCap data entries for quality and assurance.

8.1 Qualitative Fit Test Pass Rate

Descriptive statistics will be used to summarize the proportion of participants that were able to obtain a passing QLFT by cohort. Differences in the proportion of passing QLFT EHMR fit by occupation, gender, and age can be examined through non-parametric statistical techniques such as the Wilcoxon Rank Sum test or by comparing the proportions with a z score. In addition to comparisons, the population parameters (e.g., the proportion of participants passing the

qualitative fit tests) will be estimated for the total population and each subgroup delineated by occupation, gender, and age.

8.2 Time Measurements

Descriptive statistics will be used to derive estimates of the population parameters on the time it takes for each participant to conduct a USC, and to pass a QLFT. Differences in USC and QLFT times will be assessed between the cohorts and among different occupations, genders, and ages, examined through parametric or non-parametric statistics depending on the resulting distributions.

8.3 Evaluation of Elastomeric Respirator Use

Descriptive statistics will be used to derive estimates of the population competency scores with which individual participants are likely to display after training. Population parameters will be estimated for the total assessment score, the time it takes participants to complete the total assessment (in seconds), each of the core competencies, and each of the tasks aligned under individual competencies. Population estimates will be made for each of the three attempts individually. Differences in the overall scores, the time it takes subjects to complete the total assessment, the core competency and task scores and among different occupations, gender, and ages will be examined through parametric or non-parametric statistics depending on the resulting distributions. An analysis of the differences will be examined within each of the three attempts individually. Differences in each of the metrics (total score, time it takes to do the assessment, competency and task scores) across the three attempts will be statistically examined through a repeated measures statistical technique (such as repeated measures ANOVA or generalized linear mixed models) depending on the distribution of each of the metrics.

8.4 Predictive Value of User Seal Checks for Qualitative Fit Testing

The design of the study will result in a sample of participants that completed both a USCs and QLFT. This one to one matched dataset can be used to explore the association between the USC and the QLFT. Both the USC and the QLFT will result in pass/fail (0/1) attributes. Thus, descriptive statistics, point Biserial Correlations, and logistic regression will be used to determine the degree to which the USC (pass/fail) correlates with and predicts the results of the OSHA QLFT (pass/fail). The proportion of tests that resulted in non-equivalent outcomes will also be reported.

8.5 NIOSH/NPPTL Bivariate Panel for Elastomeric Sizing in Healthcare

The design of the study requires that participants be initially sized for EHMR allocation according to the NIOSH Bivariate Panel facial length and width measurements. Subject recruitment and inclusion will not be designed to be randomized within each panel of the NIOSH Bivariate Panel. Rather, the sample obtained is designed to be representative of the total population of HCP subject to respirator use at the three participating healthcare institutions. Sizing each participant according to the NIOSH Bivariate Panel will be completed to maximize the fit potential of the first respirator provided to each subject. This step, however, does not guarantee that the initial provided respirator will fit the participants as the panel was not derived using a complete population of HCP and instead designed using subjects recruited from manufacturing, construction, health care, law enforcement, and firefighting industries to provide a national population distribution.[21] In order to investigate the applicability of the

NIOSH Bivariate Panel for use as a tool within the healthcare industry, a profile of HCP distribution within the NIOSH Bivariate Panel will be derived. In addition, the alignment between the panel allocation and the results of the OSHA QLFT will be conducted. This alignment will be assessed by investigating the consistency between the assigned size (according to the NIOSH Bivariate Panel) and the results of the OSHA QLFT.

APPENDIX A: Study Calendars

1. EHMR Cohort Study Calendar

Study Interventions	Screening[1]	Education[6]	USCs & Fit Test[6]	Evaluation[6]
Informed Consent	X[1]			
OSHA/NIOSH Medical Evaluation form	X[2]			
NIOSH/NPPTL Bivariate Panel DCF	X[3]			
NIOSH Photo Release form documentation	X[4]			
Taste Threshold Test DCF	X[5]			
Eligibility Checklist	X			
Randomization	X			
Infographic & EMHR Cohort Educational Handout		X[7]		
EHMR NIOSH Demonstration Video		X		
Practice Session		X[8]		
Positive Pressure USC DCF			X[9]	
Negative Pressure USC DCF			X[9]	
QLFT DCF			X[9]	
Inspection Competency				X[10]
Donning Competency				X[10]
Positive Pressure USC Competency				X[10]
Negative Pressure USC Competency				X[10]
Doffing Competency				X[10]
Between Patient/Use Cleaning and Disinfection Competency				X[10]

[1] Written informed consent (Appendix B.) must be completed prior to all screening and study interventions. All screening items must be completed prior to study registration and within 60 days of the simulated public health emergency active study date(s)

[2] To be completed by the participant and reviewed/signed by a licensed healthcare professional such as a nurse or physician designated by the PI/PM at the site (Appendix C.)

[3] NIOSH Bivariate Panel will be completed during screening and recorded on DCF (Appendix D.)

[4] Documentation of General Photo Release agreement or decline must be recorded for each subject (Appendix E.)

[5] Taste threshold test must be completed during screening and recorded on DCF (Appendix F.)

[6] Active study interventions for ALL participants at a site must be completed within one (1) designated seven (7) day week including weekend days (NOT business days)

[7] Infographic and N95 Cohort Educational Handout (Appendix I.) will be provided to subjects prior to the EHMR NIOSH Demonstration Video

[8] Participants will be given 15 minutes (+15 minute window to prevent deviation) to review and practice the skills they have learned

[9] USCs and QLFT will be completed after the practice session. USCs are first completed and next QLFT. Subjects may not adjust or remove their respirator after the USCs are completed, so QLFT result is in part based on USCs. Study staff will record USCs and QLFT data (Appendix K.).

[10]Competency evaluation scores will be completed for each participant by site study personnel in triplicate, timed, and in sequential order. This will be recorded on the DCF (Appendix K.)

2. N95 FFR Cohort Study Calendar

Study Interventions	Screening[1]	Education[6]	USCs & Fit Test[6]
Informed Consent	X[1]		
OSHA/NIOSH Medical Evaluation form	X[2]		
NIOSH Bivariate Panel Measurements DCF	X[3]		
NIOSH Photo Release form documentation	X[4]		
Taste Threshold Test DCF	X[5]		
Eligibility Checklist	X		
Randomization	X		
Infographic & Educational Handout		X[7]	
Demonstration Video		X	
Practice Session		X[8]	
Positive Pressure USC DCF			X[9]
Negative Pressure USC DCF			X[9]
QLFT DCF			X[9]

[1] Written informed consent (Appendix B.) must be completed prior to all screening and study interventions. All screening items must be completed prior to study registration and within 60 days of the simulated public health emergency active study date(s)
[2] To be completed by the participant and reviewed/signed by a licensed healthcare professional such as a nurse or physician designated by the PI/PM at the site (Appendix C.)
[3] NIOSH Bivariate Panel will be completed during screening and recorded on DCF (Appendix D.)
[4] Documentation of General Photo Release agreement or decline must be recorded for each subject (Appendix E.)
[5]Taste threshold test must be completed during screening and recorded on DCF (Appendix F.)
[6]Active study interventions for ALL participants at a site must be completed within one (1) designated seven (7) day week including weekend days (NOT business days)
[7]Infographic and N95 Cohort Educational Handout (Appendix J.) will be provided to subjects prior to the N95 FFR NIOSH Demonstration Video
[8]Participants will be given 15 minutes (+15 minute window to prevent deviation) to review and practice the skills they have learned
[9]USCs and QLFT will be completed after the practice session. USCs are first completed and next QLFT. Subjects may not adjust or remove their respirator after the USCs are completed, so QLFT result is in part based on USCs. Study staff will record USCs and QLFT data (Appendix K.).

