Study Protocol with Statistical Analysis Plan
SAFE Workplace Intervention for People With IDD

Official Title: Efficacy of the SAFE Program to Promote Preventative Behaviors of Airborne Diseases (COVID-19) and Improve Well-Being for People with Intellectual and Developmental Disabilities in the Workplace

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1) Abstract of the study

The purpose of this study is to examine the feasibility and efficacy of a systematic training approach targeting behaviors to increase safety and prevention of airborne diseases such as COVID-19 in the workplace for individuals with Intellectual and Developmental Disabilities (IDD). *This project is designed to determine proof of concept and proof of product for a peer support intervention, the **SAFE** program, to increase knowledge and safe workplace practices.* There is an identified immediate need for individuals with IDD to receive training in an accessible format. The ***SAFE program*** has been developed in an accessible format for those with IDD. It focuses on education regarding actionable behaviors that reduce the risk of acquiring and transmitting COVID-19 and other airborne diseases. The study will implement a peer-mediated and occupational therapy lead program, ***SAFE***, to identify and address potential implementation issues and further refine the program curriculum. Additionally, the efficacy of the program on perceived safety and well-being, observable preventative behaviors and self-advocacy will be examined.

2) Protocol Title

Efficacy of the *SAFE* Program to Promote Preventative Behaviors of Airborne Diseases (COVID-19) and Improve Well-Being for People with Intellectual and Developmental Disabilities in the Workplace

3) Investigator

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4) Sponsor:

PA Department of Health

5) Objectives

It is hypothesized that the ***SAFE** program* will have a positive effect on perceived well-being and knowledge of the actionable behaviors for the prevention of COVID-19 and other airborne diseases. The program will have a larger effect on outcomes when provided using peer support compared to staff training. Individuals with IDD will demonstrate increased knowledge and safe behaviors after completing the ***SAFE** program*. Peer-interventionists will report perceived benefits and limitations of participating in training and providing peer-mediated travel training interventions to identify potential outcomes for future research.

The research intends to answer these questions:

1. Does participation in the ***SAFE** program* increase perceived safety and well-being in the workplace for people with ASD and/or IDD?

2. Does participation in the ***SAFE*** *program* increase knowledge of actionable behaviors to prevent transmission of airborne diseases (i.e. COVID-19) in the workplace for people with IDD?
3. When implemented through *peer support*, does the ***SAFE*** *program* have a larger increase in perceived well-being and knowledge of actionable behaviors to prevent transmission of airborne diseases (i.e. COVID-19) than when implemented through staff training and supports?

The research further intends to:

- Develop health communication messages related to safe interactions and the prevention of COVID-19 and other infectious airborne diseases for autistic adults
- Refine and expand the SAFE program based on stakeholder priorities and input Evaluate the SAFE program training with Autistic adults

Phase 2

1: Identify stakeholder priorities for additional health communication content related to staying safe from infectious airborne diseases.

2: Develop new content based on the identified needs and incorporate it into the SAFE program for individuals with IDD.

3: Pilot the new curriculum with direct care providers and refine materials based on feedback to ensure effectiveness.

6) Rationale and Significance

Employment is emerging as a significant socioeconomic factor that influences health outcomes. As a social determinant of health, employment is closely linked to income and subsequent access to goods, services, and environments that promote health. The COVID-19 pandemic sweeping the nation and protective stay-home orders have had a significant impact on the economy, impacting the employment status of millions. Many of those fortunate enough to retain employment have shifted to remote work from home, while others continue to work onsite providing “essential” services. Essential employment includes but is not limited to work in healthcare facilities, the food service industry, commercial retail (including grocery, pharmacy, and convenience stores), and maintenance and sanitation services. All essential workers are facing new policies and procedures intended to promote health and safety. Our ongoing work on supportive community-based employment for people with intellectual and developmental disabilities (IDD) highlights the unique needs of this population as we navigate unprecedented workplace challenges introduced by COVID-19, especially as many people with IDD find themselves employed in some of these essential positions. People with IDD are a vulnerable population facing increased health risks and disparities due to their disabilities.

People with ASD and/or IDD are also believed to be at increased risk for COVID-19 and other airborne diseases due to unavoidable close contact with direct care providers, difficulty communicating that they are experiencing symptoms, and difficulty understanding and following Centers for Disease Control and Prevention (CDC) recommendations for protective practices like social distancing, handwashing, and use of personal protective equipment (PPE). These recommendations, especially for workplace precautions, are not in formats that are readily accessible to people with IDD. Training and interventions are rapidly emerging to meet the needs of essential workers with IDD and their employers. There is a need to create accessibly trainings for individuals with IDD.

Peer-mediated interventions are identified as effective and are provided in natural social contexts (Zhang & Wheeler, 2011). Peers act as intervention agents to model or reinforce a particular skill and facilitate social interactions. This is an essential component in learning the skills needed for implementation of new safety procedures due to Covid-19. Much of the research on peer-mediated interventions has focused on developing social and academic skills (Chan et al., 2009; Wong et al., 2015)**.** The majority of research targets the pediatric population. Although social skills and supports are important for safe workplace habits, there are additional skills that the peer-mediator needs to model and target for proper workplace precautions. This project expands the use of peer-mediated interventions to adult populations and specific skills necessary for consistently participating in proper workplace procedures.

