Best Practices to Prevent COVID-19 Illness in Staff and People with Serious Mental Illness and Developmental Disabilities in Congregate Living Settings

NCT04726371

Full Study Protocol

Version date: April 5, 2022

Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.

PRINCIPAL/OVERALL INVESTIGATOR

Stephen J. Bartels, MD, MS

PROTOCOL TITLE

Best Practices to Prevent COVID-19 Illness in Staff and People with Serious Mental Illness and Intellectual/Developmental Disabilities in Congregate Living Settings

FUNDING

PCORI

VERSION DATE

04/05/22

SPECIFIC AIMS

Concisely state the objectives of the study and the hypothesis being tested.

This is a COVID-19 related protocol.

Our overall goal is to reduce COVID-19 and other infectious-disease incidence, hospitalizations, and mortality among staff and adults with serious mental illness (SMI) and intellectual disabilities/developmental disabilities (ID/DD) in congregate living settings.

Aim: To compare the effectiveness of "Tailored Best Practices" (TBP) specifically adapted for staff and residents with SMI and ID/DD in congregate living settings and "Generic Best Practices" (GBP) consisting of state and federal standard guidelines for all congregate living settings. The purpose of this comparison is to determine if the additional effort entailed in implementing TBP and the associated training and coaching result in better outcomes and warrant system-wide dissemination.

Hypothesis: TBP will be associated with greater implementation fidelity to COVID-19 prevention best practices and lower staff and resident rates of COVID-19 and hospitalization than GBP.

BACKGROUND AND SIGNIFICANCE

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Persons with SMI and ID/DD are disproportionately vulnerable to COVID-19 for three reasons: **(1) Medical vulnerability.** Smoking, chronic obstructive pulmonary disease, cardiovascular disease, and diabetes all increase COVID-19 mortality and are about 2–3 times more prevalent among persons with SMI. People with ID/DD suffer higher rates of COVID-19 risk factors, including pre-existing chronic conditions, heart defects, obesity, chronic respiratory problems or lung disease, lower immune function, cancer, and diabetes. **(2) Residential vulnerability.** The congregate care settings in which many people with SMI and ID/DD live carry many of the same higher risks of COVID-19 transmission currently affecting assisted-living settings and nursing homes across the nation. **(3) Health behavior vulnerability.** Some people with SMI and ID/DD have cognitive, behavioral, and physical challenges that heighten COVID-19 risk by hampering personal protective practices (PPP) (i.e., hand hygiene, physical distancing, use of face masks). Moreover, the staff who work in congregate care settings are often subject to high rates of exposure, have low socioeconomic status, use public transportation, and lack personal protective equipment. This collection of factors contributes to an extraordinarily high risk of COVID-19 morbidity, and mortality. **Despite payment reforms and mandated best practices for COVID-19 for congregate care by the MA Department of Public Health, rates of coronavirus illness for residents with SMI and ID/DD are 8 times higher (12%), and for staff 2 times higher (3.0%), compared to the general population in the surrounding "hot spot" communities (1.5%) selected for this study**. *This tragic health disparity confirms that we lack the knowledge of how to optimally tailor best practices for this highly vulnerable population and the staff who provide their care to effectively reduce their high risk of COVID-19 and COVID-19 related mortality.* We do not know (1) optimal practical screening practices for people with SMI and ID/DD, (2) how to feasibly and effectively provide isolation in the close shared quarters of group homes, (3) how to conduct reliable contract tracing for staff and residents, or (4) how to support pragmatic and effective personal protective practices. The proposed study will produce actionable results addressing these knowledge gaps that can be immediately implemented within the first few months of the project.

RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

Our study will include a target of 400 state-funded congregate care homes for adults with SMI (DSM-V Diagnosis of Axis-I Mental Illness with persistent functional impairment) and for adults with ID/DD (Intellectual and Developmental Disabilities) (age 18+), operated by public-sector community-based human service organizations (Vinfen, Bay Cove, Advocates, North Suffolk, Open Sky, and Riverside). We anticipate recruiting up to 450 group homes in order to achieve our final sample of 400 group homes that will be appropriately balanced when randomized by stratification with respect to group home type (SMI versus ID/DD), incident COVID-19 infection in the staff and residents (high incidence versus low incidence), and race/ethnicity (proportion

non-Hispanic Caucasian versus other). We anticipate that there will be approximately 1400 residents with SMI and approximately 800 residents with ID/DD in the participating group homes. In addition, we anticipate that there will be approximately 3300 group home staff: approximately 1650 working in group homes for adults with SMI and approximately 1650 working in group homes for adults with ID/DD. No human subjects will be enrolled by Partners researchers or at Partners sites.

We will employ a cluster-randomized trial design with 200 group homes randomized to the implementation of TBP compared to 200 group homes randomized to GBP. TBP consists of optimized, tailored, and highly specific COVID-19 best practices and training materials specific to the setting, staff, and residents with SMI and ID/DD in congregate living settings based on the comparative effectiveness of different types, intensities, and combinations of COVID-19 prevention practices (screening, isolation, contact tracing, use of PPP, vaccination) specifically modeled for residents and staff of congregate living settings for people with ID/DD and SMI derived by a simulation model. There are four main components to Tailored Best Practices: Measurement, Feedback, and House Plans; Motivational Interviewing; Interactive Education; and Trusted Messengers. Detailed descriptions of each component, along with supplemental materials, have been included in this submission in the attached TBP Manual [file name: "02_TBP Manual_2021NOV29_clean"]. In brief:

Measurement, Feedback, and House Plans:

Following each completion of the Fidelity survey (described below) by program directors (i.e., group home leaders) at baseline, 3-, 6-, 9, and 12-months post-randomization, the group home's program director will receive a statistical dashboard that shows the group home's fidelity performance in relation to other group homes. Visual, group home-level, easy-to-view displays will be provided, comparing current measures to prior measures and to the average performance and range of performance of other group homes in this study. The benchmarks also provide the opportunity for group home managers to discuss potential ways to improve and to potentially consult with "high performing" sites on strategies and lessons learned.

After receiving the statistical dashboard, each group home will receive assistance in creating and executing a group home-specific House Plan for fidelity performance improvement. We will work with the program directors to review areas that need improvement, discuss barriers that are preventing each program from increasing their success, set reasonable goals, and identify target completion dates. If deemed feasible and appropriate, group homes may receive Motivational Benefits (i.e., celebrations, accommodations, or rewards) as part of the House Plan. The framing of the House Plan is consistent with mirroring and complementing the global goal of resuming highly valued activities and relationships. All group homes will receive the Measurement, Feedback, and House Plans component of TBP once every three months for the duration of the study following the completion of each program director survey.

