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1) Protocol Title

Promoting A School Culture of Safety in the era of COVID-19: Assessing Feasibility and Impact of a Health Education Initiative

2) Objectives*

The primary purpose of this study is to evaluate the feasibility and impact of a COVID-19 health initiative in at-risk urban school settings. This protocol is comprised of 3 components:

- **Part 1A**: Evaluating the feasibility and acceptability of a health education initiative in school health settings.
- **Part 1B**: Assessing COVID-19 knowledge and experience among caregivers of students in at-risk urban school settings post-intervention.
- **Part 1C:** Evaluating the impact of the health education initiative on vaccination rates and other health behaviors 3 months following the intervention.

The second purpose of this study is to compare COVID-19 knowledge, experiences, and health behaviors between participants who received the health initiative and those who did not (controls), through:

- **Part 2A**: Comparing COVID-19 knowledge, experience, and health behaviors of participants in the health education initiative to controls, immediately following the initiative.
- **Part 2B**: Comparing COVID-19 knowledge, experience, and health behaviors of participants in the health education initiative to controls, three months after the initiative.

3) Background*

Covid-19 has infected over 31 million individuals in the United States (CDC, 2021), over 3.54 million of whom were children (AAP, 2021). The pandemic has disproportionately affected racial/ethnic minorities, including children, in terms of infections, hospitalizations, and death (Lopez, Hart, & Katz, 2021; Van Dyke et al., 2021). Other sociodemographic risk factors such as household composition, socioeconomic status, limited English proficiency, housing type, and transportation are also associated with Covid-19 incidence and mortality (Karmakar, Lantz, & Tipireni, 2021).

To mitigate the spread of Covid-19, widespread school closures and shifts to online learning were enacted worldwide. School closures may have disproportionately affected children in low-resourced communities, English learners, and students with disabilities, due to lack of access to remote learning technology and fewer support services outside of school (CDC, 2021). Additionally, children may experience mental distress related to the pandemic and its sequalae, parental stress, risk of abuse and neglect, disruption of routine, and separation from friends (Imran, Zeshan, & Pervaiz, 2020).

Recent data show that there is minimal transmission of Covid-19 between students at schools adhering to safety protocols like masking (Zimmerman et al., 2021). Risks include community transmission, which should be assessed regularly to understand the burden of disease (CDC, 2021). Our own research of positive COVID cases in over 10,000 children in Miami-Dade County found a positivity rate of 11%. When comparing the positivity during the remote-only schooling time period vs. in-person/hybrid time period, the positivity rates dropped from 12.7% to 7.5% supporting the notion that opening schools in person did not increase COVID 19 spread in children. Yet still compared to non-Hispanic white, black Hispanic (aOR=2.53, 95%CI= 1.38-4.66) and white Hispanic (1.96, 1.63-2.37) participants in our sample had higher odds of being COVID-positive.

Though spread of COVID-19 is minimal in the school setting, it is important that vulnerable youth, their families, and school staff feel safe and maintain healthy behaviors, to

avoid absences or quarantine. The school community may therefore benefit from education on the importance of key strategies that stop the spread of Covid-19 – community mitigation and vaccination. The CDC's community mitigation framework includes healthy hygiene, staying home when sick, physical distancing, and use of face coverings (CDC, 2021b). Vaccines have been proven a safe and effective strategy for preventing Covid-19 infection (Thompson et al., 2021). Yet, both are met with mixed reactions by the public. Additionally, there are high rates of vaccine hesitancy among racial/ethnic minority populations, particularly Black Americans (Bunch, 2021; Nguyen et al., 2021).

In a previous study supported by this same funding source, we administered surveys and focus groups to ascertain the knowledge and concerns related to COVID-19 of parents, students (age 14+), and school staff in urban schools in Miami, Florida. Preliminary findings revealed several concerns among stakeholders related to COVID-19 testing and vaccination. Notable barriers identified during the focus groups included questionable information, mixed messages, politicized messages and mistrust. Concerns about the development of the COVID-19 vaccine and potential side effects of the vaccine was highlighted in both qualitative and quantitative data. Resoundingly, transparency about what is known and unknown about the COVID-19 illness and vaccine was emphasized across focus groups. Consideration of cultural beliefs and practices and their relation to health behaviors was also noted. Who delivers health-related information (e.g., healthcare worker, peers) was also noted as important. Preliminary examinations of cross-sectional measures further indicated that perceptions of trust among sources of information differed for students, parents, and school staff. Despite variations in perceived trust, the desire to keep oneself, their family, and their community safe was rated as a motivator for getting vaccinated for most participants.

We propose to incorporate the feedback from the previous study to design a COVID-19 health education initiative that fits the need and culture of the school communities in Miami. We are interested in learning whether attitudes and behaviors about COVID-19 change post intervention. Specially, we predict increased COVID-19 knowledge, increased self-efficacy, and increases in children's vaccination rates.