7) Resources and Settings

Research staff for this study will receive extensive training, including completion of the Temple University CITI social and behavioral health human subjects training program and the research lab's interviewer training. The lab's interviewer training includes: regulations and assessing risk, the informed consent process, upholding privacy and confidentiality, unanticipated problems and how to report them, cultural competency and project management (procedures for recruitment, consent, data collection, retention, data entry, data storage and debriefing study participants). Weekly staff meetings, as well as individual and group supervision, are utilized to ensure procedures are followed and issues are addressed appropriately.

Participants will complete the ***SAFE program*** course, focus groups and qualitative interview in a place that is private, quiet and convenient for the participant. This could include remote meetings using programs like Zoom or FaceTime, or in person sites such as private conference room or office at Temple University, the person's home, or a community setting such as the recruitment site. For example, if potential participants are identified or recruited through a specific organization or agency where private rooms are available, researchers can use these sites to discuss the study and also to conduct the consent and interview process. Individuals will also be able to call research staff at our research offices to discuss the study and to set up a time to meet in person at one of the

identified locations. All data collection activities will comply with the recommended social distancing requirements currently in place at the time.

Quantitative study measures will be implemented through the use of on-line REDCAP survey software and is available to interested individuals through an on-line link. Participants can complete the survey in any environment in which they have access to the Internet (i.e., public library; home; work). If the interested participant does not have a device to access the Internet and the survey or communicate with the researcher to indicate their responses, the primary researcher will meet them a place identified as convenient for the participant with the necessary equipment to complete the survey (i.e., laptop computer with Internet connectivity).

8) Prior Approvals

N/A

9) Study Design

Recruitment Methods

Recruitment will occur through local community partners, which include Philadelphia Independence Network, Community Integrated Services, Carousel Connection GRASP, ASERT, Philadelphia the Institute of Disability at Temple University, and the Philadelphia Area Charter School. We have an established relationship with all of these organizations. An introductory recruitment e-mail (see materials submitted with IRB protocol) will be sent to potential participants through the organization, which includes a link to the survey questions on REDCAP.

Phase 1

We intend to recruit 20 employed individuals with ASD and 20 employed individuals with IDD to complete in depth qualitative interviews, 100 employed individuals with ASD and 100 employed with IDD to complete **quantitative** perceptual mapping surveys. We will recruit 40 individuals 10 ASD 10 IDD, 10 vocational staff, and 10 from the project Advisory Board to conduct vector modeling analysis with and complete sample messaging. We aim to recruit at least 120 participants with ASD and 120 participants with IDD for the pilot SAFE program, which we anticipate will yield a total of 96 participants in the final sample when accounting for 20% attrition rates commonly identified in prior intervention studies of people with ASD and/or IDD.

Phase 2

We will recruit 60 individuals—30 with IDD and 30 vocational staff—to participate in focus groups aimed at identifying stakeholder priorities for additional health communication related to staying safe from infectious airborne diseases and ensuring workplace safety. Focus groups will ideally include 5-10 people, but that they may be as small as 1, thus turning it into an interview instead.

The project team will recruit 5-10 staff members from community partners listed above to participate in a pilot training session. Following the training, staff

member participants will provide feedback to inform any necessary revisions to the training materials or processes, ensuring the content is effective and practical for future use. The additional lessons will be developed based on feedback from the focus group. Once completed, the materials (including recruitment materials) will be submitted as an amendment to the IRB and will not be used until approval is granted. After IRB approval, the materials will be provided to the staff and used in the training.

This will require between 2-3 one to two hour sessions.

a) Inclusion and Exclusion Criteria

We anticipate recruiting young adults 18years old and over with ASD or IDD who are currently employed or actively looking for employment to participate in the study. Participants will have a diagnosis of ASD or IDD. Participants will self-report their ASD or IDD diagnosis. Additionally, the community agencies have access to documentation that identifies their consumer's diagnoses. Based on this, we will ask them to only provide information to those individuals who have a diagnosis of IDD. Potentially eligible participants with documented intellectual and developmental disabilities will be recruited through large vocational rehabilitation organizations (Community Integration Services [CIS] and Project Search) that together serve over 1200 adults with IDD. Participants must be working a minimum of 10 hours a week outside the home and/or receive vocational rehabilitation services. We aim to recruit at least 120 participants, which we anticipate will yield a total of 96 participants in the final sample when accounting for 20% attrition rates commonly identified in prior intervention studies of people with ASD/IDD.

The participants must have communication skills or a system to engage in the learning process, which will be determined during the initial meeting and assessment. All participants must speak English. For those participants who are nonverbal, visual and communication systems can be used, although participants must be able to cognitively answer questions on their own and provide consent/assent. These devices can also be used during the initial interview process to provide yes or no answers to formal interview questions. Participants with ASD or IDD can have assistance completing the questionnaire if they need help in reading and understanding the questions or checking the appropriate answer box. For any participants that are not able to participate in the SAFE program methodology or qualitative interviews, a support staff, parents or caregiver proxy can be used.

Phase 2

For phase 2, we will recruit young adults aged 18 and over with ASD or IDD who are currently employed or seeking employment, as well as staff who support young adults with ASD or IDD in employment settings. Participants must either self-report their diagnosis. Additionally, community agencies have access to documentation that identifies their consumer's diagnoses and, based on this, research personnel will ask them to only provide information to those individuals who have a diagnosis of IDDRecruitment will occur through large vocational rehabilitation organizations that serve over 1,200 adults with IDD. Eligible participants must work at least 10 hours per week

and/or receive vocational rehabilitation services. We aim to recruit 60 participants. All participants must have communication skills or systems to engage in the focus groups and be able to provide consent.