Motivational Interviewing:

We have adapted the principles of motivational interviewing to focus on COVID-19 prevention practices by engaging individuals in discussing personal goals, wellness behavior practices, COVID-19 prevention, pros and cons of different approaches, and aligning future prevention practice goals with overall personal and group home goals. This component will be delivered primarily in small groups with separate sessions for residents and staff. We will also create an electronic version of Motivational Interviewing with a prerecorded video that program directors may use in their group homes. All residents with SMI and staff will be encouraged to participate in an initial motivational interviewing session within the first eight months of the intervention and a booster session in the latter seven months of the intervention.

Interactive Education:

The Interactive Education component of TBP will be available to residents and staff in multiple forms to accommodate the needs and wants of each group home. Interactive Education involves sharing an educational material (e.g., a video, handout, or demonstration) and discussion of that material. Interactive Education will be delivered either by 1) program directors on their own time or 2) a COVID-19 Physician Expert from the research team during a Zoom session. Interactive Education will utilize Educational Toolkits – collections of publicly available materials (e.g., flyers, videos, social stories) from reputable sources, such as the CDC and the WHO, curated by a COVID-19 Physician Expert in collaboration and with input from stakeholders. The Educational Toolkits contain materials that are tailored to our target populations, including people with SMI and ID/DD, non-English language speakers, and people identifying with racial and ethnic minorities. All residents and staff will receive some form of Interactive Education within the first eight months of the intervention and a second dose in the latter seven months of the intervention.

Trusted Messengers:

As with Interactive Education, the Trusted Messenger component of TBP may be delivered in multiple forms to tailor it to each group home's unique needs. Data from research and input from stakeholders supports the potential value of trusted messengers as a source for information and stories of personal experiences that can be highly persuasive in supporting personal health behavior change. Video testimonials of peers provide an accessible and scalable format for participants to hear from peers, so we have created five Peer Testimonial Videos featuring frontline staff, certified peer specialists, residents, and legal guardians telling their personal stories with COVID-19 and emphasizing why they chose to receive a COVID-19 vaccine. Residents and staff may view these videos during Motivational Interviewing. For residents with legal guardians, we will email a video or mail a link to the video to the legal guardians, as guardians play a crucial role in the decision for a resident to get vaccinated. Separate from the videos, we will encourage participants to serve as trusted messengers for their peers by sharing their personal experiences during Motivational Interviewing sessions and other study activities. All residents and staff will receive some form of Trusted Messenger within the first eight months of the intervention and a second dose in the latter seven months of the intervention.

TBP was determined as described in IRB protocols 2020P003803, 2020P003957, and 2020P000967. In brief, TBP was determined through a process that combined: (1) knowledge learned from the community providers on the prior course of COVID-19 in the group homes; (2) qualitative data from key informant interviews of residents and staff on the barriers and facilitators to using recommended best practices; (3) a validated simulation model to determine the comparative effectiveness of different COVID-19 preventive practices (screening, isolation, contact tracing, use of PPP, vaccination) using the previously collected data; followed by (4) engaging decision-makers and stakeholders in selecting specific priorities for "tailored best practices". The cluster randomized trial will compare the effectiveness of "Tailored Best Practices" (TBP) specifically adapted for staff and residents with SMI and ID/DD in congregate living settings to "Generic Best Practices" (GBP) consisting of state and federal standard guidelines for all congregate living settings. *The purpose of this comparison is to determine if the additional effort entailed in implementing TBP and the associated training and coaching result in better outcomes and warrant system-wide dissemination.*

We will engage in several activities to help inform program directors in participating group homes about the study. We will 1) draft an email for the CEOs of the six provider organizations to send to program directors, including a short video explaining the Fidelity survey; 2) distribute flyers to program directors explaining the study; and 3) use a brief slide deck to explain the study to program directors. All materials used for these outreach activities have been included in this submission as attachments [file names: "00_Project Flyer SMI_2021SEP22", "01_Project Flyer IDDD_2021SEP22", "00_TBP Orientation Slides_2021SEP20", "00_TBP CEO Letter_2021SEP22", and "00_PD video_2021SEP20"].

Randomization will occur at the level of the group home stratified by group home type (SMI versus ID/DD), incident COVID-19 infection in the staff and residents (high incidence versus low incidence), and race/ethnicity (proportion non-Hispanic Caucasian versus other). TBP and GBP will be delivered within each agency as part of routine training activities. TBP sites will receive coaching to implement TBP specific to the setting, staff, and residents. Implementation fidelity will be measured including the proportion of staff and residents participating in recommended screening, isolating, contact tracing, PPP protocols, and vaccination interventions, along with the outcomes of new COVID-19 incidence as co-primary outcomes with group home as the unit of analysis. The outcomes will be assessed at baseline, 3, 6, 9, 12, and 15 months.

At each data collection point, we will evaluate implementation and effectiveness outcomes by secondary analysis of routine data collected by our community partners (e.g., dates of COVID-19 infection, hospitalization, mortality) as well as data from surveys completed by program directors (i.e., those who oversee individual group homes) assessing each group home's **fidelity and adoption** of their assigned set of best practices (TBP or GBP). These fidelity outcomes will be assessed at baseline, 3, 6, 9, 12, and 15 months.

We will also send the same fidelity survey to a second staff member at an equivalent level of the program director within the same group home (e.g., group home nurses). The purpose of this second fidelity survey will be to measure the intra-rater reliability of fidelity measures

within the same group home. If we have ≥ 80% concordance between two raters in the first 10% of group homes surveyed, we will stop the second survey collection. If the concordance is < 80%, we will continue to measure intra-rater reliability, using the same process above, until concordance is ≥ 80% or until all group homes are surveyed again, whichever comes first. Re-training of TBP may occur between time points if concordance is < 80% and areas for improvement are identified by our research team.

The fidelity survey data will be collected using REDCap. Individual survey links will be e-mailed to the group home managers by the provider organizations who will also provide the group home study IDs. Survey responses will be directly submitted back to the MGH research team. The provider organizations will not have access to the individual responses. No PHI data will be collected as part of the survey. No individual-level group home data will be shared with the individual's employer (provider organization), although overall summary statistics across group homes may be shared for quality improvement.