4) Inclusion and Exclusion Criteria*

Inclusion and exclusion criteria are the same for all components of this protocol.

Inclusion criteria:

(a) Parents/guardians of students enrolled in: Arch Creek Elementary, Fulford Elementary, Greynolds Park Elementary, Sabal Palm Elementary, North Miami Middle school, JFK Middle School, North Miami Senior High, North Miami Beach High, and Booker T. Washington High.

(b) Able to read and write in English, Spanish, or Creole at a 5th grade level

Exclusion criteria:

(a) Does not speak English, Spanish, or Creole.

(b) Under the age of 18.

5) Procedures Involved*

Arms	Assigned Interventions
Experimental: Health Education Initiative	Behavioral: Health Education Initiative

Participants will receive the health education session for up to 6 months.	Participants will receive a one time 45 minute intervention session. During the session participants will receive information regarding COVID-19 disease process and behavioral effects and had the opportunity to ask questions.
No Intervention: Control Group Participants in this group will not receive any health education and total participation is up to 6 months.	

Intervention Participants

Part 1A (Intervention participants only)

Overview: A health education initiative will be conducted one or more times at each intervention school (i.e., Arch Creek Elementary, Sabal Palm Elementary, JFK Middle, North Miami High, and Booker T. Washington High). This initiative will consist of a panel of health experts, individuals with firsthand experience, and other trusted messengers (e.g., teachers, student champions) presenting on the topic of COVID-19, health safety behaviors, and vaccination. Audience participation and questions will be solicited; content will be adjusted slightly to address each audience's priorities. The initiative may be recorded and made available to the broader school community to expand accessibility. The team will work with representatives from each school to determine the best method for distributing the initiative (e.g., social media). The recording will feature only the images of the panel, to protect the identity of participants.

Consent: To reduce undue burden on participants, we are requesting a waiver of written consent for this portion of the study (see the *Consent Process* section below for more details). Prior to beginning the health education initiative, participants will be provided with information about the study, including study procedures, potential risks/benefits of participation, voluntariness of the study, their right to withdraw, and contact information for the research team, and asked to complete a brief evaluation about the program. Participants will indicate their consent by completing the evaluation form.

Primary Outcome Measures: Participants can choose to complete the following measure immediately following the intervention:

- **Evaluation of acceptability of intervention as measured by Acceptability Questionnaire:** Participant satisfaction will be assessed via a brief survey evaluating the knowledge gained during the initiative, the value of session, their ability to apply and use information learned, and whether they would recommend the program. Upon completing the survey, participants will be given the option to be contacted in the future to complete an additional survey 3 months later. Demographic information will also be collected. Measure is attached to this protocol.

  - Scores range from 1 ("strongly disagree") to 5 ("strongly agree"), with higher scores indicating more knowledge, value, application, or satisfaction.
  - Time Frame: up to 6 months
- **Evaluation of confidence in COVID healthcare decision making as measured by COVID Confidence Questionnaire**
  - Scores range from 1 ("strongly disagree") to 5 ("strongly agree"), with higher scores indicating more knowledge, value, application, or satisfaction.
  - Time Frame: up to 6 months
- **Number of caregivers who received COVID-19 vaccine**
  - unit of measure number of caregivers
  - Time Frame: up to 6 months
- **Number of children who received COVID-19 vaccine**
  - unit of measure number of children
  - Time Frame: up to 6 months
- **Health behaviors as measured by Health Behavior Questionnaire**
  - Scores range from 1 ("strongly disagree") to 5 ("strongly agree"), with higher scores indicating greater intent to engage in health behaviors to prevent COVID-19.
  - Time Frame: up to 6 months

Part 1B

Overview: Following completion of the program evaluation, participants will be invited to complete a survey through a secure online data collection method (e.g., REDCap or Qualtrics) or via paper forms that assesses their COVID-19 knowledge and experience. If interested and eligible, participants will be given access to the online survey via a link sent by email, by scanning a QR code, by paper at the event, or may respond to the survey verbally over the phone or in-person, with a study staff member reading aloud questions and recording the participant's responses.

Informed Consent: Informed consent will be obtained electronically via REDCap (detailed below) or on paper, depending on internet availability and participant preference. During the consent process, participants will be given ample time to review study procedures and provided contact information for the research team should they have questions.

Measures: Participants will also be asked to complete the following measure immediately following the intervention:

COVID-19 Knowledge and Experience. COVID-19 knowledge and experience using items from the RADxUP common data elements and the PhenX Tookit (Hamilton et al., 2011). Data to be collected include basic demographic data, COVID-19 knowledge and attitudes, health risk beliefs, vaccine confidence, COVID-19 related stigma/discrimination, COVID-19 trauma, and COVID-19 anxiety. Measures are attached.