Project team members will include 5-10 staff members from a selected service provider organization to participate in a pilot training session. Staff will directly support young adults with IDD with their employment goals.

b) Study Timelines

Phase 1
We intend to complete the ***SAFE program*** and interviews over the course of three years starting as soon as IRB approval is obtained. We intend to complete the qualitative interviews and quantitative surveys in the first year. We intend to implement the SAFE program until approximately 120 participants have completed the program and data collection during year two and three. Recruitment will occur throughout the course of the study until the targeted number of participants is obtained. We will use block randomization, which will allow us to have continuous enrollment in the study. Participation in the ***SAFE program*** is completed over the course of 2-4 weeks. Participants will meet 2-3 times a week for approximately 60 minutes with either staff, a peer support specialist peer, or occupational therapy graduate students. The meetings will provide direct instruction and role play experiences covering the main concepts and proper use of preventable behaviors to protect against COVID-19 and other airborne diseases in the workplace.

Phase 2
Phase 2 will be completed over the course of one year following IRB approval. During the first two months, recruitment for the focus groups will take place. In months 2-4, focus groups will be conducted, and their feedback will be analyzed. Months 4-8 will involve revising the SAFE curriculum by adding lessons based on the focus group feedback. The final months will focus on recruitment and training.

Study Procedures and Data Analysis

Procedures.

To assess perceptions of peer-support interventions and use of preventative decision-making practices for individuals with ASD and or IDD in the workplace we will conduct in-depth qualitative interviews with individuals with ASD and or IDD working 10 hours or more a week (n=20 or until data saturation) who receive employment services or supports in order to: 1) understand the barriers and facilitators of implementing preventative decision-making practices for IADs and individuals with IDD in the workplace; 2) examine the perceptions and acceptability of peer support intervention strategies; and 3) develop a perceptual mapping survey instrument based on these findings.

Perceptual Mapping Survey Development. Once qualitative data is analyzed, we will develop a perceptual mapping survey using the themes from the interviews. Surveys are constructed using statement blocks with 5 to 7 related statements each. Participants indicate how much they agree or disagree with a statement using a 0 to 10 scale (0=totally disagree, 10=totally agree). For example, barriers statements may include "I do not think I am at risk of getting an infectious airborne disease" or "I don't trust that masks really protect me." Other statement groups might include facilitators to or beliefs about preventive behaviors, such as "I believe that standing six feet from someone can protect me". These surveys are set up to reflect how study elements are conceptualized relative to each other and relative to "Self", based on the mean scores of the group being studied. Then perceptual maps are constructed for each block.

Refine peer-support components of the *SAFE program* intervention and assess feasibility and acceptability of program components based on vector modeling findings. We will: 1) Conduct surveys with individuals with ASD and or IDD working 10 or more hours a week (n=100); 2) Conduct vector modeling analysis to identify: a. acceptable and feasible peer-support strategies *and* b. messages around preventative decision-making processes for airborne diseases in the workplace; 3) Concept-test refined strategies and messages with individuals with ASD and IDD working 10 hours a week (n=10), vocational rehabilitation staff (n=10), and the project Advisory Board (n=10) for feedback on acceptability; and 4) Refine intervention materials, fidelity processes and conduct usability testing with the same groups to assess potential feasibility of the intervention.

Perceptual Mapping Survey Analysis and Vector Message Modeling. We will be responsible for the analysis of quantitative data from the survey to construct perceptual maps. These maps will be created using multidimensional scaling (MDS) software developed based on the Galileo system (The Galileo Company, 2018). Input associations among the risks/benefits are derived from the inter-item correlations. The software then performs a metric MDS analysis and produces graphic arrays of the distances among the elements to produce a 3-dimensional map (Figure B). A percentage of explained variance is calculated as an index of the explanatory power of the map, showing validity of the method. The software is highly valid; if you enter distances between American cities into the program, a map that shows the cities in proper relative positions to each other, including longitude and latitude, is constructed with very little error (SSTRESS = .003). Possible differences in perceptual maps by subgroup will be assessed using k-mean cluster analyses. This "segmentation", usually by psychographic variables such as perception variables or demographics (gender, age etc.), is important to understand potential perceptual differences by segment. Should differences exist, maps will be generated separately for subgroups to assess whether significant differences would impact message design and incorporated into the **SAFE** *program*. Surveying 150-200 people with ASD and IDD should be adequate to do this sub-analysis if needed.

Once perceptual maps are constructed, we will conduct vector analyses to design messages that optimize the fit between people with ASD's perceptual maps and the **SAFE** *program* intervention content. These messages will be embedded in the intervention to help people with ASD and IDD make positive, protection decisions about measures that will reduce their risk of IAD transmission. To do this, the software

determines optimum strategies to emphasize in a message, including both the positive and negative attributes that should be moved and where in the space they should be repositioned to "pull" the group (see dotted lines in Figure B) toward the behavior (in this case, mask wearing). Mathematically, this defines the "target vector". This is then used to create message strategies to use in an intervention. For this study we will construct maps with multiple targeted vectors, including mask wearing, social distancing, and hand washing/hand sanitizing. While the construction of the message is left to the researcher, the content of the messages is made clear by the modeling. Once these messages are constructed, we will integrate them into the existing **SAFE** *program* intervention and develop processes to evaluate fidelity to the intervention. We will then "concept test" these with our advisory board to assess salience, acceptability and understanding.