In addition to the data collected at the six time points described above, we will analyze the responses of residents, staff, and (where applicable) legal guardians of residents to a short **Needs Assessment questionnaire** at two time points: baseline and 12 months. The needs assessment questions have been developed collaboratively with stakeholders and have direct value to provider organizations by helping to organize and standardize questions that they would otherwise need or want to ask in order to manage COVID at the individual level for quality improvement and COVID care planning. The needs assessment will be completed by staff, residents, and legal guardians with support as needed by members of the research staff, community-based research implementation team, or community-based project managers. The Needs Assessment questionnaire data will be collected using REDCap or on paper. Individual survey links will be e-mailed, or paper surveys will be delivered to the staff, residents, and legal guardians by the provider organizations who will also provide the individual study IDs. Survey responses will be directly submitted back to the research team. The provider organizations will not have access to the individual responses. No PHI data will be collected. No individual-level data will be shared with the provider organizations, although overall summary statistics across group homes may be shared for quality improvement. These data will inform ways to improve the TBP intervention package and will provide an evaluation as to how TBP is impacting the experiences of individuals.

Consistent with good practice in clinical trials, we will conduct a nine-month interim analysis of outcomes by an independent *Data and Safety Monitoring Board* (DSMB). In the event that there is a clinically and statistically significant difference favoring TBP with respect to COVID-19 incidence and related hospitalizations and/or mortality, the DSMB will have the authority to then terminate the randomized trial, and the comparison group will also receive TBP. We would then continue to collect scheduled follow-up data at the predetermined points in time and conduct appropriate subsequent pre-post analyses. Finally, in the event that the final analysis (at the end of the active trial) shows that TBP is superior to GBP, we are committed to providing training and implementation support of TBP to the control group homes over the last few months of the study. Of note, the cluster randomized trial design was discussed in detail with

the CEOs of our partnering community organizations and, given the safeguards described above (continued incorporation by GBP of state-of-the-art recommended best practices; an interim analysis and DSMB; and commitment to provide training and accommodation support to all group homes if shown to be effective), the CEOs were enthusiastically in support of this final study design.

FIGURE 2: Cluster Randomized Trial Design

	Group Homes	Months	YEAR 1												YEAR 2						
			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
				Baseline			Implement														
Highest Prevalence GHs	~100						Tailored Best Practices (TBP)														
Lower Prevalence GHs	~100						(n=~200 Group Homes)														
Highest Prevalence GHs	~100						Generic Best Practices (GBP)														
Lower Prevalence GHs	~100						(n=~200 Group Homes)														
Total Sample Group Homes (GH)	~400																				
Period of Data Abstraction																					
Data Collection Points						BL			1			2			3			4			5
Total Sample Units of Observation	~2400						*~2400 units of observation: 6 collection points X ~400 group homes*														

4 RANDOMIZATION CLUSTERS*		
Vinfen	~100	~100
Bay Cove	~100	~100
Advocates	~66	~100
North Suffolk	~34	
Open Sky	~60	~100
Riverside	~40	
Total Group Homes (GH)	~400	~400

Top ~200 and Lower ~200 Covid SMI & ID/DD GHs Randomized
*For Each randomization cluster of ~100 group homes
~50 Assigned to High Covid Prevalence Group Homes
~50 Assigned to High Covid Prevalence Group Homes

(GH Residents=~2050 GH Staff=~3300) COMPARATORS: Tailored Best Practices (TBP); Generic Best Practices (GCP)

Briefly describe study procedures. Include any local site restrictions, for example, "Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study." Describe study endpoints.

The study does not involve recruitment of human subjects at Partners. The sources of material for the study include (1) COVID-monitoring data already routinely collected by the participating provider organizations, (2) a Fidelity, Adoption, and Adaptation survey that program directors will complete through REDCap, and (3) a Needs Assessment questionnaire that will be completed by residents, staff, and legal guardians through REDCap or on paper with support (as needed) by the community-based implementation team, community-based project managers, and research staff.

For (1) COVID-monitoring data already routinely collected by the participating provider organizations: At baseline, 3, 6, 9, 12, and 15 months post-baseline, we will request a limited data set, as defined in Section 164.514 (e) of the Privacy Rule, whereby our community partners will send us routinely collected data that includes dates of COVID-19 events for individual staff and residents (i.e., dates of positive test results, hospitalizations, deaths, and vaccinations). We will also receive the unique, encrypted identifiers of the group home(s) that residents lived in and staff worked in during each 3-month data collection period. For staff who were not initially

included in the secondary data we received from provider organizations as part of IRB protocol 2020P003803, we will also obtain information on demographic characteristics (e.g., age, gender, race/ethnicity, ZIP code). For residents who were not initially included in the secondary data we received from provider organizations as part of IRB protocol 2020P003803, we will obtain similar information on demographic characteristics, and health status (e.g., diagnoses, use of assistive equipment). The data elements we will receive will be associated with only a unique, encrypted identifier (detailed below) that will not be linkable with any personal identifiable information by the investigative/research team.

For (2) the Fidelity, Adoption, and Adaptation survey, the data elements will consist of information at the group home level. At the six time points mentioned above, we will ask all program directors to complete the Fidelity, Adoption, and Adaptation survey on behalf of the group home at which they work. The fidelity section will consist of questions that evaluate how well the group home has adhered to the assigned best practices for five intervention areas: screening, isolation, contact tracing, personal protective practices (PPP), and vaccination. For example, the fidelity section will ask program directors to report the proportion of residents and staff observed to have received the recommended type and frequency of screening.

The adoption section will include 12 questions on the acceptability, appropriateness, and feasibility of the assigned best practices. For example, we will ask program directors to score on a scale of 1 to 5 how suitable the assigned best practices seem for the group home. The adaptation section will include 9 questions where program directors can describe any adaptations they have made to the assigned best practices.

We will also send the same fidelity survey to a second staff member at an equivalent level of the program director within the same group home (e.g., group home nurses). The purpose of this second fidelity survey will be to measure the intra-rater reliability of fidelity measures within the same group home. If we have ≥ 80% concordance between two raters in the first 10% of group homes surveyed, we will stop the second survey collection. If the concordance is < 80%, we will continue to measure intra-rater reliability, using the same process above, until concordance is ≥ 80% or until all group homes are surveyed again, whichever comes first. Re-training of TBP may occur between time points if concordance is < 80% and areas for improvement are identified by our research team. Prior to February 2022, participants will receive a $5 gift card for their participation, and beginning in February 2022, participants will receive a $10 gift card for their participation. For the 12-month and 15-month follow-up Fidelity surveys (beginning in May 2022), we will implement a raffle process wherein all respondents will be entered into the raffle to win one of three $50 gift cards in addition to the $10 they will receive for completing the survey. Community research staff at Vinfen and community-based project managers will distribute all cards to protect identities from the MGH research team. As described above, for (2) these data elements will be linked to the group home, which will be identified with only a unique, encrypted identifier (detailed below).