Specific Secondary Outcome Measures:

- **PTSD as measured by the University of California Los Angeles (UCLA) Brief COVID-19 Screen for Child/Adolescent Post Traumatic Stress Disorder (PTSD)**

- scores range from 0 to 4, higher scores indicate more symptoms of PTSD
- Time Frame: up to 6 months

- **COVID anxiety as measured by the Coronavirus Anxiety Scale**
  - scores range from 0 to 4, higher scores indicate more symptoms of COVID specific anxiety
  - Time Frame: up to 6 months

Part 1C

Overview: To assess the impact of the health education initiative on vaccination status and other health behaviors.

Consent: We are requesting a waiver of consent for the first section of Part C which is a few simple questions about the intervention. Informed consent will be obtained electronically via REDCap (detailed below), on paper, or verbally over the phone or in-person, with a study staff member reading aloud questions and recording the participant's responses. During the consent process, participants will be given ample time to review study procedures and provided contact information for the research team should they have questions.

Primary Outcome Measures: Participants will be asked to complete a few questions about the impact of the education session in the last 3 months. Measure is attached.

- **Number of caregivers who received COVID-19 vaccine**
  - unit of measure number of caregivers
  - Time Frame: up to 6 months
- **Number of children who received COVID-19 vaccine**
  - unit of measure number of children
  - Time Frame: up to 6 months
- **Health behaviors as measured by Health Behavior Questionnaire**
  - Scores range from 1 ("strongly disagree") to 5 ("strongly agree"), with higher scores indicating greater intent to engage in health behaviors to prevent COVID-19.
  - Time Frame: up to 6 months

If participants agree they will also be given the opportunity to complete the COVID-19 assessment battery offered in Part B for additional compensation:

COVID-19 Knowledge and Experience. COVID-19 knowledge and experience using items from the RADxUP common data elements and the PhenX Tookit (Hamilton et al., 2011). Data to be collected include basic demographic data, COVID-19 knowledge and attitudes, health risk beliefs, vaccine confidence, COVID-19 related stigma/discrimination, COVID-19 trauma, and COVID-19 anxiety. Measures are attached.

Specific Secondary Outcome Measures:

- **PTSD as measured by the University of California Los Angeles (UCLA) Brief COVID-19 Screen for Child/Adolescent Post Traumatic Stress Disorder (PTSD)**

- scores range from 0 to 4, higher scores indicate more symptoms of PTSD
- Time Frame: up to 6 months

- **COVID anxiety as measured by the Coronavirus Anxiety Scale**
  - scores range from 0 to 4, higher scores indicate more symptoms of COVID specific anxiety
  - Time Frame: up to 6 months

Control Participants

Part 2A

Overview*:* Control participants will be invited to complete a survey that assesses their COVID-19 knowledge and experience. The survey will be conducted through a secure online data collection method (e.g., REDCap or Qualtrics), paper, or verbally over the phone or in-person, with a study staff member reading aloud questions and recording the participant's responses . If interested and eligible, participants will be given access to the online survey via a link sent by email or by scanning a QR code. If preferred, they will be given the option to complete the survey verbally over the phone or in-person, or to complete it on paper. Control participants may be recruited from any of the study schools (i.e., intervention or control). They must not have participated in the intervention.

Informed Consent: Informed consent will be obtained electronically via REDCap (detailed below) or via paper forms. During the consent process, participants will be given ample time to review study procedures and provided contact information for the research team should they have questions.

Primary Outcome Measures*:* Participants will complete the following measures:

- **Number of caregivers who received COVID-19 vaccine**
  - unit of measure number of caregivers
  - Time Frame: up to 6 months
- **Number of children who received COVID-19 vaccine**
  - unit of measure number of children
  - Time Frame: up to 6 months
- **Health behaviors as measured by Health Behavior Questionnaire**
  - Scores range from 1 ("strongly disagree") to 5 ("strongly agree"), with higher scores indicating greater intent to engage in health behaviors to prevent COVID-19.
  - Time Frame: up to 6 months

- **COVID-19 Knowledge and Experience.** COVID-19 knowledge and experience using items from the RADxUP common data elements and the PhenX Tookit (Hamilton et

al., 2011). Data to be collected include basic demographic data, COVID-19 knowledge and attitudes, health risk beliefs, vaccine confidence, COVID-19 related stigma/discrimination, COVID-19 trauma, and COVID-19 anxiety. Measures are attached.