APPENDIX B: Informed Consent

CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: **J**ust-in-time **E**lastomeric **T**raining and **Fit**-Testing **(JET FIT)**

Site Principal Investigator
Name
Contact info

Site Project Manager
Name
Contact Info

Site Co-Investigator(s)

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Source of Support:
National Personal Protective Technology Laboratory (NPPTL), NIOSH, CDC
Office of Public Health Preparedness and Response (OPHPR), CDC
National Center for Immunization and Respiratory Diseases (NCIRD), CDC

Consent Version 1: 01/18/2019

Consent to be in a Research Study

Just-in-time **E**lastomeric **T**raining and **Fit**-Testing **(JET FIT)**

You are being asked if you would like to volunteer for a research study. All devices and procedures conducted in this study are commercially available and commonly used in industrial settings. The research is solely to identify if these devices and procedures can be used in healthcare. This document provides you with the information about the study. A member of the research team will review this study with you and answer all your questions. Please read the information below and ask questions about anything you do not understand before deciding if you want to volunteer.

1. Who is conducting the study?	The National Institute for Occupational Safety and Health (NIOSH) is a federal agency that studies worker safety and health. We are part of the Centers for Disease Control and Prevention (CDC).
2. What is the purpose of this study?	The purpose of this study is for the research team to learn more about preparing healthcare workers to wear **reusable** respirators during a supply shortage of **disposable** respirators. The team also wants to better understand how to train healthcare workers to use **reusable** respirators. This study will help determine how quickly healthcare workers can be assessed for respirator fit and learn to properly use reusable respirators. To accomplish this, the volunteers in this study will **pretend** they are learning about reusable respirator use during a public health emergency. A real public health emergency, such as a worldwide outbreak of influenza infection, could cause a supply shortage of **disposable** respirators, so we want to study a way to provide respiratory protection with reusable respirators to healthcare workers if a shortage were to happen. You are being asked to be in this research study because you are a health care worker in a setting that periodically requires you to wear respiratory protection.
3. How many people will be in this study?	Up to 100 healthcare workers from your institution will be asked to be in this study. Up to 300 healthcare workers nationwide will be asked to be in this study. Workers in units that are likely to wear respiratory protection while caring for patients will be offered participation by the study team.
4. What will I do for the study if I volunteer?	If you decide to volunteer for this study, you will be scheduled for about one to three visits at *campus here* to complete screening and study tests at: *address here*. The first visit will include informed consent. Next, if you decide to volunteer, you will complete "screening" tests to make sure it is safe for you. If it is safe for you to participate, and you meet all study requirements, you will be randomized to either education and fit testing a

disposable respirator (estimated to take about 60 minutes) or to education, fit testing, and competency evaluation of a reusable respirator (estimated to take about 90 minutes). Randomization is conducted using a random number generator provided by a computer program, and much like a flip of the coin is an unbiased and unpredictable way to separate volunteers into groups. For every 2 volunteers randomized to the disposable respirator fit testing, 8 volunteers will be randomized to the reusable respirator testing.

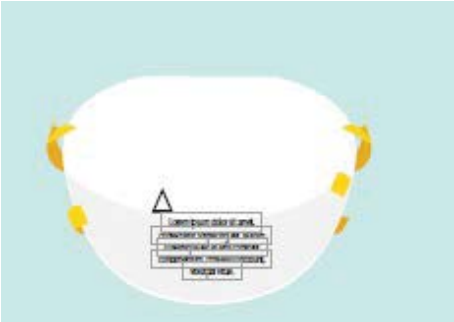
Once randomized you may be asked to attend educational presentation(s) and practice session(s) about the way your assigned respirator fits on your face and instructed how to properly use the respirator.

Screening

Before screening, a written consent process to inform you about the study will be completed. If you want to volunteer after reading and signing this consent and asking any questions you have, you will next be "screened" to assess if it is safe for you to participate. These screening activities will include filling out a Medical Evaluation form, an optional Photo Release form, face measurements, and completing a taste threshold test. The taste threshold test determines if you have the ability to taste saccharin, a sweet tasting substance. This test will require you to put on a see through hood over your head with an opening at the mouth. Next, a study team member will spray the sweet tasting saccharin into the opening to see if you can taste it. You will also need to discuss with a research team member your ability to safely join the study. If you are healthy enough and meet the requirements to join the study, you will be randomized into your group and informed again on what to expect and what date and time you will need to be available to participate.

Disposable Respirator

The group of volunteers in the disposable respirator fit testing group will use a NIOSH approved N95 Filtering Facepeice Respirator that the hospital system keeps in stock and that you may already be familiar with. The below is a cartoon of what this may look like.



Reusable Respirator

The group of volunteers in the reusable respirator fit testing group will use a RU8500 elastomeric half mask respirator made by Honeywell (see photos below). This has been certified by NIOSH and is commercially used in the United States. If you are in this group you will also be provided with two 7580P100 filters that accompany this respirator, which are also commercially used. This type of respirator is typically worn by construction and manufacturing workers, and has not been routinely used in healthcare. Unlike **disposable** respirators that should be discarded after each use, the reusable respirator in this study may be repeatedly cleaned, disinfected, and re-worn.

Honeywell North RU8500 Elastomeric Respirator A. Front B. Back

A. 

B. 

Education ***(Disposable and Reusable Respirator Groups)***

You will be given a handout explaining the difference between respirators. You will also be given a handout specific to your assigned respirator. You will next watch a NIOSH demonstration video about your assigned respirator. After you have reviewed the educational materials you will get about 15 to 30 minutes to practice the skills you were taught.

Respirator Fit Testing ***(Disposable & Reusable Respirator Groups)***

You will be given a respirator that matches your face size based on your facial measurements. A study staff team member(s) will complete a fit test with you. This will be done according to steps required by the Occupational Safety and Health Administration (OSHA), which includes the use of saccharin, an artificial sweetener. Saccharin is used because it has a distinct sweet taste that most people recognize easily. Depending on how well the first respirator fits, it may be necessary to conduct this fit test more than once. The steps for the fit test include:

1. Do not eat or drink for at least 15 minutes prior to the start of the test

2. Next, you will put on your respirator and then put a fit test hood over your head and respirator. A study team member will spray the saccharin into the opening near your mouth, and you will notify the study personnel if are able to taste it.
3. Finally you will complete seven activities (see below chart) to be sure movement does not affect the fit of your respirator. Each activity will be performed for about one minute. Again, saccharin will be sprayed inside your hood during each of the following activities:

Your Activity	Your Body Position
Normal breathing	In a normal standing position
Deep breathing	In a normal standing position
Turning head side to side	Standing in place and inhale at each side
Moving head up and down	Standing in place and inhale in the head up position
Read a paragraph	Standing in place you will try to talk loud & slow
Bending over	Bend at the waist if comfortable and safe for you
Normal breathing again	In a normal standing position

Reusable Respirator Evaluation *(Reusable Respirator Group Only)*
If you are in the resuable respirator group, a study team member(s) will also evaluate you performing the skills you have been taught during the education. This is to see how effective the education was. You will be asked to perform the skills three times and you will be evaluated after each try.

5. Are there any risks?

The activities in this study are performed by workers in a variety of workplaces, however elastomeric respirators are infrequently worn by U.S. healthcare workers. This study will assess if these respirators may also be used in healthcare.

This is considered a minimal risk study. However, if an injury occurs while you are participating in this study, you may be sent to the emergency room, employee health department, or a dermatologist if needed, at the discretion of your principal investigator or designee.