Concept testing. To confirm whether the mapping strategies are salient to individuals with IDD and/or ASD, we will conduct concept testing with participants including working individuals with ASD (n=10) and IDD (n=10), vocational rehabilitation staff (n=20), and the project Advisory Board (n=20). The project Advisory Board is made up of 10 stakeholders including working individuals with ASD, family or caregivers, researchers and staff or administrators from employment service providers. We will develop a testing interview guide based on the Feedback Sessions Toolkit[80] for testing health communication messages. These groups will assess salience, understanding and acceptability. All interviews will be audio-recorded and analyzed. Once these messages are constructed study staff to integrate messages into the **SAFE** *program* content.

We will collect data using quantitative and qualitative interviews. We will use surveys to obtain demographic, general COVID-19 knowledge, self-advocacy/self-determination and workplace safety information. We will conduct qualitative interviews to determine acceptability and feasibility of intervention. Participants will be asked to discuss their experiences during the intervention specific to their assigned intervention group.

Potential participants will be provided with an introductory email with the link to research staff or administrative contacts of our community contacts identified under recruitment methods. Participants support staff will also be contacted with an introductory email to identify their role in the research process. Organizational administrators will provide information on the study to individuals that meet the inclusion criteria. Interested individuals will contact the project research coordinator to determine inclusion and provide consent/assent prior to participation in a qualitative interview or focus groups. Research procedures will occur in a format and location convenient for the participant. Although in-person interviews are the preferred method, participants can engage in the research procedures through audio-video conferencing or other web-based platforms. We will complete inclusion, consent and interviews in locations and methods that ensure privacy for the participant (e.g., a private room or area available to the primary investigators at Temple University, the participants jobsite, or the recruiting organization; HIPPA compliant Zoom room). All participants will receive a $25 gift card.

We will use similar recruitment methods as proposed for the quantitative perceptual mapping survey, qualitative interviews and focus groups. We will leverage current relationships with community organizations to recruit 100 participants with ASD and or IDD who are employed 10 hours or more a week and receiving employment services or supports. Organizational administrators will provide information on the study to individuals that meet the inclusion criteria. Interested individuals will contact the project research coordinator to determine inclusion. Eligible participants will receive a survey link to complete consent and the on line **Perceptual Mapping Survey.** The survey will confirm eligibility again before the consent will appear. The visible consent will highlight key areas including study purpose, procedure, confidentiality, risks and benefits, and participants' rights. In addition a pdf link will allow participants to see the complete consent form before agreeing to participate. Participants are prompted throughout the online survey to check a box if support is needed or they have any questions. If a participant checks this they will then be linked to a research staff member to finish completing the consent and/or survey. The consent/assent from will be completed prior to participation. Participants must check that they understand and agree to participate in the study prior to the actual survey being open. We will implement data collection procedures successfully used in prior studies with individuals with IDD and ASD. When participants ask for support research staff will read survey questions out loud to the participant and document responses. Participants will have a hard copy of the survey and response options in an accessible format to follow along with the verbal administration.

If the participant is assigned to the staff intervention support staff will be contacted with an email or phone call. Staff members will be required to complete human subjects training. Researchers will obtain informed consent for all participants. During the first contact made with participants, written information will be provided remotely using Zoom/FaceTime or in person to all participants explaining the following in simple terms: 1) the criteria for participation, 2) the purpose of the research and the procedures involved, 3) the subject's right to withdraw at any time without penalty of any sort, 4) potential benefits to the subject, 5) potential risks, 6) assurance of anonymity, and 7) terms of remuneration. All research staff will complete training about the informed consent process prior to consenting subjects. The information described above will be reviewed and any questions answered. Participants will be obtained signed or a printed signature box used for signature when electronic signatures are unable to be obtained for consent either in person or virtually.

We will collect data from young adults or transitional aged-youth with ASD or IDD to determine the efficacy and feasibility of the intervention. Recruitment occurs through the sites identified in the participant recruitment section of this proposal. Participants interested in the study will contact the primary investigator or research staff who will schedule an initial physical or virtual meeting at a place and time convenient for the participant to determine inclusion and obtain consent/assent. Participants are randomly assigned to either peer-support intervention, staff intervention or a control group. We will randomize in blocks of 12 (4 to each group) until we reach the targeted number of 120 or

40 participants in each group. Pre-test and post-test measures will be administered by researcher staff prior to the start of the intervention (Pre-test) and at the end of the intervention 4 weeks (Post-test). Key stakeholders, including the participants and interventionists (occupational therapists and peer mediators), will complete qualitative interviews at the end of the intervention period for each participant. The information gathered will determine acceptability and feasibility of intervention. Participants will be asked to discuss their experiences during the intervention specific to their assigned intervention group.