Specific Secondary Outcome Measures:

- **PTSD as measured by the University of California Los Angeles (UCLA) Brief COVID-19 Screen for Child/Adolescent Post Traumatic Stress Disorder (PTSD)**
  - scores range from 0 to 4, higher scores indicate more symptoms of PTSD
  - Time Frame: up to 6 months
- **COVID anxiety as measured by the Coronavirus Anxiety Scale**
  - scores range from 0 to 4, higher scores indicate more symptoms of COVID specific anxiety
  - Time Frame: up to 6 months
-

Part 2B

Overview: Control participants will be invited to complete a follow-up survey that assesses their COVID-19 knowledge and experience approximately three months following the initial survey. The survey will be conducted through a secure online data collection method (e.g., REDCap or Qualtrics), on paper, or verbally over the phone or in-person, with a study staff member reading aloud questions and recording the participants' responses . If interested and eligible, participants will be given access to the online survey via a link sent by email, by scanning a QR code. If preferred, they will be given the option to complete the survey verbally over the phone or in-person, or to complete it on paper.

Informed Consent: Informed consent will be obtained electronically via REDCap (detailed below) or on paper. During the consent process, participants will be given ample time to review study procedures and provided contact information for the research team should they have questions.

Primary Outcome Measures*:* Participants will complete the following measures:

- **Number of caregivers who received COVID-19 vaccine**
  - unit of measure number of caregivers
  - Time Frame: up to 6 months
- **Number of children who received COVID-19 vaccine**
  - unit of measure number of children
  - Time Frame: up to 6 months
- **Health behaviors as measured by Health Behavior Questionnaire**
  - Scores range from 1 ("strongly disagree") to 5 ("strongly agree"), with higher scores indicating greater intent to engage in health behaviors to prevent COVID-19.
  - Time Frame: up to 6 months

- **COVID-19 Knowledge and Experience.** COVID-19 knowledge and experience using items from the RADxUP common data elements and the PhenX Tookit (Hamilton et al., 2011). Data to be collected include basic demographic data, COVID-19 knowledge and attitudes, health risk beliefs, vaccine confidence, COVID-19 related stigma/discrimination, COVID-19 trauma, and COVID-19 anxiety. Measures are attached.
  Specific Secondary Outcome Measures:

  - **PTSD as measured by the University of California Los Angeles (UCLA) Brief COVID-19 Screen for Child/Adolescent Post Traumatic Stress Disorder (PTSD)**
    - scores range from 0 to 4, higher scores indicate more symptoms of PTSD
    - Time Frame: up to 6 months
  - **COVID anxiety as measured by the Coronavirus Anxiety Scale**
    - scores range from 0 to 4, higher scores indicate more symptoms of COVID specific anxiety
    - Time Frame: up to 6 months

Compensation
Participants and champions will be issued a Greenphire ClinCard, a reloadable debit card that can be used for studies at the University of Miami. Funds will be loaded on the card according to the payment schedule. The study staff will provide information about how the card works. The company administering the card, Greenphire, requires name, address and date of birth entered online for payment; mobile phone number and/or email address are optional for study related communications. This information will only be used for payment and communication purposes and will not be given to another company or linked to any of the study data. If participants are hesitant to enroll in the study due to requirements for payment with ClinCard, they may be offered a gift card as an alternative.

6) Data and Specimen Banking*
N/A

7) Data Management*

Part 1A: Evaluating the feasibility and acceptability of a health education initiative in school health settings. Post-attendance surveys will be summarized and described by school.
Part 1B: Assessing COVID-19 knowledge and experience among caregivers of students in at-risk urban school settings post-intervention.
Part 1C: Evaluating the impact of the health education initiative on vaccination rates and other health behaviors 3 months following the intervention. Three month post surveys will be summarized and described by school. Assessing COVID-19 knowledge and experience among caregivers of students in at-risk urban school settings 3 months post-intervention.

Part 2A & 2B: Mixed models will be used to examine change in knowledge over time (repeated measure) among participants who have participated in the education session, compared to those who haven't. Likewise, vaccine confidence will be analyzed with a mixed

model to examine change over time, compared to those who did not participate in the education session.

8) Risks to Subjects*

The potential risks in this study are minimal. It is possible some subjects may experience discomfort while responding to questions about COVID-19. However, we incorporated stakeholder feedback on most acceptable methods (i.e., culturally sensitive, addressing their concerns) to discuss COVID-19 testing, diagnosis, and vaccination with participants, to minimize discomfort.

9) Potential Benefits to Subjects*

Participants may gain knowledge about how to maintain health and safety during the era of COVID-19. However, some participants may experience no direct benefit.

10) Vulnerable Populations*

N/A

11) Setting

This study will take place at 9 Miami Dade County Public Schools served by the UM School Health Initiative:

- Intervention schools: Arch Creek Elementary, Sabal Palm Elementary, JFK Middle, North Miami High, and Booker T. Washington High.
- Control schools: Fulford Elementary, Greynolds Park Elementary, North Miami Middle school, and North Miami Beach High or those who did not participate in the intervention at "intervention schools": Arch Creek Elementary, Sabal Palm Elementary, JFK Middle, North Miami High, and Booker T. Washington High.