For (3) the Needs Assessment Questionnaire, the data elements collected will be at the individual resident and staff levels. All residents, staff, and legal guardians who consent will

complete the Needs Assessment questionnaire over a 2-4 week period at the two time points mentioned above. Where applicable, verbal, written, or electronic consent will be first obtained from legal guardians of residents before obtaining residents' assent and administering the questionnaire to the residents. The content of the questionnaire has been agreed on between MGH researchers and stakeholders. This set of questions is brief (~20 questions) and covers three subject areas: (1) knowledge and reported use of COVID-19 protective practices; (2) vaccine acceptance and (for refusers) reasons for hesitancy/refusal; and (3) mental health, physical health, social support, and vocational secondary impacts of COVID-19. For example, respondents may be asked to select from a list the reasons they declined vaccination. We have worked with stakeholders to adapt the questionnaire so that it is accessible for the ID/DD residents. The ID/DD resident version has now been submitted as an amendment to this protocol. The legal guardian version is abbreviated, containing only questions relating to vaccines. De-identified data from this needs assessment will help to inform refinement of the Tailored Best Practices intervention and will also be provided to the provider organizations to support setting program priorities and planning.

The Needs Assessment questionnaire data will be collected using REDCap or on paper (to accommodate participants' needs). **For those completing the questionnaire on-line**, individual survey links will be e-mailed to the staff, residents, and legal guardians by the provider organizations who will also provide the individual study IDs. Survey responses will be directly submitted back to the MGH research team. **For those completing the questionnaire on paper**, provider organizations will distribute paper copies of the survey and provide the individual study IDs. Deidentified survey responses will be handed or mailed directly to the community research staff at Vinfen for the purposes of providing remuneration. The community research staff at Vinfen will not see any responses, and after remuneration has been provided, they will hand-deliver the deidentified paper surveys to the MGH research team.

The provider organizations will not have access to the individual responses. No PHI data will be collected. No individual-level data will be shared with the provider organizations, although overall summary statistics across group homes may be shared for quality improvement. Our community partners will assist in the scheduling of online secure Zoom sessions to provide support for questionnaire administration as needed, and they will handle all identifying information for participants. Partners researchers who provide assistance in administering the Needs Assessment questionnaires will do so virtually and will only know the first name of participants. There will be no audio or video recording involved in the questionnaire administration. Participants will receive a $10 gift card for their participation; community research staff at Vinfen and community-based project managers will distribute the cards to protect identities from the MGH research team. If needed, we will provide tablets to our community partners pre-programmed with the questionnaire.

For (3) the Needs Assessment Questionnaire, all residents and staff will be identified with only a unique, encrypted identifier (detailed below) that will not be linkable with any personal identifiable information by the investigative/research team. Where applicable, all legal guardians will be identified using the unique, encrypted identifier of their ward.

Consistent with hybrid effectiveness-implementation trials, there are co-primary outcomes: a primary effectiveness outcome and a primary implementation outcome.

The primary effectiveness outcome is new COVID-19 group home incidence (new laboratory-confirmed COVID-19 cases among residents and staff). Secondary effectiveness outcomes are rates of hospitalization and mortality.

The primary implementation outcome is Best Practices Fidelity measured by the COVID-19 Best Practices Fidelity Measure developed for this project and refined with input from stakeholders (uploaded as an attachment to this IRB submission) consisting of fidelity to COVID best practices (e.g., number of staff and residents participating in recommended screening, isolating, contact tracing, PPP protocols, and vaccination interventions by staff and residents of the group homes). Of note, measuring implementation fidelity as the primary outcome provides a test of the effectiveness of TBP vs. GBP independent of the incidence of new cases over the 15-month project if rates of new COVID-19 happen to sharply decline due to temporal trends or a vaccine. Secondary implementation outcomes (informed by the RE-AIM implementation framework) include the following: staff and resident Best Practices Adoption (Acceptability, Appropriateness, and Feasibility Measures); Reach (% of homes using TBPs with 80% fidelity); and Maintenance (% of homes maintaining 80% fidelity over the 15-month study period).

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

N/A. This study does not involve treatment or diagnosis.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

This proposal involves a cluster-randomized trial design where Tailored Best Practices (TBP) and Generic Best Practices (GBP) will be delivered within each agency as part of routine training activities. TBP sites will receive coaching specific to the setting, staff, and residents.

The primary risk is the potential loss of confidentiality. However, we will implement several existing security structures described below to minimize this risk and will only present aggregated data.

All COVID-monitoring data, Fidelity, Adoption, and Adaptation survey data, and Needs Assessment questionnaire data received from provider organizations during this study will exclude personal identifiable information (PII) and we will limit protected health information (PHI) to the minimum necessary to attain the project goals to assess the implementation and

effectiveness of TBP compared to GBP in five prevention pillars (i.e., screening, isolation, contact tracing, use of PPP, and vaccination).

To protect against loss of confidentiality, in all datasets, sites and subjects will be assigned an encrypted study identifier that is distinct from other identifying information. Through identifier and PHI multilayered blinding, data transferred to MGH will thus be deidentified. Each of the 6 provider organizations will be assigned a letter or number series that cannot be used to easily identify them. Vinfen, as a primary collaborating provider organization, will hold the organizational key used to identify each organization. Each provider organization will keep their own key for identifying homes, staff, and residents. For purposes of presentation and publication, data will be presented in aggregate form with no cells with fewer than 10 subjects. All data will be transmitted from the provider organizations to Massachusetts General Hospital using a secure e-mail portal and then stored behind the Massachusetts General Hospital firewall in a password-protected folder on a shared research drive. Data will not be stored on removable devices (e.g., laptops, external drives), and no persons outside of the study team will have access. In addition to security measures (e.g., password protection of files, encoded identifiers, network firewalls, and locked, magnetic card secured work premises), investigators and staff are required to be CITI certified in Human Subjects Research and sign a confidentiality agreement. Data will be transferred to MGH via secure file transfer or through REDCap.

Individuals will receive standard of care for general best practices for COVID-19 prevention in the GBP arm and no less than that strategy in the TBP arm. We will convene an independent group of experts in a Data Safety Monitoring Board (DSMB) to meet at 9 months into the trial to review the interim analysis of outcomes and at 15 months into the trial. The DSMB will monitor the recruitment status, adverse events, and follow-up rates and advise the study and make recommendations on continuation, modification, or termination of the trial (e.g., early stopping rules). In the event that the interim 9-month follow-up analysis reveals a highly clinically and statistically significant difference in COVID incidence and related adverse outcomes between TBP and GBP, the DSMB will determine if the trial should be halted and if all sites should receive TBP. In the event of this determination, we will continue to collect scheduled follow-up data at the predetermined points in time and conduct appropriate subsequent pre-post analyses.