A member from the research team will then contact interested individuals to set up a convenient meeting time and place for the SAFE program training. These meetings will occur remotely or in a private location convenient to the participant. The SAFE program course training will occur in small group settings or individually. The course trainings will occur 2-3 times per week for between 45-60 minutes. An appropriate curriculum has been developed by Temple University Researchers and Occupational therapy students based on many qualitative interviews, research of proper education methods, and COVID-19 practices. The curriculum is based on a series of classes designed to create an understanding of best practices and behaviors to prevent the spread of COVID-19 in the workplace. The curriculum will be adapted to meet the needs of this project and study population. The course will provides instruction in the following areas: 1) COVID-19 and how it spreads 2) PPE and How to use it properly 3) Social Distancing 4) Community Participation 5) Employment 6) Self Efficacy.

Participants will complete the SAFE program sessions remotely or in person in a private, quiet and convenient setting.. Participants will be randomized into two treatment arms and a control group. The first treatment arm will receive the **SAFE** program implemented through a staff training model. The second group will receive the program using a peer support model. The control group will continue to receive their standard vocational rehabilitation supports.

Training of the **SAFE** program will occur remotely or person by staff who are trained within our research team or we will implement it in collaboration with staff or a peer specialist remotely as part of their current services. If it is in person it will be implemented at their vocational rehabilitation centers or places of employment. Research staff will be available to support the process after the training is complete.

We will use a questionnaire to assess knowledge of actionable behaviors to prevent COVID-19, which reflect the core components of the ***SAFE*** *program* (social distancing, proper use of PPE, personal hygiene practices, and self-advocacy in the workplace). We will also administer measures to determine the degree of self-advocacy and self-efficacy in the work place reported by staff and self-reported by participants. We will determine how well a participant follows workplace procedures. Data will be collected either in person or virtually both at pre-test and post-test for all outcome measures. Finally, we will assess perceived anxiety.

Phase 2

Focus Group Participation

Recruited and consented participants will take part in focus groups consisting of 5-10 people. These focus groups will be held in convenient, private locations such as agency centers or conducted via Zoom to ensure both accessibility and privacy for all participants. During the focus groups, participants will be presented with a summarized and accessible version of the SAFE program. After reviewing the material, participants will share their experiences, priorities, and concerns, specifically focusing on any important priorities that they feel are missing from the current SAFE program curriculum. Research staff will facilitate these discussions. Each session will be recorded and transcribed using Zoom built in features to accurately capture the data. Focus groups will last no longer than two hours. Participants will be compensated $30 for their participation.

Content Development for the SAFE Program

- Once the focus group analysis is completed, research staff will proceed with the creation of new content for the SAFE program. The team will draft educational materials that address the priorities identified during the focus groups. The draft content will undergo a rigorous review process through an advisory board involving subject matter experts, stakeholders, and individuals with lived experiences to ensure the content's accuracy and relevance. **Five to ten stakeholders will review the new content developed for the SAFE program. They will receive the newly developed content and provide feedback on its accessibility, clarity, and overall engagement. The content will be sent via email, and stakeholders will be asked to provide their feedback either through email or during a scheduled group Zoom meeting.**

  Based on the feedback received, research staff will make any necessary revisions to ensure the materials are both effective and accessible.

  Once finalized, the new content will be integrated into the existing SAFE program materials. Research staff will adapt the content into various formats, including written guides, videos, and infographics, to meet the diverse learning needs of participants.

Pilot Testing for Service Providers

- Research staff will recruit 5-10 staff members from a large service provider organization to participate in pilot testing of the training materials. This pilot testing will occur over a 1-2 month period, during which staff will be trained on the new SAFE materials and additional content. The trainings will occur using Zoom meetings. The training sessions will be conducted either in groups or individually, depending on scheduling availability. Feedback will be collected from participants through surveys, interviews, or debriefing sessions to evaluate the effectiveness of the training. The training feedback will be audio recorded to ensure that we capture all important information you share. The audio recordings will be transcribed by the project team using Zoom's transcription feature. By signing the consent form, you are giving permission to be recorded.
    - Only people working on this project will have access to the recordings.
    - Information and transcripts will be stored securely in locked filing cabinets or on password-protected computers.

  Based on this feedback, research staff will refine the training materials and curriculum, making necessary adjustments to improve clarity, accessibility, and applicability. These

trainings will not be recorded. Feedback will only be collected using FIM surveys, AIM surveys and exit interview.

Once these refinements are complete, the finalized curriculum will be prepared for broader implementation within service-based organizations that support individuals with IDD. Participants will receive $50 for the training. Participant will receive $25 after the first training sessions and an additional $25 after completion.

Data Analysis. Descriptive statistics including mean, median, standard deviation, skewness, frequencies, and percentages will be computed on demographic and measures as appropriate. We will complete ANOVAs to determine if there were significant changes in scores on outcome measures within and between groups. We will use SPSS to complete the analyses.

Qualitative data analysis will utilize the Kruegar method of analyzing narrative data: familiarization, identifying a thematic framework, indexing, charting, mapping and interpretation.[75] We will use the cross-platform app, Dedoose,[76] for analysis. Transcribed, verbatim digital recordings of focus groups and interviews will be read by study staff to become familiar with what participants said. A thematic framework will be developed to create categories and quotes and will be indexed according to categories to reduce data. Charting of quotes to enable analysis will then occur.[77] During the indexing/coding steps, data will be coded by at least 2 coders and intercoder reliability rates will be randomly assessed. Once this is achieved, interpretation of the thematic framework and supporting quotes will be conducted, accessing context, internal consistency, frequency of comments, specificity of comments, intensity of comments and "big ideas" (Krueger, Casey 2000). Results will inform survey development.