Expected Rare Adverse Events may include:

	• *Difficulty breathing:* Due to user error or device malfunction, is rare, however may occur in a small number of participants. If this occurs, you will be instructed to remove the device and inform research staff • *Contact Dermatitis:* The respirator is made of elastomer silicone, which may cause a skin sensitivity in a small number of participants. If this occurs, you will be instructed to remove device and inform the research staff. • *Claustrophobia:* May occur in a small number of participants, however is rare. If this occurs, you will be instructed to remove the device and inform the research staff • *Sodium Saccharin Solution Irritation:* May occur in a very small number of participants, however is very rare. You will be referred for medical attention if symptoms occur, such as: ➢ *Breathing problems* ➢ *Skin irritation* ➢ *Eye irritation* ➢ *Digestive problems*
6. 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.
7. What if I am injured or harmed?	A licensed medical professional will be on site to refer you to your primary care practitioner or emergency services as needed. Study staff will refer you to medical services if needed, however medical care or compensation will not be provided because all devices and procedures in this study are nationally approved and commercially available. If harmed through negligence, you might obtain compensation under Federal Law by contacting the Public Health Service, General Law Division of OGC, request the Claims Office at phone # 202-619-2155. If you believe that the research sessions have resulted in an injury to you, immediately contact the investigator (listed on the first page of this document) and your doctor.
8. Will I be reimbursed or paid?	If you decide to volunteer, you will be reimbursed a one-time amount of $50.00 at the end of the study. Screening visit is expected to take about 1 hour. Training, fit test, and evaluations are expected to be take about 2 hours. A total of 1-2 visits are expected for this study if you are safe to participate and complete all study tests. You will also get to keep the reusable elastomeric respirator and filter set that you will be given during

	the study meeting at no charge, if you are randomized to the reusable respirator group.
9. Are there other benefits?	This research may not benefit you personally, however it may in the future benefit anyone that requires personal protective equipment. The benefit of this study may include providing researchers the opportunity to learn more about personal protective equipment and ways to improve safety for the public. If you agree to volunteer, your information will only be used for research and will not be sold. The research completed with your data 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 such new products, tests, and/or processes will not be shared with you.
10. Will my personal information be kept private?	This research study will involve the recording of medical information that you will provide on the OSHA/NPPTL approved Medical Evaluation Form. The information that will be recorded will be limited to the items on the Medical form and information collected at the screening and study meetings. This information will be used to establish your eligibility to participate in the research study and to determine response to the study interventions. This research study will result in identifiable information that will be placed in your study chart at your place of work. Only de-identified information will be provided to NIOSH. Your name and date of birth will not be provided to anyone outside of the study team, and only de-identified study information will be utilized in the research data reports and publications.
11. Who will know about my participation in this study?	The following organizations will or may have access to identifiable information (which may include medical information) related to your participation in this research study: • Your Investigator and research team, place of work, and/or any affiliating health care provider • Department of Health and Human Services (HHS), CDC, and NIOSH • U.S. Food and Drug Administration (FDA) • Collaborating researchers to conduct further investigations • The Department of Justice or the Department of Labor In unusual cases, the investigators may be required to release identifiable information (which may include your medical information) related to

participation in this research study. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by local, state, and federal laws, the appropriate agency.

This study is in collaboration with NIOSH. NIOSH is part of the CDC, a government agency of HHS. Though NIOSH will only receive de-identified information about you, NIOSH is allowed to collect and keep information, including the results from your physical examination, because of three laws passed by Congress. These laws include:

- The Public Health Service Act (42 U.S.C 241)
- The Occupational Safety and Health Act (29 U.S.C. 669)
- The Federal Mine Safety and Health Act of 1977 (30 U.S.C. 951)

If you have questions about this testing, contact the local principal investigator, contact information can be found on the first page of this form. If you have any questions about your rights as a member of this study, contact the ____site specific info___ Institutional Review Board at __site specific contact info_____.

The overall results of the study may be written in a scientific article or report. By signing the optional photo release form during the screening meeting, 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 your name in any public research study or presentation, unless you sign a release and we will notuse a picture of you unless you agree to the optional photo release.

You will decide whether you want to participate in this study by completing this written informed consent. You are free to choose not to be in this study. It is up to you. The information we are collecting is maintained by de identified participant identification numbers so that we do not use your name when reviewing results.

Authorized representatives of US government regulatory agencies such as the FDA may review and/or obtain your identifiable information (which may include your OSHA medical evaluation form and study records) related to your participation in this research study for the purposes of monitoring the accuracy of the research data. While government agencies understand the importance of maintaining confidentiality of your identifiable research and medical records information, your place of employment and NIOSH cannot guarantee the confidentiality of this information after it has been obtained by them.

	Authorized representatives of your place of work or other affiliated health care providers may have access to identifiable information (which may include your OSHA medical evaluation form and study records) related to your participation in this research study for the purposes of (1) fulfilling orders for healthcare services associated with research participation; and/or (2) internal hospital operations (i.e. quality assurance). Your place of employment is required by the Privacy Act to protect your health information. After your information is shared with others, such as NIOSH, it may no longer be protected by the Privacy Act. The people who receive this information could use it in ways not discussed in this form and disclose it to others. NIOSH will use and disclose your de identified information only for research or regulatory purposes or to prepare research publications. In addition to using it for this study, NIOSH may re analyze the study data later or combine your information with information from other studies for research purposes not directly related to this study. The goal of any such research would be to learn more about healthcare worker education, respiratory protection, airborne diseases, or to help make better studies in the future. When using your information in these ways, the sponsor may share it with regulatory authorities, other researchers, business partners, and/or companies it hires to provide research related services. This could result in the transfer of your information outside of the United States. However, your name will never appear in any sponsor reports or publications, or in any future disclosures by NIOSH, unless you consent to it. In rare cases, the investigators may be required to release identifiable information related to this research study for safety. If the investigators learn that you or someone with whom you are involved is in danger or potential harm, they will need to alert, as required by local, state, and federal laws, the appropriate agency.
12. Who can I talk to if I have more questions?	If you have questions about this study, contact the principal investigator found on the first page of this document. For questions about your rights, your privacy, and/or harm that may have occurred to you, you can contact the Institutional Review Board (IRB) in the Human Research Protection Program at _____
13. How long will my information be stored or used?	The research team may continue to store and use your information for this study for a minimum of 3 years and possibly indefinitely.

14. 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 identifiable research or medical information recorded during your participation before the date you withdraw your consent may be continued to be used. To formally withdraw your consent, you should provide a written and dated notice of this decision to the study team contacts on the first page of this document.
15. Can I be removed from the study?	It is possible that you could be removed from the study. This could be because of safety reasons or if you are non-compliant or unable to perform the study visits or tests. If you experience side effects 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.
16. Study Team Personnel Only (skip this section if you are not a study team personnel	As a study team employee, your participation must be voluntary. You will not receive any monetary reimbursement for your participation. You will not be required to take annual leave to participate in testing. Testing will occur during normal duty hours during the site initiation visit (SIV) conducted by NIOSH for training purposes and to obtain preliminary data to help your study team prepare for training and fit testing subjects once your site is activated. As a study team employee, it is extremely important that your participation be truly voluntary and that all data obtained about you be kept confidential. Data from SIV study team members participation will be collected by NIOSH staff only and be completely de-identified during collection so that no records of identifiable data are available to the site staff or NIOSH. If you believe in any way that you have been coerced to participate, or your data has not been kept confidential, you should immediately contact the Institutional Review Board Chair at_____.