12) Resources Available

Our research staff consists of personnel familiar with the protocol. Members of the research team have experience in patient outreach and follow up, conduct of clinical research, statistical analysis and methodology. Additionally, students could seek comprehensive medical services delivered by the School Health Initiative.

Principal Investigator Dr. Lisa Gwynn is a board-certified pediatrician and Associate Professor of Clinical Pediatrics and Clinical Public Health Sciences at the University of Miami Miller School of Medicine. She is Interim Chief of Child and Adolescent Health, the Medical Director for the University of Miami Pediatric Mobile Clinic, and Program Director for the John T. Macdonald Foundation School Health Initiative. Dr. Gwynn has been leading community-based health initiatives throughout South Florida for 20 years. She is a staunch advocate for children and school health policy and has served on the District Superintendent's Medical Advisory committee which assisted in the development of policies for reopening of schools, and the local health department School Health Services Plan Committee. Dr. Gwynn will have primary responsibility for the administration of the project, including recruitment, assessment, and intervention procedures, clinical protocols as well as supervising a weekly research meeting, and monitoring of clinical safety, data management and analyses. She will have regular meetings with project co-investigators and staff to develop, discuss, and review all aspects of program development.

Principal Investigator Dr. Elizabeth Pulgaron is the current Director of Mental Health Services for the SHI, an Associate Professor of Clinical Pediatrics at the University of

Miami Miller School of Medicine, and a licensed clinical psychologist. She has experience implementing community-based interventions, focus groups and qualitative analyses, project implementation and statistical analyses. Her relationships in the school health settings will facilitate the actualization of the proposed research. Dr. Pulgaron will supervise the two psychology fellows who will conduct the qualitative work for studies 1 and 3 and deliver health promotion intervention at the schools. Dr. Pulgaron will also be involved with the design of the health promotion intervention and assist in manuscript preparation.

Co-Investigator Dr. Viviana Horigian is a Professor of Public Health Sciences and the Director of Public Health Education in the Department of Public Health Sciences at the University of Miami, Miller School of Medicine. She has over 21 years of experience in the design and implementation of multisite clinical trials, and in the efficient management and oversight of remote sites and demonstrated experience in the development and implementation of trials for Hispanics and Spanish speakers. Dr. Horigian's research career has been committed to improving practice through the implementation of clinical trials in real-world settings, and more recently in creating the local capacities that would allow the implementation of such trials. She will be responsible for monitoring the measurement and assessment protocols and will assist in manuscript preparation. She will work closely with our statistician to prepare routine reports on data collection and analyses.

13) Prior Approvals

Approval must also be obtained by the Miami Dade County Public Schools IRB prior to commencing this study.

14) Recruitment Methods

Intervention Participants

Part 1A

Recruitment: Participants will be recruited from the following schools: Arch Creek Elementary, Sabal Palm Elementary, JFK Middle, North Miami High, and Booker T. Washington High. Parents/guardians from each school will be recruited via flyers posted at their schools (see flyer attached), sent home via mailings, or posted on school websites; advertising at school events; word of mouth by school champions; and/or school messaging systems. Additionally, individuals who indicated interest in research on clinical consent forms may be contacted. The recruitment method will depend on acceptability to administrators and the school community.

Compensation: Participants will receive $50 payment for attending the education session and completing the feedback forms.

Part 1B

Recruitment: Immediately following the health education initiative, participants will be invited to complete additional questionnaires. They will receive a flyer with information about questionnaires (see flyer attached) and links to complete them electronically, or will be given the opportunity to complete paper forms in-person at study sites.

Compensation: Participants will receive $20 payment for completing the post-intervention measures.

Part 1C

Recruitment: Participants will be re-contacted via the information they provided during Part A and ask if they are still interested in participating. If so, they will be given the link to complete the consent and 3-month follow-up measures, or will be given the opportunity to complete paper forms in-person at study sites.

Compensation: Participants will receive $30 payment for completing one measure and a $25 payment for completing the rest of the 3-month post intervention measures if they choose to do so.

Control Participants

Part 2A

Recruitment: Participants will be recruited from the following schools: Fulford Elementary, Greynolds Park Elementary, North Miami Middle school, and North Miami Beach High; they may also be from "intervention schools," (i.e., Arch Creek Elementary, Sabal Palm Elementary, JFK Middle, North Miami High, and Booker T. Washington High) but must not have participated in the intervention. Parents/guardians from each school will be recruited via flyers posted at their schools (see flyer attached), sent home via mailings, or posted on school websites; advertising at school events; word of mouth by school champions; and/or school messaging systems. Additionally, individuals who indicated interest in research on clinical consent forms may be contacted. The recruitment method will depend on acceptability to administrators and the school community.

Compensation: Participants will receive a $50 payment for completing the questionnaires.

Part 2B

Recruitment:

Participants will be re-contacted via the information they provided during Part 2A and asked if they are still interested in participating. If so, they will be given the link to complete the consent and 3-month follow-up measures, or will be given the opportunity to complete paper forms in-person at study sites.