Any risks from administering the Needs Assessment questionnaire are minimized by engaging residents in settings that are familiar to them. Administration will be conducted by trained clinicians and researchers.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

We request a waiver of written consent from residents and staff for COVID-monitoring data because we will receive only limited data sets with no transfer of individually identifiable data from participating provider organizations to MGH investigators. This data will be sent to

Partners researchers through the Partners Secure File Transfer Service (PSFTS). We will implement a process (detailed below) to ensure proper handling and transfer of protected health information (PHI) in the limited data sets from the provider organizations to Partners researchers.

Partners researchers will not have any contact with program directors, and there is no PHI data collected as part of the survey, so completion of the Fidelity, Adoption, and Adaptation survey by program directors will imply consent. The fidelity survey data will be collected using REDCap. Individual survey links will be e-mailed to the group home managers by the provider organizations who will also provide the group home study IDs. Survey responses will be directly submitted back to the MGH research team. The provider organizations will not have access to the individual responses. No PHI data will be collected as part of the fidelity survey. The introduction to the survey will inform program directors that no individual-level group home data will be shared with the individual's employer (provider organization), although overall summary statistics across group homes may be shared for quality improvement.

The major risk to participants who complete the Needs Assessment questionnaire will be discomfort with the questions. Study recruitment materials and the preamble to the questionnaire inform participants that they can refuse to answer any questions and can terminate the questionnaire at any time. For residents who have legal guardians, a legal guardian will provide verbal, written, or electronic consent to participate, and verbal assent will be gathered from the resident by group home staff before administering the questionnaire. The decision to complete the Needs Assessment questionnaire by Frontline Staff will imply consent. The decision to complete the Needs Assessment questionnaire by legal guardians will imply consent.

All potential participants will be informed that neither their names nor the name of their group home or agency will be included in any published reports and that their identities will remain confidential with agency and state leadership.

Agency directors will provide written consent for their sites to be included in the study.

To protect against loss of confidentiality, in all datasets, sites and subjects will be assigned an encrypted study identifier that is distinct from other identifying information. Through identifier and PHI multilayered blinding, data transferred to MGH will thus be deidentified. Each of the 6 provider organizations will be assigned a letter or number series that cannot be used to easily identify them. Vinfen, as a primary collaborating provider organization, will hold the organizational key used to identify each organization. Each provider organization will keep their own key for identifying homes, staff, and residents. For purposes of presentation and publication, data will be presented in aggregate form with no cells with fewer than 10 subjects. All data will be transmitted from the provider organizations to Massachusetts General Hospital using a secure e-mail portal and then stored behind the Massachusetts General Hospital firewall in a password-protected folder on a shared research drive. Data will not be stored on removable devices (e.g., laptops, external drives), and no persons outside of the study team will

have access. In addition to security measures (e.g., password protection of files, encoded identifiers, network firewalls, and locked, magnetic card secured work premises), investigators and staff are required to be CITI certified in Human Subjects Research and sign a confidentiality agreement. Data will be transferred to MGH via secure file transfer or through REDCap. Specifically regarding the Needs Assessment questionnaires, facilities will manage recruitment and MGH researchers will not know the full names of participants.

FORESEEABLE RISKS AND DISCOMFORTS

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

The primary risk to subjects is the potential loss of confidentiality, which we believe is minimal given the security measures we have in place for data transmission.

EXPECTED BENEFITS

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.

The intent is that subjects in group homes randomized to receive the Tailored Best Practices intervention package (TBP) will experience reduced rates of COVID-19 incidence, hospitalization, and mortality. Subjects in group homes randomized to receive Generic Best Practices (GBP) will not receive any personal health benefits as a result of participation.

This study will advance knowledge on the comparative effectiveness of different strategies and implementation approaches for preventing COVID-19, morbidity, and mortality in high-risk congregate living environments for staff and people with SMI and IDD/DD. Additionally, this study will help determine if the additional effort entailed in implementing TBP and the associated training and coaching result in better outcomes and warrant system-wide dissemination. This study could also contribute to knowledge on COVID-19 prevention for future infectious disease outbreaks in these settings.

EQUITABLE SELECTION OF SUBJECTS

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

It is expected that the recruited sample will resemble the racial/ethnic composition of the general population of congregate living facilities in MA. Children will be excluded. No groups of persons will be categorically excluded from the study.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

N/A. People who do not speak English are not categorically excluded from the study. Upon IRB approval, we will obtain certified translations of all study materials into Spanish and Haitian Creole. We will then submit the translated materials and the documents with the certification of translation to the IRB as an amendment.

For guidance, refer to the following Partners policy:
Obtaining and Documenting Informed Consent of Subjects who do not Speak English
http://healthcare.partners.org/phsirb/nonengco.htm

RECRUITMENT PROCEDURES

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

Participants for the Needs Assessment questionnaires will include frontline staff, residents with SMI and ID/DD at congregate living settings, and (where applicable) legal guardians of residents. The Chief Executive Officers (CEOs) of the 6 community provider organizations have expressed their willingness to participate in this study and each provided a letter of support for the proposal.

Before completing each questionnaire, all staff, residents, and legal guardians will receive a recruitment letter and fact sheet explaining the study and containing all information necessary to consent to participate. For individuals whose participation requires consent from a legal guardian (consistent with provider organization policies and compliant with EOHHS requirements), the Vinfen implementation team will partner with the provider organizations to send a recruitment letter and fact sheet to the legal guardian and obtain consent via e-mail or postal mail. The community research staff at Vinfen and community-based project managers may also call legal guardians to obtain verbal consent for the resident's participation. All phone calls will follow an IRB-approved script. A final assent will be gathered from the participant by group home staff at the start of the questionnaire.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

Participants in the Needs Assessment questionnaire will receive remuneration in the amount of $10 after each completion of the questionnaire. If a participant completes both questionnaires, this will amount to a total of $20.