17. Voluntary Study Consent	**VOLUNTARY INFORMED CONSENT:** This study was explained to me, and 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 certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual had about this study have been answered, and the study team will be available to address future questions as they arise. I further certify that no research component of this protocol was started until after this consent form was signed. _____ _____ Signature of **Study Representative** **Date** _____ Printed Name of **Study Representative**

18. Future Contact - Additional Consent	**FUTURE CONTACT CONSENT:** We may offer future research studies and opportunity to participate. If you agree, we would like to add your identifiable information to our secured secure list so that we can discuss with you future study participation opportunities. 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 identifiable information. We will do our best to make sure that your personal information remains private. The chance that this information will be given to someone else that is not approved to access the future contact registry is very small. See the " *Who can I talk to if I have more questions?* " section for your rights if this occurs. Storage of Data for Future Contact The information we collect will be kept in a secure location and may be stored indefinitely. If you agree to this, and change your mind later, you can contact us and state that you no longer want to be on the Future Contact List. At that point, you will be removed from the registry, and you will not be contacted thereafter about study participation opportunities. Please read the sentence below and think about your choice. After reading it, check "Yes" or "No". Regardless of what you select, it will not affect your participation in this current study. You can include me on the Future Contact List ____ Yes, I agree ____ No, I do not agree Subject Initials _____ Date_____

APPENDIX C: OSHA/NPPTL Medical Evaluation Form

NATIONAL PERSONAL PROTECTIVE TECHNOLOGY LABORATORY (NPPTL)

OSHA Mandatory Medical Evaluation Requirements

Part A.

1. Today's Date: _____

2. First and Last Name: _____

3. Date of Birth: _____

4. Sex (circle one): Male Female

5. Height: _____ ft. _____ in.

6. Weight: _____ lbs.

7. Job Title/Occupation: _____

8. Phone number where you can be reached if needed by the health care professional who reviews this questionnaire (include the Area Code):_____

9. The best time to phone you at this number: _____

10. Has the study team told you how to contact the health care professional who will review this questionnaire if needed (circle one): Yes / No

11. Check confirmed understanding of the type of respirator you will use below:

_____ Elastomeric Half Mask Respirator or N95 Filtering Facepiece Respirator

12. Have you worn a respirator previously (circle one): Yes/No

If "yes," do your recall which type(s):_____

If “yes” for approximately how many years have you used respirators? _____ years

Part B.

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 (sugar 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: Yes / No

b. Shortness of breath when walking fast on level ground or walking up a hill: Yes / No

c. Shortness of breath when walking at an ordinary pace on level ground: Yes / No

d. Have to stop for breath when walking at your own pace on level ground: Yes / No

e. Shortness of breath when washing or dressing yourself: Yes / No

f. Shortness of breath 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, have you noticed your heart skipping or missing a beat: Yes / No

e. Heartburn or indigestion that is not related to eating: Yes / No

d. Any other symptoms that 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. 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 problems? (If you've never used a respirator, select not applicable (NA) and go to question 9.) Yes / No / NA

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 health care professional who will review this form? Yes / No

Participant Signature: _____

Date: _____

PARTICIPANT STOP HERE

Licensed Healthcare Professional to Complete this Section:

Note to Licensed Healthcare Professional:

In accordance with good clinical practice and as required by the IRB, 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 health care professional is expected to use good clinical judgment in this process.

Evaluation notes (if applicable for abnormal findings):

Licensed Healthcare Professional Printed Name: _____

Signature: _____

Date: _____

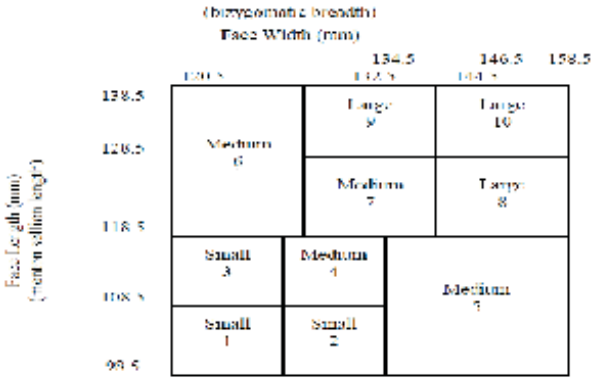
NOTE: If participant selected "yes" in Part B, to any items within questions 3, 4, and/or 8 they are ineligible to continue. If participant selected "yes" in Part B. to any items within questions 2, 5, 6, and/or 7, a licensed Physician must review the participants current and past medical history and provide documentation that they are safe to participate post assessment.

APPENDIX D: Data Collection Form – NIOSH/NPPTL Bivariate Panel[10]

NIOSH/NPPTL Bivariate Panel

Participant Name:_____ **ID:**_____ - _____

Date (mm/dd/yyyy): _____

Start Stop Watch	**Subject Result**
Distance between the zygomatic arches (face width)	mm
Distance from the menton to the sellion (face length)	mm
NIOSH-NPPTL Bivariate Panel (three-size system: small, medium, and large): Small: Cells 1, 2, 3 Medium: Cells 4, 5, 6, 7 Large: Cells 8, 9, 10  	**Cell Category *(1-10)*:** ____ **Size *(circle one)*:** **S M L**
Stop the Stop Watch	
Record Total Evaluation Time in Seconds	**Total Time: ___ Seconds**

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

APPENDIX E: NIOSH Photo Release

General Photo Release

A. I agree to allow the National Institute for Occupational Safety and Health (NIOSH) to use my photograph.
I hereby agree to allow my photographic image to be used (with or without my name, both singly and in conjunction with other persons or objects) by the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

B. NIOSH will use my photograph in a publication that other persons are free to copy.
I understand that this publication will be printed by the United States Government Printing Office without copyright protection and may be distributed free or sold. I also understand that additional printings may be conducted by the United States Government Printing Office in the future. I understand that other persons will be allowed to make copies of these government publications.

C. No one will ever pay me for the use of this photograph.
I understand that for the use of my photographic image in this publication, I will receive no financial compensation or payment of any kind from the United States Government or from any agency of the Government or from any person making a copy of the government publication now or at any time in the future.

Signature_____Date_____

Printed name_____

Address _____

Telephone _____

CDC2.151 - 7/95

APPENDIX F: Taste Threshold Test

TASTE THRESHOLD TEST

Participant Name:_____ ID:_____-_____

Date (mm/dd/yyyy):_____

Screening Taste Threshold Test	Subject Result
Start Stop Watch *(immediately before step 1)*	
Step 1: Confirm participant did not eat or drink in the past 15 minutes **Cannot proceed if they have ate or drank within 15 minutes and must wait 15 minutes and restart test*	____YES **(check yes to confirm)**
Step 2: Instruct participant to don the OSHA approved fit test hood and breathe normally with a slightly open mouth and tongue extension	____YES **(check yes to confirm)**
Step 3: Study personnel completes 10 squeezes of the saccharin threshold check solution into the participant's hood and asks participant if the saccharin (sweet taste) can be tasted. **Note that if the test subject reports tasting the sweet taste at any time during the ten squeezes, screening test is completed and final score is 10.* ***If you checked "YES" stop here and check NA for Steps 4 & 5, and proceed to Final Score. If you checked "NO" proceed to Step 4.***	**Tasted saccharin within 10 squeezes?** **____Yes ____No**
Step 4: Study personnel completes 10 additional squeezes totaling 20 now, of the saccharin threshold check solution into the participants hood, and asks participant if the saccharin (sweet taste) can be tasted. **Note that if the test subject reports tasting the sweet taste at any time during this additional ten squeezes, screening test is completed and final score is 20.* ***If you checked "YES" stop here and check NA for Step 5, and proceed to Final Score. If you checked "NO" proceed to Step 5.***	**Taste saccharin within 20 squeezes?** **___Yes___No___NA**
Step 5: Study personnel completes 10 additional squeezes totaling 30, of the saccharin threshold check solution into the participants hood, and asks participant if the saccharin (sweet taste) can be tasted. **Note that if the test subject reports tasting the sweet taste at any time during this additional ten squeezes, screening test is completed and final score is 30.* ***Now stop the stop watch and proceed to Final Score.***	**Taste saccharin in 30 squeezes:** **___Yes___No___NA**
Stop the Stop Watch and Record Total Time in Seconds	**Total Time:_____seconds**
Final Score: participant will be given a score of 10, 20, 30 or ineligible based on Steps 3-5 results above. *If participant does not taste the sweet taste during any of the steps above they will be considered ineligible and screen failed.*	**Final Score** *(circle one)*: **10, 20, 30, ineligible**