Measures

We anticipate that some of the participants will need assistance to complete the assessments (i.e. reading questions, marking answers). Researchers, family or support persons will provide assistance as needed.

Qualitative Data collection- Qualitative interviews will be administered prior to the *SAFE program* completion remotely or in person, 1:1 and privately. The interviews will be 30 minutes and will be completed in one meeting. Individual interviews will be completed by one of the primary investigators, research assistant, or OT graduate student and will be audio recorded and transcribed for further review. Transcriptions will be cross checked to ensure accuracy. Each person facilitating the interviews will use guiding questions determined by the research team and practice interview techniques prior to implementing interviews. There will be one interview per participant completed.

Qualitative interviews will be transcribed and cross-checked. Per the methods described by Creswell and Plano Clark (2011), qualitative data will be analyzed using constant comparison. Specifically, transcripts will be coded (i.e., horizontalization) and collapsed into clusters of meaning (i.e., themes) by at least 3 analysts. Analysts will 1) meet to

review codes, 2) identify areas of disagreement, 3) recode data until consensus is reached, and 4) collapse initial codes into a preliminary framework of interrelated themes. The transcripts will be reanalyzed until a final thematic structure is reached. The research team will implement a number of methodological actions to strengthen the data collection process and trustworthiness including reflexivity, triangulation, and stakeholder checks.

Demographics and Potential Moderators.
The research team, primary investigators or research assistant, will collect demographic data including age, gender, ethnicity, education, type of area lived in, and primary and other diagnosis. The demographic form is completed *only* during pre-test data collection. Additionally, we will track participants who acquire an infectious airborne disease (IAD) during the course of participation in the study. This is not considered a primary outcome as we are not able to incorporate contact tracing within the scope of this project. Therefore, it is unlikely that we can confidently identify whether the participant acquired the IAD in the workplace. We will rely on self or caregiver report to acquire this information. The process of collecting this information will help in determining if it is feasible to include this as an outcome in future research.

Primary Outcomes Measure will be collected by the research team, primary investigators or research assistant.
Workplace Health and Safety Assessment. The Workplace Health and Safety Assessment assesses ***both*** knowledge and actionable behaviors participants exhibit to prevent IADs. The items for the tool were developed from recommendations provided by the CDC to reduce exposure to IADs including use of personal protective equipment, personal hygiene and social distancing. The assessment includes 20 items and takes approximately 15-20 minutes to complete through both administrator observations in the workplace environment (8 items) and questions completed by the participant (12 items). Response options are "rarely, never, sometimes, most of the time, always" and are scaled from 1 to 5 respectively. A total raw score is provided for data analysis.

PROMIS General Self-Efficacy Item Bank. This measure assesses a person's belief in their capacity to manage daily stressors and have control over meaningful events. Participants will complete the 10-question tool which is designed for people 18 years and older. It has established acceptable reliability and validity.[81] The responses are on a 5 point scale from "I am a little confident" (1) to "I am very confident" (5) with higher scores reflecting greater general self-efficacy. A total standard T-score will be used to analyze the data.

VocFit Safety Subscale. The VocFit is an assessment tool used to measure the best fit for a worker with a job.[8] The tool was specifically developed for individuals with developmental disabilities and has strong psychometric properties for this population.[82] The VocFit safety subscale consists of 8 questions asking to what degree the participant demonstrates the ability to engage in safety protocol at their employment. The tool identifies the degree to which the participant is able to follow safety protocols and precautions in their work setting. The response options include "high", "some", and "low".

Workplace Health and Safety Self-Advocacy Scale (WHSSS). This measure was adapted from employment-centered items on the Self-Determination and Self-Advocacy Questionnaire, which assesse the degree of self-advocacy in the workplace as reported by staff and self-reported by participants. The measure has ten question and takes 5-10 minutes to complete. The modified WHSSS assesses the skills used to advocate for preventative practices for IADs in the workplace and the degree to which the person uses these skills. The response options range from "none of the time" (1) to "all of the time."

Perceptual Survey Items. To assess perceptions of IADs and protective behaviors, we will utilize the perceptual mapping items developed in the formative phase. These will be determinmed at baseline and the one-month follow-up to see if perceptions have changed based on intervention content. We will be able to compare perceptual maps of interventions groups to see if specific messaging affected the relationship between the group and the target protective behavior.

NIH Toolbox Item Bank/Fixed Form v2.0 – Perceived Stress (Ages 18+). This measure assesses **"**perceptions about the nature of events and their relationship to the values and perceived coping resources of an individual" for adults 18 years and older. This self-report measure has 14 items with a response range from "Never" (1) to "Very Often" (5). Higher scores reflect greater levels of perceived stress. The tool has established acceptable reliability and validity. A total standard T-score will be used to analyze the data.

PROMIS Item Bank v1.0 – Anxiety Short Form 8. This measure assesses anxiety for adults 18 years and older. This self-report measure has 8 items with a response range from "Never" (1) to "Very Often" (5). Higher scores reflect greater levels of anxiety. It has established acceptable psychometrics and is sensitive to change. A total standard T-score will be used to analyze the data.