Prior to February 2022, participants completing the fidelity survey will receive remuneration in the amount of $5 after each completion of the survey. The baseline, 3-month, and 6-month-follow-up time points occur prior to February 2022. Beginning in February 2022, participants completing the fidelity survey will receive remuneration in the amount of $10 after each completion of the survey. The 9-month, 12-month, and 15-month-follow-up time points occur after January 2022. If a participant completes all six surveys, this will amount to a total of $45, as participants receive $5 each for the first 3 surveys and $10 each for the last 3 surveys. For the 12-month and 15-month follow-up Fidelity surveys (beginning May 2022), we will implement a raffle process wherein all respondents will be entered into the raffle to win one of three $50 gift cards in addition to the $10 they will automatically receive for completing the survey. The first pull for a $50 gift card will occur 2.5 weeks into the survey period, including all respondents who have completed the survey up to that point. The second pull for a $50 gift card will occur 5 weeks into the survey period, again including all respondents who have completed the survey up to that point. The third and final pull for a $50 gift card will occur after the survey period has concluded, including all respondents who completed the survey. This design allows respondents who complete the survey within the first 2.5 weeks to have three opportunities to win a $50 gift card; those who complete the survey after the first 2.5 weeks but within the first 5 weeks will have two opportunities to win a $50 gift card; and those who complete the survey after 5 weeks will have one opportunity to win a $50 gift card. This raffle process will be run by community research staff at Vinfen, as they will be responsible for remuneration, as described below.

For all surveys and questionnaires completed in REDCap: The last page of the survey in REDCap will give participants the opportunity to specify how they would like to receive their gift card: via e-mail or (for residents and staff only) in-person. The participant must then provide contact information (their e-mail address or the physical address of their group home) to receive remuneration. The survey responses will automatically go to MGH, and the contact information will automatically go to community research staff at Vinfen. This way, no researchers will be able to link the responses to the contact information. If a participant chooses to receive the gift card via e-mail, community research staff at Vinfen and community-based project managers will send an electronic gift card to the provided e-mail address. If a participant chooses to receive the gift card in-person (only available for residents and staff), the community research staff at Vinfen and community-based project managers will deliver a

physical gift card to the participant at their group home. If the participant is not present at the time of delivery, the gift card will be delivered in a sealed envelope to the participant's mailbox.

For all resident and staff questionnaires completed on paper: We will provide each group home with a log to track who has completed the questionnaire on paper. This log will have a space for participants to specify how they would like to receive their gift card: via e-mail or in-person. The participant must also provide their contact information (their e-mail address or the physical address of their group home) to receive remuneration. If members of the study team are unable to hand-deliver the paper surveys to the group home, group home staff (who will have been trained to respect residents' autonomy and confidentiality regarding the questionnaire, as described below) will work with residents to assemble a package and send the package to community research staff at Vinfen via postal mail. The package will contain: 1) all completed, de-identified paper questionnaires and 2) a sealed envelope containing the log sheet. Community research staff at Vinfen will keep the sealed envelope containing the log sheet and give the de-identified questionnaires to MGH researchers. This way, no researchers will be able to link the responses to the contact information. If a participant chooses to receive the gift card via e-mail, community research staff at Vinfen and community-based project managers will send an electronic gift card to the provided e-mail address. If a participant chooses to receive the gift card in-person, the community research staff at Vinfen and community-based project managers will deliver a physical gift card to the participant at their group home. If the participant is not present at the time of delivery, the gift card will be delivered in a sealed envelope to the participant's mailbox.

For all legal guardian questionnaires complete on paper: We will provide each legal guardian with a form where they can provide their e-mail address to receive remuneration. Legal guardians will assemble a package and send the package to community research staff at Vinfen via postal mail. The package will contain: 1) the de-identified paper questionnaire and 2) a sealed envelope containing the remuneration form (and the consent form for their ward's participation in the Needs Assessment). Community research staff at Vinfen will keep the sealed envelope containing the remuneration form and the consent form and give the de-identified questionnaires to MGH researchers. This way, no researchers will be able to link the responses to the contact information. Community research staff at Vinfen and community-based project managers will send an electronic gift card to the provided e-mail address.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects
http://healthcare.partners.org/phsirb/recruit.htm

Guidelines for Advertisements for Recruiting Subjects
http://healthcare.partners.org/phsirb/advert.htm

Remuneration for Research Subjects
http://healthcare.partners.org/phsirb/remun.htm

CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

This study is a cluster-randomized trial design where TBP and GBP will be delivered within each agency as part of routine training activities.

Agency directors will provide written consent for their sites to be included in the study.

We request a waiver of written consent from residents and staff for COVID-monitoring data because we will receive only limited data sets with no transfer of individually identifiable data from participating provider organizations to MGH investigators.

Partners researchers will not have any contact with program directors, and there is no PHI data collected as part of the survey, so the decision to complete the Fidelity, Adoption, and Adaptation survey by program directors will imply consent.

For the Needs Assessment questionnaires, each time the questionnaires are administered, all staff, residents, and legal guardians will receive a recruitment letter and fact sheet explaining the study and containing all information necessary to consent to participate.

Frontline Staff Consent: Partners researchers will not have any contact with Staff participants, and there is no PHI data collected as part of the questionnaire, so the decision to complete the Needs Assessment questionnaire by Frontline Staff will imply consent.

Resident Consent or Consent from Legal Guardian for Resident: MGH researchers, community research staff at Vinfen, and community-based project managers will train group home staff to administer the survey to residents in a way that respects residents' autonomy and privacy. This training will specifically emphasize that: 1) a resident's decision to participate or not is completely voluntary and staff may not pressure residents in any way and 2) if a resident chooses to participate, the resident should feel free to respond to questions however they want and not feel pressure from staff to respond in a specific way. For residents whose participation requires consent from a legal guardian (consistent with provider organization policies and compliant with EOHHS requirements), the Vinfen implementation team will partner with the provider organizations to send a recruitment letter and fact sheet to the legal guardian and obtain electronic or written consent (yes/no) via e-mail or postal mail. <u>If the legal guardian is contacted by e-mail</u>, an on-line form will be included in a secure REDCap link where the legal guardian can provide electronic consent for their ward's participation. The completed electronic consent form will go directly to community research staff at Vinfen. <u>If the legal guardian is contacted by postal mail</u>, a paper form will be included where the legal guardian can