APPENDIX G: Eligibility Checklist

Page 1 of 3

Just-in-time **E**lastomeric **T**raining and **Fi**t-**T**esting **(JET FIT)**

ELIGIBILITY CHECKLIST

Inclusion Criteria ***(all responses must be YES in this section for participant to be considered eligible)***

Ability to understand, the willingness to participate, and the completion of a written informed consent document	☐ **YES** ☐ **NO**
Understands spoken and written English language as required for consent, demonstration comprehension, and evaluation measures	☐ **YES** ☐ **NO**
Age ≥ 18 years old **Age _____**	☐ **YES** ☐ **NO**
OSHA Medical Evaluation Form completed by the participant and reviewed/signed by a licensed medical professional such as a registered nurse, nurse practitioner, physician assistant, or physician (Appendix B of protocol) **Date Completed**: _____ If a subject reports "yes" to any medical condition listed on the OSHA/NPPTL Medical Evaluation Form (Appendix B.) in Part B Questions 2, 5, 6, and/or 7, a Physician must review the subject's current and past medical history and provide documented clearance for them to participate. **If participant answered "yes" to any items in Part B questions 2, 5, 6, and/or 7, did a Physician complete required past and current medical history review assessment and documented clearance for them to participate? Check one:** **No / Yes / NA**	☐ **YES** ☐ **NO**
Participant is employed in a healthcare setting requiring OSHA's respiratory protection program requirements and provides estimated number of years utilizing respirators *(may have zero to unlimited years of experience)* **Unit: _____** **Position Title: _____** **Number of Years Utilizing Respirators: _____**	☐ **YES** ☐ **NO**
NIOSH General Photo Release Form reviewed with participant (Appendix G). Participants may decline participation for photos or videos. If they agree, they must complete the form, if they decline study staff must document and may not release photos or videos of subjects that decline. **Check only one option below:** **Participant agreed and completed Appendix G form: _____** **Participant declined photos or videos participation: _____**	☐ **YES** ☐ **NO**
NIOSH/NPPTL Bivariate Panel facial measurements completed **Size Respirator based on cell category allocation: _____**	☐ **YES** ☐ **NO**
Taste Threshold Test score of 10, 20, or 30 (Appendix G.) **Score: _____**	☐ **YES** ☐ **NO**

Exclusion Criteria ***(all responses must be NO in this section for participant to be considered eligible)***

Participant non-adherence to screening, study, and/or evaluation procedures	☐ **YES** ☐ **NO**
Participant has facial injury, facial hair and/or adornments that may interfere with the facial seal region of the elastomeric respirator	☐ **YES** ☐ **NO**
Known or suspected hypoguesia or ageusia (as previously known by subject or assessed during taste threshold test as "ineligible" final score).	☐ **YES** ☐ **NO**
Reviewed with subject the dates for planned simulated health emergency and subject unavailability	☐ **YES** ☐ **NO**
Chronic or current pulmonary or lung problems reported by subject (reports "yes" to any item in Part B. questions 3 or 4 of OSHA/NPPTL Medical Evaluation Form)	☐ **YES** ☐ **NO**
Prior problems using a respirator as reported in Part B. question 8 of the OSHA/NPPTL Medical Evaluation Form	☐ **YES** ☐ **NO**

Date(s) of Screening Items (must be completed within 60 days of scheduled study interventions)

Screening Activity	**Date Screening Activity Completed** mm/dd /yyyy	**Number of Days Must Be Completed Within**	**Earliest Date Screening Activity Times Out** mm/dd/yyyy
Written Informed Consent		60	
OSHA/NPPTL Medical Evaluation Form		60	
Optional NIOSH General Photo Release		60	
Eligibility Checklist		60	
NIOSH/NPPTL Bivariate Panel Measurement DCF		60	

Page 3 of 3

Consent Process Note:

Date of Scheduled Feasibility Assessment: _____
(MUST BE PRIOR TO ANY DATE LISTED IN THE "EARLIEST DATE SCREENING TEST TIMES OUT" ABOVE)

If eligible based on above checklist, Registration Number Assigned to Participant:
_____ _____ - _____ _____ _____
(2 digit site #) (3 digit number ID #)

Cohort patient randomized into (N95 FFR or EHMR group)? _____

Research Personnel completing this form (Printed Name): _____

Research Personnel completing this form (Signature): _____

Date Completed: _____
mm/dd/yyyy

APPENDIX H: Infographic

Just-in-time Elastomeric Training and Fit-Testing (JET FIT)

Pandemic preparedness is a vital component of healthcare worker safety. The historical morbidity and mortality rates caused by pandemics point to a need for awareness in the present day. For example 20th century strains of influenza alone are estimated to have caused 100 million deaths in 1918, 2 million deaths in 1957, 1 million deaths in 1968, and 284 thousand deaths in 2009.

Many healthcare workers are familiar with face masks, also known as surgical masks. However face masks are not respirators. The National Institute for Occupational Safety and Health (NIOSH) is a division of the Centers for Disease Control and Prevention (CDC), and the federal agency responsible for testing and certifying respirators . Unlike NIOSH - approved respirators, face masks are NOT designed to prevent inhalation of most small particulate airborne transmissible pathogens. Disposable N95 filtering facepiece respirators are the most common type of respirator used in healthcare. However, in the event of a pandemic or public health emergency, many healthcare institutions may not have enough disposable N95 respirators to meet the demand. In the event of a supply shortage of disposable N95 respirators, a reusable elastomeric half mask respirator may serve as a backup method for healthcare worker protection.

PERSONAL PROTECTIVE EQUIPMENT	 Face Mask	 N95 Filtering Facepiece Respirator (FFR)	 Elastomeric Half Mask Respirator (EHMR)
Testing and Approval	Cleared by the U.S. Food and Drug Administration (**FDA**) *ASTM F2100-11.*	Evaluated, tested, and approved by **NIOSH** as per the requirements in *42 CFR Part 84.*	Evaluated, tested, and approved by **NIOSH** as per the requirements in *42 CFR Part 84.*
Intended Use and Purpose	A face mask is intended to aid in blocking large-particle droplets, splashes, sprays or splatter that may contain pathogens. Face masks may also help reduce exposure of your saliva and respiratory secretions to others.	An N95 respirator is a disposable respiratory protection device. The 'N95' designation means that the respirator blocks at least 95% of very small (0.3 micron) particulates, such as infectious airborne pathogens.	An EHMR is a reusable respiratory device made of synthetic or rubber material permitting repeated disinfection and reuse. EHMRs are assigned the same protection classification (APF) as N95s. EHMRs reduce theusersexposure tovapors, gases, and/or particulates such as airborne infectious pathogens.
Face Seal Fit	Loose-fitting	Tight-fitting	Tight-fitting
Fit Testing Requirement	No	Yes	Yes
Designed for Reuse	No	No[1]	Yes
User Seal Check	No	Yes	Yes
Assigned Protection Factor	No assigned protection factor	10 - workplace level of respiratory protection that a respirator is expected to provide to employees when the employer implements a continuing, effective respiratory protection program, per OSHA 1910.134.	10 - workplace level of respiratory protection that a respirator is expected to provide to employees when the employer implements a continuing, effective respiratory protection program, per OSHA 1910.134.
Use Limitations	A face mask does not filter or block small particles in the air that may be transmitted by coughs, sneezes, and/or certain medical procedures. Face masks also do not provide complete protection from germs and contaminants due to the loose fit. They are disposable and must be discarded after each patient interaction - potential for supply shortage during a public health emergency	Disposable and must be discarded after each patient interaction. Potential for supply shortage during a public health emergency	Reusable and must be cleaned/disinfected and stored between each patient interaction.