Acceptability of Intervention Measure (AIM) and Feasibility of Intervention Measure (FIM). These measures were developed concurrently as the constructs are highly related. The AIM measures the acceptability of the intervention defined as "the perception among stakeholders that a given intervention is agreeable, palatable, or satisfactory" (Weiner et al., 2017). The FIM measures the feasibility of the intervention as defined as "the extent to which a new intervention can be successfully used or carried out within a given agency or setting (Weiner et al., 2017). Both tools demonstrated substantive and discriminant content validity and moderate to good test/re-test reliability. Preliminary research identified that the tools are sensitive to change in either direction. The tools take less than 5 minutes to complete and have a Flesch reading ease score at a 5th grade level. Response options range from completely disagree (1) to completely agree (5) with higher scores indicating greater acceptability or feasibility. A total raw score is provided.

Feasibility Data. The research team will evaluate the feasibility of the intervention and research methodology. Methods and benchmarks for evaluating feasibility include recruitment and retention rates, data about assessment procedures, feasibility survey

questionnaires, and qualitative exit interviews of interventionists and participants.**The**participants and will complete the Acceptability of Intervention measure (AIM) and the interventionist the Feasibility of Intervention Measure (FIM) at post-test 1.

In Phase 2, feasibility data will be collected exclusively by the staff completing the SAFE curriculum training. They will assess how feasible and acceptable the SAFE program, including the new lesson, is for their clients or students. This phase will not involve a pilot study with participants.

c) Withdrawal of Subjects

Participation is voluntary and there is no penalty if a person chooses not to join the research study. They will continue to receive services as usual. If a person enrolls in the study and later chooses to withdraw from the study, they may do so at any time without any penalty. They can withdraw from the study by contacting the primary researcher through telephone or email.

d) Privacy & Confidentiality

The study team has placed safeguards to maintain the confidentiality of participants' personal information.

Phase 1: Personal information will be kept electronically in password protected files and hard copies will be stored in locked cabinets at the TU Collaborative on Community Inclusion, located at 1913 North Broad Street, Mitten Hall, Philadelphia. Except for the legal requirements described below, only research staff will have access to personal information. By law, however, the Temple University Institutional Review Board (IRB), National Institute of Disability, Independence Living and Rehabilitation Research (NIDLRR), the Office for Human Research Protections, and the Philadelphia Department of Public Health IRB, are required to have access as well. Study files will be kept for seven years after the last publication of the data. Any information about child abuse or intent to harm oneself or others will be reported to authorities, as is required by law. Efforts will be made to limit personal information access to people who have a need to review this information.

Phase 2: Personal information will be kept electronically in password protected files and hard copies will be stored in locked cabinets at the Reach Lab, located at 1913 North Broad Street, Mitten Hall, Philadelphia. Except for the legal requirements described below, only research staff will have access to personal information. By law, however, the Temple University Institutional Review Board (IRB), and PA Department of Health, , are required to have access as well. Study files will be kept for seven years after the last publication of the data. Any information about child abuse or intent to harm oneself or others will be reported to authorities, as is required by law. Efforts will be made to limit personal information access to people who have a need to review this information.

All research funded by NIDILRR falls within the ACL requirements for public access to scientific data. The data must be publicly available no later than 24 months after award's end date. Data must be stored in such a way that enables retrieval and use at no cost to users. All scientific data resulting from a NIDLRR award must be made publicly available. Each data set must have a Digital Object Identifier (DOI) for future reference and citation. Final Report must include DOIs and data release date. The data will be deposited in Inter-university Consortium for Political and Social Research (ICPSR). All data will be de-identified before it is deposited. ICPSR is the preferred repository for NIDILRR-funded research. Within Institute for Social Research at the University of Michigan. Established in 1962. ICPSR contains over 10,000 achieved studies. This does not apply to Phase 2 of the study as it is not funded by NIDILLR .

The study does not use or disclose participants' Protected Health Information and therefore a HIPPA Authorization Form is not included in this proposal.

All information gathered about participants for this study is confidential, except as may be required by law. For example, confidentiality would not be honored if a person expressed a current plan to harm themselves or others, or if they report they have committed child abuse or neglect. Completed interviews will contain a coded identification number to prevent loss of confidentiality. Confidentiality of data files will be achieved by separating code numbers from individual identifying information. Information taken about participants will be kept electronically only in password protected files on an encrypted network and hard copies will be stored in locked cabinets. Research investigators will be the only people with access to this data, with the exception of authorized representatives of the Temple University Institutional Review Board (IRB), who are required to have access by law. For phase 2, No hard copies will be retained. If a person is unable to sign electronically and a physical signature is required, the document will be scanned, stored as a PDF in the confidential digital system, and the hard copy will be destroyed.Protected health information will not be collected for participants during the qualitative interviews. Participant contact information will always be kept separate from the data. Participant information will be password protected and stored on an encrypted network. Whenever feasible, identifiers will be removed from study-related information. All published reports will contain data reported either in aggregate form (where no individual responses can be identified), or in composite individual examples that are constructed so that identification is impossible.

During the consent process, individuals will be informed that they can stop the interview at any time should they feel uncomfortable. They will also be told that they do not have to answer any question that they do not want to answer. All data will be assigned a number for data management purposes. Data collected from participants will only be kept electronically in password-protected files on an encrypted network. Research investigators will be the only people with access to this data, with the exception of authorized representatives of the Temple University Institutional Review

Board (IRB), who are required to have access by law. All published reports will contain data reported either in aggregate form (where no individual responses can be identified), or in composite individual examples that are constructed so that identification is impossible.