Compensation: Participants will receive a $55 payment for completing the follow-up questionnaires.

15) Confidentiality

The study team will meet regularly to discuss project implementation, including data and safety monitoring. Any paper consent forms or measures will be stored in a locked cabinet within a locked office. Data management and analyses will be performed by the research specialist under the close supervision of the PI (Dr. Lisa Gwynn). All data files will be backed up daily and copies will be stored at more than one location. The PI will take ultimate responsibility for ensuring the safety of the participants, as well as adhering to FERPA and HIPAA guidelines.

Intervention Participants

Part 1A

The only data collected will be the Acceptability and Feasibility Assessment, does not require signed consent because it is being used for program evaluation purposes This form can be completed anonymously, or participants have the option to provide their name and contact information if they would like to be re-contacted for future research opportunities. Those names/contacts will be recorded on REDCap or University of Miami's Box and stored by

research team members, who are CITI certified and approved by University IRB. Only internal investigators of the project and their research staff will have access to the dataset that can link participants' personal identifier information to their survey.

Part 1B
Individual-level data will be collected during the collection of cross-sectional measures to gain an understanding of COVID-19 knowledge and experiences. Participants may choose to enter their contact information on the form for follow-up for future research opportunities. Those names/contacts will be recorded on REDCap or University of Miami's Box and stored by research team members, who are CITI certified and approved by University IRB. Only internal investigators of the project and their research staff will have access to the dataset that can link participants' personal identifier information to their survey, unless participants provide permission to share data with collaborators at the Duke Clinical Research Institute (see below for more details).

Data will be shared with Duke University, or Duke will be given access to de-identified research subjects' information including, but not limited to, research subjects' contact information and (ii) other information that Discloser considers to be confidential ("Discloser Confidential Information") to enable Duke to: (a) obtain research subjects' written informed consent, RADx-UP Common Data Elements, related questionnaires, surveys and forms for performing data analyses and for collecting follow up data from research subjects; (b) better understand COVID-19 testing patterns among underserved and vulnerable populations; (c) strengthen the understanding of the impact of relevant data on disparities in infection rates, disease progression, and outcomes; (d) develop strategies to reduce disparities in COVID-19 testing; and (e) fulfill Duke's obligation as the CDCC under the Project to provide de-identified Project data and the results of its analyses to the Awarding Agency (collectively, "Duke Purpose"); and WHEREAS, Duke will share with Discloser, or Discloser will have access to, reports and resources in the Project's RADx-UP resource library, confidential testing-related documentation, and other information that Duke considers to be confidential ("Duke Confidential Information") to inform Discloser's decisions and response to the COVID-19 crisis ("Discloser Purpose"). Discloser Confidential Information and Duke Confidential Information shall be collectively referred to hereinafter as "Information".

Part 1C
Individual-level data will be collected during the collection of cross-sectional measures to gain an understanding of COVID-19 knowledge and experiences. Participants may choose to enter their contact information on the form for follow-up for future research opportunities. Those names/contacts will be recorded on REDCap or University of Miami's Box and stored by research team members, who are CITI certified and approved by University IRB. Only internal investigators of the project and their research staff will have access to the dataset that can link participants' personal identifier information to their survey, unless participants provide permission to share data with collaborators at the Duke Clinical Research Institute (see below for more details).

Data will be shared with Duke University, or Duke will be given access to de-identified research subjects' information, including, but not limited to, research subjects' contact information and (ii) other information that Discloser considers to be confidential ("Discloser Confidential Information") to enable Duke to: (a) obtain research subjects' written informed consent, RADx-UP Common Data Elements, related questionnaires, surveys and forms for performing data analyses and for collecting follow up data from research subjects; (b) better understand COVID-19 testing patterns among underserved and vulnerable populations; (c)

strengthen the understanding of the impact of relevant data on disparities in infection rates, disease progression, and outcomes; (d) develop strategies to reduce disparities in COVID-19 testing; and (e) fulfill Duke's obligation as the CDCC under the Project to provide de-identified Project data and the results of its analyses to the Awarding Agency (collectively, "Duke Purpose"); and WHEREAS, Duke will share with Discloser, or Discloser will have access to, reports and resources in the Project's RADx-UP resource library, confidential testing-related documentation, and other information that Duke considers to be confidential ("Duke Confidential Information") to inform Discloser's decisions and response to the COVID-19 crisis ("Discloser Purpose"). Discloser Confidential Information and Duke Confidential Information shall be collectively referred to hereinafter as "Information".