[1] Limited reuse may be permissible during a public health emergency. Read more at: https://www.cdc.gov/niosh/topics/hcwcontrols/recommendedguidanceextuse.html

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APPENDIX I: EHMR Cohort Educational Handout[22, 26, 27]

EHMR COHORT **EDUCATIONAL HANDOUT**	
Inspection	
1. Inspect face piece for damage	
2. Examine head straps for twists, breaks, and/or loss of elasticity	
3. Remove exhalation valve cover and inspect exhalation valve	
4. Examine filters, covers, and attach to the mask	
Donning *(putting on)*	
1. Position face piece under chin and over bridge of nose	
2. Position head harness above the ears and across crown of head	
3. Hook neck strap below ears and around neck	
4. Adjust straps to correct fit	
Positive Pressure User Seal Check (exhale to check seal)	
1. Cover exhalation valve opening with thumb, fingers, or hand and **exhale** for 10 seconds	
2. Determine if there are leaks	
3. If leaks are noted, readjust straps and device to properly seal	
4. Check again if needed (repeat all tasks as needed until no leaks)	
Negative Pressure User Seal Check *(inhale to check seal)*	
1. Remove filter covers, cover both filter intakes with both hands, and **inhale** for 10 seconds	
2. Determine if you feel the facepiece slightly collapse during inhalation	
3. If slight collapse is not noted, readjust straps and device to properly seal	
4. Check again if needed (repeat all tasks as needed until slight facepiece collapse noted)	
Doffing *(taking off)*	
1. Perform hand hygiene and don gloves	
2. Unhook the neck strap	
3. Pull the straps overhead, without touching respirator	
4. Place respirator on appropriate surface such as a chux pad to avoid contaminating surface	
Between Patients/Use Cleaning & Disinfection	
1. Prepare **clean** surface such as a chux pad to place device on after task three (disinfecting outside of device)	
2. Next complete hand hygiene & don gloves	
3. Holding the inside of respirator, wipe **outside** of facepiece and head straps with cleaning & disinfectant wipes	
4. Set device face down on the clean chux pad, complete hand hygiene, and don new gloves	
5. Finally, wipe the **inside** of the respirator with a cleaning & disinfectant wipe	
6. Lastly, discard gloves and perform hand hygiene	

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APPENDIX J: N95 FFR Cohort Educational Handout

N95 FFR COHORT **EDUCATIONAL HANDOUT**	
Donning *(putting on)*	
1. Position facepiece under chin and over bridge of nose	
2. Position head straps above the ears and across crown of head	
3. Adjust straps to correct fit	
Positive Pressure User Seal Check *(exhale to check seal)*	
1. Cover entire facepiece with both hands and **exhale** for 10 seconds	
2. Determine if there are leaks around the outside of the facepiece	
3. If leaks still noted, readjust straps and device to properly seal	
4. Check again as needed (repeat all tasks until no leaks)	
Negative Pressure User Seal Check *(inhale to check seal)*	
1. Cover entire facepiece with both hands and **inhale** for 10 seconds	
2. Determine if you feel the facepiece slightly collapse during inhalation	
3. If slight collapse is not noted, readjust straps and device to properly seal	
4. Check again as needed (repeat all tasks until slight facepiece collapse noted)	
Doffing *(taking off)*	
1. Perform hand hygiene and don gloves	
2. Pull the straps overhead, without touching respirator	
3. Dispose of respirator	
4. Remove gloves and complete hand hygiene	

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APPENDIX K: Data Collection Form – Participant USCs and QLFT[16]

Page 1 of 3: Positive Pressure USC

POSITIVE PRESSURE USER SEAL CHECK

Participant Name:_____ **ID:**_____-_____ **Size Respirator:** _____

Date (mm/dd/yyyy):_____ **N95 or Elastomeric:**_____

Start Stop Watch (immediately before step 1)	Start Stop Watch
Positive Pressure Seal Check(s)	**Subject Response** *(participant states yes or no)*
Instruction 1. Instruct participant: Ensure the seal around your nose and mouth is without leaks during the positive pressure seal check(s) to follow. Now place your thumb, fingers, or hand over the opening of the exhalation valve cover. You may need to rotate it upwards to make it easier. Finally exhale slowly for a count of 5-10 seconds and see if you feel any leaks around your nose or mouth seals. If you feel leaks that is OK, and please report it so we can assess why or provide a more accurate size of respirator for you if needed after the qualitative fit test.	
USC Attempt 1: Any leaks reported by participant? *If answer is "No" mark NA for USC 2 & 3 and finish test/stop the stop watch. If answer is "Yes" go to Instruction 2 and continue with USC attempt 2.*	**Leaks?** Yes_____ No _____
Instruction 2. Instruct participant: Place your thumb, fingers, or hand over the opening of the exhalation valve cover. You may need to rotate it upwards to make it easier. Finally exhale slowly for a count of 5-10 seconds and see if you feel any leaks around your nose or mouth seals. If you feel leaks that is OK, and please report it so we can assess why or provide a more accurate size of respirator for you if needed after the qualitative fit test.	
USC Attempt 2: Any leaks reported by participant? *If answer is "No" mark NA for USC 3 and finish test/stop the stop watch. If answer is "Yes" go to Instruction 3 and continue with USC attempt 3.*	**Leaks?** Yes_____ No_____ NA _____
Instruction 3. Instruct participant: Place your thumb, fingers, or hand over the opening of the exhalation valve cover. Finally exhale slowly for a count of 5-10 seconds and see if you feel any leaks around your nose or mouth seals. If you feel leaks that is OK and please report it so we can assess why or provide a more accurate size of respirator for you if needed after the qualitative fit test.	
USC Attempt 3: Any leaks reported by participant? *After this attempt no matter the response, move to Negative Pressure User Seal Check test and DCF*	**Leaks?** Yes_____ No_____ NA _____
Start Stop Watch and Record Total Time in Seconds	**Total Time:**_____**seconds**
Did Participant Subjectively Pass the Positive Pressure Seal Check? *Record "Pass" if participant subjectively felt no leaks during any one of the three attempts. Select "fail" if the participant felt leaks during all 3 attempts.*	**(Circle one): Pass Fail**
How Many USC Attempts Required?	**(Circle one): 1 2 3**