11) Risks to Subjects

Participants will receive the ***SAFE program*** training and may interact with peers, occupational therapists, community members, and researchers directly. This interaction may be perceived as stressful for the participants, especially for the participants who have social and communicative challenges. Participants do not need to answer any questions that make them uncomfortable. Participation in the study requires a commitment of a 4 week time period for the course and additional time for inclusion and consent processes.

12) Potential Benefits to Subjects

There are direct benefits to participating in the study. Participants will contribute to society through the knowledge gained in the research process in an area that is meaningful and important to them. After participants have completed the ***SAFE program,*** participants will have gained knowledge and behaviors to assist them as they work and properly implement safety precautions and procedures**.** Participants in Phase 1 will receive a $25 gift card electronically or in person when the qualitative interview or focus group is complete. Participants in Phase 2 will receive a $30 gift card electronically or in person when the qualitative interview or focus group is complete. Participants will receive $20 gift card electronically or in person if they complete the quantitative survey. Participants invited to be a part of the intervention will receive a $50 gift card electronically or in person when complete. Staff completing the SAFE pilot training for future implementation will receive $50 electronic gift card.

13) Costs to Subjects

There are no anticipated costs associated with participation in the study.

14) Informed Consent

All adult participants in the study will provide informed consent. Consent will be obtained remotely and through electronic signatures until it is safe to meet one on one with participants. Individuals will meet remotely with research staff to review and obtain informed consent in REDCAP via a zoom meeting or comparable. The primary investigator or a research assistant will obtain informed consent and when needed assent when possible for each participant. The research assistant will obtain training in the consent process to ensure that there is no coercion and proper procedures are followed. During the first contact made with adult participants (either in person, electronically, or over the phone), written information will be provided in person or through electronic formats. Researchers will explain the following in simple terms to all participants: 1) the criteria for participation, 2) the purpose of the research and the procedures involved, 3) the subject's right to withdraw at any time without penalty of any sort, 4) potential

benefits to the subject, 5) potential risks, 6) assurance of anonymity, and 7) terms of remuneration. Although it is anticipated that many participants will be able to provide informed consent, a process for obtaining informed consent from a legally authorized representative (i.e. parent, caregiver, or another individual with legal guardianship) and assent from the participant will be used if the individual is under guardianship or not able to provide consent. Some participants may not have a legally authorized representative. In those cases investigators will take special care for all participants who have an intellectual or developmental disability to ensure that participants understand the consent process by going over the information slowly with them and asking them to repeat back to the investigator each aspect of the consent process. Accommodations will be made to ensure that communication between the participant and the investigator is as clear as possible (i.e., use of sign language interpreter, assistive communication devices as needed).

The following format will be used to obtain informed consent/assent process and to assess each potential participants understanding of that to which they are agreeing.

(A) Each potential participant will be provided with a copy of the informed consent/assent form and askes to read the form.

(B) Each section of the form will be read to the potential participant if they are an individual with a disability.

(C) When an individual has completed reading through each section of the form or the section of the form has been read to them, they will first be asked if they have any questions. Once these general questions have been answered, those individuals obtaining consent/assent will ask the following questions to ensure comprehension of content:

(1) Please tell me what you will be asked to do if you take part in this study?

(2) Tell me what might go wrong or the potential risks/negative things that might happen to you if you take part in this study?

(3) If you do not want to take part in the the study what will happen?

(4) If you say "yes" you want to be a part of the study, but change your mind, what can you do?

(5) What can you do if someone asks you a question as part of the study that you do not feel comfortable answering?

(6) Will the people running the study share information they get from you with anyone else?

(7) How will the people running the study keep the information you provide them private or confidential?

(8) Who can you call or tell if something you don't like happens during the study?

(9) What do you remember about what I told you about the study?

Phase 1: If the person is not able to accurately answer the questions above, they will not be able to participate in the study unless there is a parent or legal representative that can provide consent. If the person has a parent or representative, then researchers will attempt to obtain assent. Informed consent from parents or guardians will be obtained for all participants under the age of 18.

Informed consent is obtained by the participant or the legally authorized representative signing the informed consent form. The research specialist will read the assent form to the adult participant who cannot provide informed consent and obtain a signature, verbal, or non-verbal indication of consent from the participant. If the person is not able to complete a signature, the research specialist will document on the assent form if the person provided verbal assent or how non-verbal assent was provided. Individuals who are not able to provide assent will not be included in the study, as identified in the inclusion/exclusion criteria. We will follow the policy "Legally Authorized Representatives Children and Guardians (HRP-021)" to guide procedures to obtain consent for adults who are not able to provide consent.

Phase 2: If individuals are unable to answer the questions in the section above, they will be excluded from Phase 2.

All participants will receive a copy of the signed or electronic version of the consent form and assent form if applicable. Please see attached Informed Consent Forms and Assent Form.

15) Vulnerable Populations

For Phase 1, some of the adult participants may have cognitive impairments, which would require informed consent to be obtained by a legally authorized representative. For these individuals, assent will also be obtained through written, verbal or non-verbal methods as described above. Phase 2 will not enroll any participant who cannot provide consent.

Adolescents and adults with developmental disabilities are the population for the study. This population is at risk for decreased access to health and employment services, along with reduced community participation and therefore is the targeted population for inclusion in the study. No pregnant women or prisoners will participate in the study.