provide written consent for their ward's participation. The completed consent form will be sent by the legal guardian to community research staff at Vinfen via postal mail. The community research staff at Vinfen and community-based project managers may also call legal guardians to obtain verbal consent for the resident's participation. All phone calls will follow an IRB-approved script. Community research staff at Vinfen and community-based project managers will be responsible for documenting and tracking consent from guardians. For residents who remain eligible (i.e., excluding residents whose legal guardians did not explicitly provide consent), a group home staff member will go through the fact sheet with the resident and answer any questions. The staff member will ask the resident if they would like to complete the questionnaire, emphasizing that their participation is completely voluntary. If the resident provides verbal consent (or assent, if there is a legal guardian) to participate, the staff member will provide the resident with a link to the on-line questionnaire or a paper copy of the questionnaire. Residents who are non-verbal will provide consent (or assent if there is a legal guardian) using their preferred communication strategy (i.e., Yes/No from Augmentative Communication Device or Communication Board). This consent (or assent if there is a legal guardian) via device will serve as the individual's "verbal consent". Group home staff may assist in setting residents up at a computer in a private location in the house. Group home staff will be available to the resident for technical and logistical assistance while they complete the questionnaire, but they will not pressure or influence the resident's questionnaire responses in any way. The resident may ask group home staff to assist in setting up a Zoom call with community research staff at Vinfen, community-based project managers, or MGH researchers. If a member of the community research staff at Vinfen is present at the group home for study activities, they may assist the resident in person upon request. In the event that a group home resident has significant cognitive disabilities and judged by the group home director to be unable to complete the questionnaire questions (even when assisted), it will be up to the discretion of the group home director to determine if the individual is not able to participate. The provider organization will also document reasons for non-participation, when applicable.

We will take a number of precautions to prevent residents with legal guardians from mistakenly completing the survey without guardian consent. We will complete all guardian outreach prior to distributing surveys to residents. After guardian outreach has been completed, each group home will receive a packet that contains: an instruction sheet, a recruitment letter, a fact sheet, surveys, and a log sheet. The log sheet will be preprinted to only include the names of residents who have the necessary consent to complete the survey with a checkbox next to each name to indicate if they completed the survey or not. There will be no spaces on the log sheet to add additional names. This will inform group home staff who can complete the survey and discourage them from adding additional names. The list of names on the log sheet will be verified by two members of the community research staff at Vinfen prior to survey distribution to ensure that only those with the appropriate consent are on the sheet. Each survey will have a cover sheet on which the respondent's name will be preprinted. In the unlikely event that a resident completes the survey without the necessary consent, this will allow us to isolate the survey and retain those completed with the necessary consent. This should also make it extremely clear to group home staff which residents should receive a survey. When possible, community-based project managers and Implementation Coaches will hand deliver these

packets to the group homes and be present while residents complete the survey, ensuring that only those with the necessary consent receive a survey. They will then collect all surveys and the log sheet in exchange for gift cards (receipts will be signed for gift cards) and deliver them to community research staff Vinfen. If a project manager or Implementation Coach is unable to hand-deliver a packet, they will mail the packet to the group home. Shortly after delivery, the project manager and Implementation Coaches will call the group home's program director to confirm they have received the package, understand the instructions, and know which residents may take the survey. Group home staff will be instructed to use the log sheet to verify which residents are eligible to complete the survey prior to distributing surveys. Group home staff who are less familiar with the residents (e.g., temp staff) will also be instructed to verify the resident's name with the resident prior to giving them the labeled survey. Group home staff will check off the boxes on the log sheet next to the names of the residents who completed the survey. The group home staff will mail the completed surveys and the log sheet directly to the community research staff at Vinfen. Upon receiving the packets, community research staff at Vinfen will look at the cover sheet attached to each survey and verify that the resident had the necessary consent. They will then remove the cover sheet from the survey and hand-deliver the now-deidentified survey to MGH. In the unlikely event that a resident completes the survey without the necessary consent, Vinfen will discard the isolated survey.

Legal Guardian Consent: At the same time that legal guardians are asked to consent to allow their ward to participate in the Needs Assessment, we will also ask the legal guardians to complete a shortened version of the Needs Assessment that focusses exclusively on vaccines. Partners researchers will not have any contact with legal guardian participants, and there is no individually identifiable data collected as part of the questionnaire, so the decision to complete the shortened Needs Assessment questionnaire on vaccines by legal guardians will imply consent.

The fact sheet will be provided each time the individual is invited to complete the questionnaire and includes the statement that participants can withdraw at any time during the study. During informed consent administration, we shall inform participants that they can refuse to answer any questions and can terminate the questionnaire at any time. All potential participants will be informed that their names and the name of their group home or agency will not be collected and will not be included in any published reports and that their identities will remain confidential with agency and state leadership. Failure to participate in the questionnaire will not affect the services the potential subject receives from DMH and/or DDS or their provider organization now or in the future. Failure to participate in the questionnaire also will not affect any benefits the potential subject receives now or has a right to receive.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:
http://healthcare.partners.org/phsirb/newapp.htm#Newapp

For guidance, refer to the following Partners policy:
Informed Consent of Research Subjects
http://healthcare.partners.org/phsirb/infcons.htm

DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

All data will be stored on secure servers at each provider organization and Massachusetts General Hospital and will not leave the performance sites; data will not be stored on removable devices (e.g., laptops, external drives), and no persons outside of the study team will have access. In addition to security measures (e.g., password protection of files, encoded identifiers, network firewalls, and locked, magnetic card secured work premises), investigators and staff are required to be CITI certified in Human Subjects Research and sign a confidentiality agreement.

We will convene an independent group of experts in a Data Safety Monitoring Board (DSMB) to meet quarterly for the duration of the trial. The DSMB will monitor the recruitment status, adverse events, and follow-up rates and advise the study and make recommendations on continuation, modification, or termination of the trial (e.g., early stopping rules). As required by PCORI, we will provide preliminary findings within the first year of the study. In the event that the interim 9-month follow-up analysis reveals a highly clinically and statistically significant difference in COVID incidence and related adverse outcomes between TBP and GBP, the DSMB will determine if the trial should be halted and if all sites should receive TBP. In the event of this determination, we will continue to collect scheduled follow-up data at the predetermined points in time and conduct appropriate subsequent pre-post analyses.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

The PI and co-PI are responsible for routine monitoring of the progress of the research to assure that all project members are familiar and comply with human subjects protection. The PI and co-PI will assure that all research team members comply with federal regulations with respect to the protection of human subjects. A member of the study team will be responsible for tracking and reporting unanticipated events. We will convene an independent group of experts (DSMB) to meet quarterly for the duration of the trial. The DSMB will monitor the recruitment status, adverse events, and follow-up rates and advise the study and make recommendations on continuation, modification, or termination of the trial (e.g., early stopping rules).

MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

The PI and co-PI are responsible for routine monitoring of the progress of the research to assure that all project members are familiar and comply with human subjects protection. The PI and co-PI will assure that all research team members comply with federal regulations with respect to the protection of human subjects. A member of the study team will be responsible for tracking and reporting unanticipated events.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance
http://healthcare.partners.org/phsirb/datasafe.htm

Adverse Event Reporting Guidelines
http://healthcare.partners.org/phsirb/adverse_events.htm

PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data;

use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.

NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

To protect against loss of confidentiality, in all datasets, group homes (i.e., sites) and participants will be assigned an encrypted study identifier that is distinct from other identifying information. Through identifier and PHI multilayered blinding, data transferred to MGH will thus be deidentified. Each of the 6 provider organizations will be assigned a letter or number series that cannot be used to easily identify them. Vinfen, as the primary collaborating provider organization, will hold the organizational key used to identify each organization. Each provider organization will keep their own key for identifying homes, staff, and residents. The keys will not be shared with MGH investigators and will be destroyed at the earliest opportunity. For purposes of presentation and publication, data will be presented in aggregate form with no cells with fewer than 10 subjects. All data will be transmitted from the provided organizations to Massachusetts General Hospital using a secure e-mail portal and then stored behind the Massachusetts General Hospital firewall in a password-protected folder on a shared research drive. Data will not be stored on removable devices (e.g., laptops, external drives), and no persons outside of the study team will have access. In addition to security measures (e.g., password protection of files, encoded identifiers, network firewalls, and locked, magnetic card secured work premises), investigators and staff are required to be CITI certified in Human Subjects Research and sign a confidentiality agreement. Data will be transferred to MGH via secure file transfer or through REDCap.

For COVID-monitoring data, we will enter into data use agreements with each of our community partners prior to receiving the limited data sets, as required by section 164.514(e) of the Privacy Rule. The data manager and program coordinator at MGH will then organize a security awareness training with the program managers at the provider organizations to ensure proper handling and transfer of protected health information (PHI) from the provider organizations to Partners researchers. The training will cover the importance of sharing PHI-data exclusively through the Partners Secure File Transfer Service (PSFTS); directions on how to share files through PSFTS; a description of what qualifies as PHI and which PHI is permitted to be shared with Partners researchers for this project; and instructions on how to assess files for breaches in PHI protocol prior to transferring to MGH. After completing this training, the following steps will be taken:

1. Prior to sharing files with Partners researchers, provider program managers will conduct a detailed assessment of the files to ensure compliance with PHI restrictions.
2. Provider program managers will first send the files (which should already be compliant with PHI restrictions) to our community research partners at Vinfen, who will perform an additional assessment to ensure compliance with PHI restrictions. Vinfen and the other provider organizations already have Business Associate Agreements (BAAs) in place to allow this data transfer.

3. Data files will then be transferred from Vinfen to Partners researchers through the Partners Secure File Transfer Service (PSFTS).
4. On receipt of new Data Files, the study Data Manager at MGH will confirm compliance with PHI restrictions by reviewing the files for PHI on an encrypted computer. No data will be shared to others on the research team until this data review process has been conducted. Once full compliance has been confirmed, the files will be uploaded to a secure Dropbox folder for data analysis by IRB approved investigators and staff.
5. In the event that the Data Manager review determines that restricted PHI has been erroneously sent by the provider organizations to Partners researchers, the data manager will immediately delete the sensitive information and notify the provider organization and IRB. The data manager will then contact the provider program manager to establish a corrective plan for data review to ensure that the future data transfer process has fully removed restricted PHI before transfer.

Regarding the Needs Assessment questionnaires, informant identities will be known only by community partners who will recruit participants within their own organizations. Identifying information will be maintained for 7 years after the completion of the data collection (as required by PCORI) and then destroyed. All notes and records will be kept on Partners encrypted devices to assure the privacy and security of the data.

SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects

Mass General Brigham (MGB) researchers will be sharing all data collected as part of this study (i.e., secondary data from provider organizations, Fidelity survey data, and Needs Assessment survey data) with the Inter-University Consortium for Political and Social Research (ICPSR) at the University of Michigan, as required by the Patient-Centered Outcomes Research Institute (PCORI), who funds this study. PCORI requires that MGB researchers systematically create and preserve the confidential data that was generated from the project in a repository to facilitate data sharing. The project data is being sent to ICPSR on a non-exclusive basis for the purpose of allowing its Archive to examine and process the materials according to standard Archive practices and making the project data available to researchers at other institutions.

All data shared from this study will exclude personal identifiable information (PII) and we will limit protected health information (PHI) to the minimum necessary to attain the project goals. All group homes, staff, and clients will be identified with only a unique, encrypted identifier (detailed above) that will not be linkable with any personal identifiable information by the outside collaborators. The only PHI collected is zip code of staff residence and group home. This data will be thoroughly cleaned prior to being stored in the repository.

MGB researchers will enter into a Restricted-Use Data Contributor agreement [file name: "PCORI Data Contributor Agreement_Skotko_11_1_21 (1)"] with the Regents of the University of Michigan on behalf of ICPSR prior to sharing any data.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

As mentioned above, all data collected as part of this study (i.e., secondary data from provider organizations, Fidelity survey data, and Needs Assessment survey data) will be stored in a data repository at ICPSR at the University of Michigan, as required by PCORI, who funds this study. All data in the repository will be de-identified in accordance with the HIPAA Privacy Rule (45 C.F.R. § 164.514(b)), so there will be no identifiable information stored in the repository, and subjects will not be able to withdraw their de-identified data.

RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

Data collected by research collaborators outside Partners sent to Partners investigators involves collection of baseline and follow-up data on COVID screening/testing, infection, hospitalizations, and deaths; fidelity and adoption of recommended best practices; and COVID care quality. All of the data will be collected by participating provider organizations from a community sample of 400 group homes within the 6 community provider organizations. No residents or staff will be individually identified in these data. In all datasets, sites and subjects will be assigned an encrypted study identifier that is distinct from other identifying information.

For all Needs assessment questionnaire participants, the use of identifiers will only be used by community partner organizations recruiting within their organization.

Data used for analysis will be identified with a study number only. Data transfer will be secured using the SEND SECURE protocol used by Partners Healthcare to transfer encrypted data files among collaborators only on an as-needed basis. We restrict access control by limiting user accounts to only those connected with our research. We are also vigilant in maintaining operating systems and programs by keeping current with security patches and closing off unneeded or insecure ports and services. Workstations and servers on the Partners Healthcare network are behind a firewall maintained by the Partners Network Security Team. Machines

can only be accessed from behind the firewall or through the Partners VPN service using either a pre-assigned digital certificate or an RSASecurID.