Page 2 of 3: Negative Pressure USC

NEGATIVE PRESSURE USER SEAL CHECK	
Participant Name:_____ ID:_____-_____	Size Respirator: _____
Date (mm/dd/yyyy):_____	N95 or Elastomeric: _____
Start Stop Watch (immediately before step 1)	**Start Stop Watch**
Negative Pressure Seal Check(s)	**Subject Response** *(participant states yes or no)*
Instruction 1. Instruct participant: ensure the device is on properly with best seal during the negative pressure seal check(s) to follow. Now remove the filter covers from the filters. Next, cover the filter intakes on the respirator with your palms. Finally inhale slowly for a count of 5-10 seconds and see if you feel the facepiece slightly collapse when you inhale. If you do not feel slight facepiece collapse that is OK, and please report this, so we can assess why or provide a more accurate size of respirator for you if needed after the qualitative fit test.	
USC Attempt 1: slight collapse reported by participant? *If answer is "No" mark NA for USC 2 & 3 and finish test/stop the stop watch. If answer is "Yes" go to Instruction 2 and continue with USC attempt 2.*	**Slight collapse?** **Yes___No_____**
Instruction 2. Instruct participant: cover the filter intakes on the respirator with your palms. Inhale slowly for a count of 5-10 seconds until mask slightly collapses. If you do not notice slight facepiece collapse that is OK. Please report what you notice so we can assess and/or provide a more accurate size of respirator for you if needed after the qualitative fit test.	
USC Attempt 2: slight collapse reported by participant? *If answer is "No" mark NA for USC 3 and finish test/stop the stop watch. If answer is "Yes" go to Instruction 3 and continue with USC attempt 3.*	**Slight collapse?** **Yes_____No_____NA_____**
Instruction 3. Instruct participant: cover the filter intakes on the respirator with your palms. Inhale slowly for a count of 5-10 seconds until you notice mask collapse slightly. If you do not notice slight facepiece collapse that is OK. Please report what you notice so we can assess and/or provide a more accurate size of respirator for you if needed after the qualitative fit test.	
USC Attempt 3: slight collapse reported by participant? *This is the last attempt so if they still do not feel slight collapse, finish test and move to Qualitative Fit Testing to confirm fit.*	**Slight collapse?** **Yes____No_____NA____**
Start Stop Watch and Record Total Time in Seconds	**Total Time:_____seconds**
Did Participant Subjectively Pass the Negative Pressure Seal Check? *Record Pass if participant subjectively felt slight facepiece collapse during any one of the three attempts. Select fail if the participant did not note slight collapse during any of the three attempts.*	**(Circle one): Pass Fail**
How Many USC Attempts Required?	**(Circle one): 1 2 3**

Page 3 of 3: Sodium Saccharin QLFT

SODIUM SACCHARIN QUALITATIVE FIT TEST	
Participant Name:_____ **ID:**_____ - _____	**Size Respirator:**_____
Date (mm/dd/yyyy):____ /____ /_____	**N95 or Elastomeric?** _____
Saccharin Solution Aerosol Fit Test *(WITH Respirator)*	**Subject Result**
Start Stop Watch *(immediately before step 1)*	
Step 1: Instruct participant to don the OSHA approved fit test hood over their assigned respirator and breathe normally with slight opened mouth and tongue extension	
Step 2: For this step only, the number of squeezes from the participants final score during their screening Taste Threshold Test will be sprayed into the fit test hood (either 10, 20 or 30 squeezes based on replicating the number of squeezes required to elicit a taste response as noted during the taste threshold test). *If the participant tastes the saccharin, the test is stopped here, and you do not proceed to Step 3. Patient must remove equipment and readjust fit and start this test over if*	**Tasted Saccharin: Yes ___ No ___**
Step 3: Test Exercises (participant completes each of 7 test exercises for approximately one minute). Every 30 seconds study personnel will spray the aerosol concentration using **half the number** of squeezes from the final Taste Threshold Test score the subject received in screening (which will now equal 5, 10, or 15 after division). *If the participant tastes the saccharin in any of the test exercises below, the test is stopped, and participant does not proceed to next exercise. Participant must instead remove equipment and readjust fit and start test over from step 1 (provide additional DCF form for data capture and save original failed fit test form as well)*	
a. Participant completes normal breathing in a standing position	**Tasted: Yes ___ No ___**
b. Participant completes deep breathing in normal standing position	**Tasted: Yes ___ No ___**
c. Participant completes turning head side to side, and inhales at each side	**Tasted: Yes ___ No ___**
d. Participant completes moving head up and down, inhaling every time head is up	**Tasted: Yes ___ No ___**
e. Participant completes reading the Rainbow Passage loud & slowly	**Tasted: Yes ___ No ___**
f. Participant completes bending over (at the waist within participant limitations)	**Tasted: Yes ___ No ___**
g. Participant completes normal breathing in a standing position	**Tasted: Yes ___ No ___**
Stop the Stop Watch and Record Total Time in Seconds	**Total Time: _____seconds**
Step 4: Did Participant Pass or Fail? *Participant passed if they did NOT taste the saccharin in ANY of exercises a-g above. If participant DID taste the saccharin in any exercise a-g, they are a fail, and instruct participant to readjust device and start from the beginning (provide additional form)*	**PASS ___ FAIL___**

Appendix L: Rainbow Passage[23]

Rainbow Passage:

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 reach, his friends' say he is looking for the pot of gold at the end of the rainbow

APPENDIX M: Data Collection Form – Competency Evaluation[22, 26, 27]

COMPETENCY EVALUATION Evaluation Scoring Metrics: No Assist = 3 Verbal Assist = 2 Physical Assist = 1 **Participant Name:** **ID: __ __ - __ __ __ Date: mm/dd/yyyy _____**	Inform participant of each competency title (in order). Do not provide task information. If participant misses/incorrectly completes a task, first provide verbal assist. If participant is still unable, next physically assist. Scores will reflect this process. **Calculate totals after attempt complete to avoid adding time* ***Note: 5 of the tasks are labeled "if needed". If it isn't needed by the participant, ask them to state what they would do if it was. This is not considered verbal assist unless they are unsure of what to do.*		
6 Competencies and 26 Tasks	**1st Attempt**	**2nd Attempt**	**3rd Attempt**
Start Stop Watch (immediately before attempt)	**Start Stop Watch**	**Start Stop Watch**	**Start Stop Watch**
Competency 1: Inspection (4 tasks)	**Score**	**Score**	**Score**
Face piece			
Head straps			
Exhalation valve			
Filters			
Score: Inspection (4-12 points)	**Total:*	**Total:*	**Total:*
Competency 2: Donning (4 tasks)	**Score**	**Score**	**Score**
Face piece			
Head harness			
Neck strap			
Adjust straps **(if needed)****			
Score: Donning (4-12 points)	**Total:*	**Total:*	**Total:*
Competency 3: Positive Pressure USC (4 tasks)	**Score**	**Score**	**Score**
Cover exhalation valve and exhale 5-10 secs			
Check for Leaks			
Readjust **(if needed)****			
Repeat **(if needed)****			
Score: Positive Pressure USC (4-12 points)	**Total:*	**Total:*	**Total:*
Competency 4: Negative Pressure USC (4 tasks)	**Score**	**Score**	**Score**
Palms over filter intakes and inhale 5-10 secs			
Check for slight facepiece collapse			
Readjust **(if needed)****			
Repeat **(if needed)****			
Score: Negative Pressure USC (4-12 points)	**Total:*	**Total:*	**Total:*
Competency 5: Doffing (4 tasks)	**Score**	**Score**	**Score**
Hand hygiene and gloves			
Unhook neck strap			
Remove without touching respirator			
Place on chux pad			
Score: Doffing (4-12 points)	**Total:*	**Total:*	**Total:*
Competency 6: Clean/Disinfect (4 tasks)	**Score**	**Score**	**Score**
Prepare Chux pad			
Hand hygiene and gloves			
Hold inside and wipe **outside**			
Place device on chux and hand hygiene/new gloves			
Wipe **inside** (with new wipe)			
Hand hygiene			
Score: Clean/ Disinfect (6-18 points)	**Total:*	**Total:*	**Total:*
Stop the Stop Watch & Record Time (per attempt)	_____ **seconds**	_____ **seconds**	_____ **seconds**
Total Score Per Attempt: 26-78 Possible Points	**Attempt Total:*	**Attempt Total:*	**Attempt Total:*

REFERENCES

1. Osterholm MT. Preparing for the Next Pandemic. *New England Journal of Medicine*. 2005;352(18):1839-1842. doi:10.1056/nejmp058068.. 2005;352(18):1839-1842. doi:10.1056/nejmp058068.

2. Hospital Respiratory Protection Program Toolkit. Occupational Safety and Health Administration (OSHA). https://www.osha.gov/Publications/OSHA3767.pdf Published May 2015. Accessed June 6, 2018.

3. Middle East Respiratory Syndrome (MERS). Centers for Disease Control and Prevention (CDC). https://www.cdc.gov/coronavirus/mers/infection-prevention-control.html. Published September 14, 2017. Accessed June 6, 2018.