Control Participants

Parts 2A and 2B

Individual-level data will be collected during the collection of cross-sectional measures to gain an understanding of COVID-19 knowledge and experiences. Participants may choose to enter their contact information on the form for follow-up for future research opportunities. Those names/contacts will be recorded on REDCap or University of Miami's Box and stored by research team members, who are CITI certified and approved by University IRB. Only internal investigators of the project and their research staff will have access to the dataset that can link participants' personal identifier information to their survey, unless participants provide permission to share data with collaborators at the Duke Clinical Research Institute (see below for more details).

Data will be shared with Duke University, or Duke will be given access to de-identified research subjects' information including, but not limited to, research subjects' contact information and (ii) other information that Discloser considers to be confidential ("Discloser Confidential Information") to enable Duke to: (a) obtain research subjects' written informed consent, RADx-UP Common Data Elements, related questionnaires, surveys and forms for performing data analyses and for collecting follow up data from research subjects; (b) better understand COVID-19 testing patterns among underserved and vulnerable populations; (c) strengthen the understanding of the impact of relevant data on disparities in infection rates, disease progression, and outcomes; (d) develop strategies to reduce disparities in COVID-19 testing; and (e) fulfill Duke's obligation as the CDCC under the Project to provide de-identified Project data and the results of its analyses to the Awarding Agency (collectively, "Duke Purpose"); and WHEREAS, Duke will share with Discloser, or Discloser will have access to, reports and resources in the Project's RADx-UP resource library, confidential testing-related documentation, and other information that Duke considers to be confidential ("Duke Confidential Information") to inform Discloser's decisions and response to the COVID-19 crisis ("Discloser Purpose"). Discloser Confidential Information and Duke Confidential Information shall be collectively referred to hereinafter as "Information".

Choose the statements below that are applicable to this research:

15(a). ☐ Data will be collected from the EMR or subjects at UHealth or JHS.

☐ Research Subjects will sign a HIPAA Authorization before the research will collect this data.

☐ Research Subjects will not sign a HIPAA Authorization for this data collection and the research is requesting a waiver of HIPAA authorization from the IRB. (Complete Section 17 below)

15(b). Data collected:

☐ Will not include Protected Health information or Personally Identifiable Information
☒ *X* Will include Protected Health information or Personally Identifiable Information

15(c). How will the research store the data?

☐ On a University of Miami electronic device (e.g. encrypted, password-protected computer)
☒ On a cloud-based storage system that is approved by the University of Miami
☐ Other, specify: Click here to enter text.

Select one of the following:

☐ The Principal Investigator (and/or Study Team members) will record (e.g. write down, abstract) data acquired in a manner that **does not include any** indirect or direct identifiers (listed in the instructions for Section 15 of this protocol), and the recorded data will not be linked to the individual's' identity.

OR

☒ The Principal investigator (and/or Study Team members) will record (e.g. write down, abstract) the data collected in a manner that does not include any direct identifiers (see list in the instructions for Section 15 of this protocol) of any subject. Instead, the Principal Investigator and/or Study Team members shall will assign a code (that is not derived in whole or in part from any direct or indirect identifiers of the individual) to each study subject and link the code to the study subject's identity. **The link to each subject's identity and/ or other identifiable information will be maintained on a document separate from the research data.**

Biospecimens

☐ Not applicable. No biospecimens will be collected

☐ *Bio*-Specimens obtained for this research will be stored without any direct or indirect identifiers.

☐ *Bio*-Specimens obtained for this research will be stored in a de-identified coded manner.

☐ When required to transport data or bio-specimens for this research, the research team will transport the data and bio-specimens in a de-identified (or anonymous) manner with a link to the individual subject's identity maintain separately from the data and/or bio-specimen.

15d. Jackson Health System additional requirement

☒ This section is not applicable because the research is not collecting health information from JHS under a waiver of authorization (without obtaining a HIPAA authorization from the participant)

If health information, including Protected Health Information and/or Personally Identifiable Information are collected from JHS without a signed authorization from the subject (with a waiver of authorization from an IRB or Privacy Board), you must agree to the following:

☐ JHS data, including Protected Health Information (PHI) and/or Personally Identifiable Information (PII), acquired from JHS for this research with a waiver of the requirement for an authorization under HIPAA shall only be stored on the secured JHS SharePoint environment made available by JHS. I and the Study Team members shall not copy or store the JHS sourced personally identifiable information (PII), including protected health information (PHI) data to any other system, including any systems maintained or provided by the University of Miami. I and the Study Team shall only copy or transfer JHS-sourced data that has been

properly de-identified in accordance with all requirements contained in the HIPAA Rules by removing all of the identifiers listed in the instructions for Section 15 of this protocol.

If the data obtained for this research will be acquired from a retrospective "chart review" involving health information from JHS with a waiver of authorization (without obtaining an signed HIPAA authorization from the subject) then the data and the link and/or key to each subject's identity shall only be maintained in the secure JHS SharePoint environment made available by JHS.