4. Respiratory Infection Control: Respirators Versus Surgical Masks. Occupational Safety and Health Administration (OSHA). https://www.osha.gov/Publications/respirators-vs-surgicalmasks-factsheet.html. Published 2009. Accessed June 13, 2018.

5. Wizner K, Stradtman L, Novak D, Shaffer R. Prevalence of Respiratory Protective Devices in U.S. Health Care Facilities. *Workplace Health & Safety*. 2016;64(8):359-368. doi:10.1177/2165079916657108

6. Patel A, D'Alessandro MM, Ireland KJ, et al. 2017. Personal protective equipment supply chain: Lessons learned from recent public health emergency responses. *Health Secur.* 2017;15(3):244-252

7. Institute of Medicine. The Domestic and International Impacts of the 2009-H1N1 Influenza A Pandemic: Global Challenges, Global Solutions: Workshop Summary. National Academies Press: OpenBook. https://www.nap.edu/read/12799/chapter/1. Published 2010. Accessed August 21, 2018.

8. Centers for Disease Control and Prevention. Interim Recommendations for Facemask and Respirator Use to Reduce 2009 Influenza A (H1N1) Virus Transmission. https://dfw.feb.gov/wpcontent/uploads/2017/04/CDCRecommendationsforFacemasksRespirator.pdf. Published 2009. Accessed August 21, 2018

9. Occupational Safety and Health Administration (OSHA). Protect Yourself: Pandemic Flu Respiratory Protection. https://www.osha.gov/Publications/protect-yourself-pandemic-respiratory.html. Published 2009. Accessed August 21, 2018.

10. Liverman CT, Harris TA, Bonnie Rogers ME, Shine KI. Respiratory Protection for Healthcare Workers in the Workplace against Novel H1N1 Influenza A: A Letter Report. Washington, DC: Institute of Medicine. https://www.ncbi.nlm.nih.gov/books/NBK219940/. Published 2009. Accessed August 21, 2018

11. Baracco G, Eisert S, Eagan A, Radonovich L. Comparative Cost of Stockpiling Various Types of Respiratory Protective Devices to Protect the Health Care Workforce During an Influenza

Pandemic. *Disaster Medicine and Public Health Preparedness*. 2015;9(03):313-318. doi:10.1017/dmp.2015.12.

12. Ciconte R, Danyluck, Q. *Assessment and Determination of Practical Considerations for Wide-Scale Utilization of Elastomeric Half-Facepiece Respirators During a Pandemic or Outbreak Situation.* WorkSafeBC. Published May 9, 2013. Accessed May 1, 2018.

13. Radonovich LJ, Magalian PD, Hollingsworth MK, Baracco G. Stockpiling Supplies for the Next Influenza Pandemic. *Emerging Infectious Diseases*. 2009;15(6). doi:10.3201/eid1506.081196

14. Carias C, Rainisch G, Shankar M, et al. Potential Demand for Respirators and Surgical Masks During a Hypothetical Influenza Pandemic in the United States. *Clinical Infectious Diseases*. 2015;60 (suppl 1). doi:10.1093/cid/civ141.

15. Lippi D, D'Elios JP, Caini, S. Smallpox in the medici family Florence, 1519-1737: a historical cohort study. *Clin Microbio and Infect.* https://doi.org/10.1016/j.cmi.2015.01.021. Published February 10, 2015. Accessed July 23, 2018.

16. Plague. Centers for Disease Control and Prevention. https://www.cdc.gov/plague/history/index.html. Published September 14, 2015. Accessed May 13, 2018.

17. Influenza Pandemics. History of Vaccines. https://www.historyofvaccines.org/content/articles/influenza-pandemics. Accessed May 12, 2018.

18. Assessment of Respiratory Personal Protective Equipment in U.S. Acute Care Hospitals-2012. Association of State and Territorial Health Officials (ASTHO). http://astho.org/Preparedness/Respiratory-PPE-Assessment-Report/. Published November 19, 2014. Accessed May 1, 2018

19. North RU8500 Series Half Masks. North by Honeywell. https://www.partnerconnect.honeywell.com/~/media/EssPortal/Product/Files/Brochures/Personal%20Protective%20Equipment/Respiratory%20Protection/RU8500_Product%20Brief.ashx. Accessed October 4, 2018.

20. Zhuang Z, Bradtmiller B, Shaffer RE. New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force. *Journ of Occup and Environ Hygiene*. 2007;4(9):647-659. doi:10.1080/15459620701497538.

21. Respirator Fit Testing. Occupational Safety and Health Administration (OSHA). https://www.osha.gov/video/respiratory_protection/fittesting_transcript.html. Published April 23, 1998. Accessed May 15, 2018

22. Coffey CC, Lawrence RB, Zhuang Z, Campbell DL. Errors Associated with Three Methods of Assessing Respirator Fit. *Journ of Occup and Environ Hygiene*. 2006. 3(1):44-52.

23. Fit Testing Procedures (Mandatory). Occupational Safety and Health Administration (OSHA). https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=9780&p_table=STANDARDS. Published April 23, 1998. Updated August 4, 2004. Accessed June 10, 2018.

24. Respiratory Protection Infographics. Centers for Disease Control and Prevention.https://www.cdc.gov/niosh/npptl/N95DayInfoGraphics.html. Published January 23, 2018. Accessed June 6, 2018

25. Inspecting, Donning, and Doffing Half-Face Air-Purifying Respirators. Occupational Safety and Health Administration (OSHA). https://www.osha.gov/dte/outreach/disaster/performance_test_worker.html. Accessed August 15, 2018.

26. Respirator Cleaning Procedures (Mandatory). Occupational Safety and Health Administration. Appendix B-2 to § 1910.134: https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9782. Published 1998. Accessed June 22, 2018.

27. Voigt A, Berney KT, Kanne J. Adult education perspectives in primary health care training; working paper – 7654. Centers for Disease Control and Prevention. Published 1995. Accessed June 6, 2018.

28. Material Safety Data Sheet Saccharin Solutions. TSI, Inc. http://www.tsi.com/uploadedFiles/Product_Information/Literature/MSDS/6003029A-SaccharinSolutions.pdf&p=DevEx.LB.1,5492.1. Published 2009. Accessed June 6, 2018.

29. Common Terminology Criteria for Adverse Events (CTCAE) 5.0. US Department of Health and Human Services. https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf. Published November 27, 2017. Accessed August 5, 2018.

30. MEDWATCH Form FDA 3500A. US Department of Health and Human Services. https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048334.pdf. Updated February 21, 2018. Accessed August 5, 2018.

31. Health Insurance Portability and Accountability Act (HIPPA). US Department of Health and Human Services. https://aspe.hhs.gov/report/health-insurance-portability-and-accountability-act-1996. Published August 21, 1996. Accessed October 5, 2018.

32. Research Ethics and Compliance Training. CITI Program. https://about.citiprogram.org/en/homepage/. Accessed October 5, 2018.

33. Lietz J, Westermann C, Nienhaus A, Schablon A. The occupational risk of influenza A (H1N1) infection among healthcare personnel during the 2009 pandemic: A systematic review and meta-analysis of observational studies. PLoS One. 2016 Aug 31;11(8):e0162061

34. Reusable Elastomeric Respirators in Health Care: Considerations for Routine and Surge Use. National Academies of Sciences, Engineering, & Medicine. Washington, DC: The National Academies Press. Published December 06, 2018. Accessed December 27, 2018.

35. Hines, S. Brown, C. Oliver, M. Gucer, P. Frisch, M. Hogan, R. Roth, T. Chang J. McDiarmid, M. User acceptance of reusable respirators in health care. *Amer Journ of Infect Cont.* Published January 10, 2019. Accessed January 14, 2019.