16) Provisions to Protect the Privacy Interests of Subjects

Participants inquiring and discussing matters related to the study will be able to do so in clinic, privately. During the consent process, participants will be reminded that information regarding the study will be respected as private and kept confidentially.

17) Waiver of Authorization for Use and Disclosure of Protected Health Information (HIPAA)

☒ This section is not applicable, we are not requesting a waiver of authorization.

Confirm that you will destroy the Protected Health Information (PHI) you and/or your Study Team acquire receive from JHS and/or UHealth at the earliest opportunity.

☒ ***I confirm***

Confirm that the Protected Health Inform (PHI) you acquire from JHS and/or UHealth will not be re-used or disclosed to any other person or entity, except as required by law or for authorized oversight of the research study or for other research for which the use or disclosure of PHI is permissible.

☒ ***I confirm***

Notwithstanding the preceding "I confirm" statements above, I agree that neither I nor any member of the study team listed on the IRB submission for this Protocol shall ever re-use or re-disclose any of the information acquired from Jackson Health System in any format, whether **identifiable or de-identified,** to any individual or entity without first obtaining written permission from Jackson Health System, even if such re-use or re-disclosure is permissible by law (e.g., HIPAA).

_____3/15/2022____

PI Signature Date

18) Consent Process

Intervention Participants

Part 1A

We are requesting a Waiver of Documentation of Consent for this portion of the study. The feedback form will be conducted by adults who have the capacity to consent and can read and comprehend the consent language written on the information sheet/cover page of the

feedback form. Participants who do not agree will not be given an evaluation form. Participants will have the option to review consent language in English, Spanish, or Creole. The English consent form will be translated and back translated by a bilingual individual who fluently reads, writes, and speaks in both English and Spanish or English and Creole. Once the consent language has been translated and back-translated, we will submit them to the IRB prior to providing consent information to non-English-speaking participants.

Part 1B

Informed consent will be obtained from all participants via written/electronic signature. Study staff will emphasize the voluntary nature of the study, the possible benefits and outcomes, alternatives to participation, confidentiality of participation, and the participant's right to refuse and/or withdraw from the study at any time. Consents will be available in English, Spanish, and Creole. Staff who speak these languages are part of our study team and will assist with questions as need be. All participants will have sufficient time to consider their participation.

Part 1C

We are requesting a waiver of consent for the first section of Part C which is a few simple questions about the intervention. For the second section of Part C, informed consent will be obtained from all participants via written/electronic signature along with consent for part 1B. Study staff will emphasize the voluntary nature of the study, the possible benefits and outcomes, alternatives to participation, confidentiality of participation, and the participant's right to refuse and/or withdraw from the study at any time. Consents will be available in English, Spanish, and Creole. Staff who speak these languages are part of our study team and will assist with questions as need be. All participants will have sufficient time to consider their participation.

Control Participants

Parts 2A and B

Informed consent will be obtained from all participants via written/electronic signature. Study staff will emphasize the voluntary nature of the study, the possible benefits and outcomes, alternatives to participation, confidentiality of participation, and the participant's right to refuse and/or withdraw from the study at any time. Consents will be available in English, Spanish, and Creole. Staff who speak these languages are part of our study team and will assist with questions as need be. All participants will have sufficient time to consider their participation.

19) Process to Document Consent in Writing

Intervention Participants

Part 1A

We are requesting a Waiver of Documentation of Consent for this portion of the study will be obtained as study procedures pose minimal risk and the waiver will not adversely affect the rights and welfare of the participants. Although participants will not provide written consent due to this waiver, they will be provided with information relevant to consent, including information about study procedures, potential risks/benefits of participation, voluntariness of the study, their right to withdraw, and contact information for the research team. Participants will indicate their consent by completing the evaluation form.

Part 1B

Written consent for participation in the second portion will be obtained prior to completing the online survey. Participants will be informed of the nature and sensitivity of the questions, as well as the measures taken to protect confidentiality. They will indicate their consent by typing their full name and providing their electronic signature in REDCap or on paper forms. Please see the attached consent document.

Part 1C

We are requesting a waiver of consent for the first section of Part C which is a few simple questions about the intervention. For the second section of Part C, written consent for participation in this portion of the study will be obtained along with the consent for part 1B, prior to completing the online survey. Participants will be informed of the nature and sensitivity of the questions, as well as the measures taken to protect confidentiality. They will indicate their consent by typing their full name and providing their electronic signature in REDCap or on paper forms. Please see the attached consent document.

Control Participants

Parts 2A and 2B

Informed consent will be obtained from all participants via written/electronic signature. Study staff will emphasize the voluntary nature of the study, the possible benefits and outcomes, alternatives to participation, confidentiality of participation, and the participant's right to refuse and/or withdraw from the study at any time. Consents will be available in English, Spanish, and Creole. Staff who speak these languages are part of our study team and will assist with questions as need be. All participants will have sufficient time to consider their participation.