1) **Protocol Title**

Maximizing Child Health and Learning Potential: Promoting A School Culture of Safety in the era of COVID-19

2) **Objectives***

Study 1: Using the input of key stakeholders, we will create COVID-19 testing protocols and vaccine confidence initiatives for urban at-risk schools to provide realistic, feasible, and adequate levels of safety in this school community.

Specific Aim 1.1: Conduct a cross-sectional assessment of current COVID-19 knowledge and experiences of parents and school staff at schools with vulnerable students.

Specific Aim 1.2: Engage youth, parents, and school staff in focus groups about their current COVID-19 knowledge, their hesitations about testing and vaccination, and their thoughts on how to implement testing and education programs in their specific school settings.

Specific Aim 1.3: Using the quantitative and qualitative data gathered in aims 1.1 and 1.2, design COVID- 19 testing protocols and COVID -19 health and vaccine confidence initiatives. These initiatives will be presented to solicit feedback from our advisory board which will consist of a pediatric infectious disease expert, a representative from the local health department, school district operations leadership, the Children's Trust (lead funder of school health throughout the County), parent representatives, school staff representatives, and "school champions."

Study 2: We will explore the feasibility of strategic COVID-19 testing protocols in at-risk urban school settings with the goal of increasing a sense of safety for parents and staff, and elucidating information that could assist the district in adopting a testing protocol that increases the time students and staff spend in school physically. Data will be obtained via a retrospective chart review of COVID-19 testing data and school attendance data from clinic and school records.

Data on percent of students quarantined, COVID 19 test results of clinic members, and number of missed in person school days will be collected from school records which are routinely provided to the School Health Initiative program by the school district. It is hypothesized that students participating in the unique testing protocol that is implemented at each school will have shorter durations to return to school post-COVID 19 exposure, and miss fewer days of school overall. Data will be collected from August 2021 until February 1st 2022.

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 disproportionately affect 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).

It is critical that the public is educated about 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). Strategies should be employed to increase the acceptability and use of these public health measures. For community mitigation, this may include messaging that emphasizes individual choice (Taylor & Asmundson, 2021). For vaccination, it is necessary to build trust and understanding (Bunch, 2021; Razai, Osama, McKechnie, & Majeed, 2021).

COVID 19 has disrupted education in significant ways, and engagement in schools and sustainability of the learning process has been impacted particularly in underserved neighborhoods. Virtual instruction is more commonly reported by Black, Hispanic, and non-Hispanic other or multiracial parents than White parents and is associated with various risk factors (Verlenden, et al., 2021). In Miami-Dade County, the fourth largest public school district in the United States, 50% of students are attending school virtually. Of the 9 schools that participate in the University of Miami School Health Initiative (SHI) program only 41.8% of students are attending school in person. SHI provides medical and mental health services in Title 1 schools in urban at-risk areas with 72% of our student population identifying as Black/African American, 25% as Hispanic, and 90% qualifying for free or reduced lunch. Areas served include historically under resourced, culturally diverse communities such as Overtown (50% from Central and South America) and North Miami (many who identify as Haitian), The clinical team for the SHI provides high quality health care on-site in co-located clinics and advocates for the mental and physical health of our students at the district and national level. Dr. Gwynn, program director and community pediatrician, has vast experience in delivering care to underserved, minority populations in innovative ways, including pediatric mobile medical and vaccination units. She also leads mobile COVID testing units for children in schools and COVID vaccination teams serving adult minorities in the neighborhoods in which they live. She works closely with the local health department leaders and the school district on these initiatives. The lead pediatrician, Dr. Maurer, is the Chair of the School Health Advisory Committee (SHAC) and Dr. Pulgaron serves on the mental health workgroup for the SHAC. As a team we are committed to helping vulnerable youth achieve their maximum potential by ensuring their physical and psychological needs are met.

The risks and benefits of returning children to school must be considered and addressed flexibly. There are many potential benefits of reopening schools, including providing a safe environment that offsets social, emotional, and mental health impacts of virtual learning (CDC, 2021). Data from a national survey completed by parents of 5–12-year-old children indicates that children receiving virtual instruction or hybrid instruction were more likely than children receiving in-person instruction to report higher prevalence of risk on 11 of 17 indicators of child and parent well-being. Specifically, those in virtual school versus in person school reported their children had worse mental or emotional health outcomes (24.9% versus 15.9%).

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 (Gwynn et al., under review).

For vulnerable youth to return to in-person learning and maximize the time spent in school, staff, parents, and students need to feel safe. Safety measures prioritize physical and emotional well-being, which leads to a healthier learning environment. Staff, parents, and students need to be educated and understand the factors influencing COVID-19 infection rates, personal risk, and wellness. We propose to create and test the effectiveness of an urban school COVID-19 testing protocol and health education and vaccine confidence initiative. We also will explore the feasibility of COVID-specific screening and testing strategies, connecting to care, and vaccination in school health settings. We predict that these initiatives will influence both short and long-term COVID consequences including lower disease infection rates, higher vaccination compliance, and reduction in education lags for urban vulnerable youth.

4) **Inclusion and Exclusion Criteria***

Study 1

Inclusion criteria *for youth*:

a) Are enrolled in one of the high schools served by the University of Miami School Health Initiative (SHI; North Miami High School, North Miami Beach High School, Booker T. Washington High School)

Exclusion criteria *for youth*:

Individuals who:

b) Do not speak English, Spanish, or Creole
c) Less than 14 years old, or over 21 years old.
d) Individuals with significant learning disabilities that are unable to understand the study as determined by clinical staff

Inclusion criteria *for adult participants:*

a) Parent/guardian of a child who is enrolled in one of the schools served by the University of Miami School Health Initiative (SHI; Arch Creek Elementary, Fulford Elementary, Greynolds Park Elementary, Sabal Palm Elementary, North Miami Middle School, J.F.K. Middle School, North Miami High School, North Miami Beach High School, Booker T. Washington High School) OR be employed by Miami Dade County Public Schools and assigned to work at one of the University of Miami School Health Initiative schools; AND
b) Be able to read and write English, Spanish, or Creole at a 5th grade level

Exclusion criteria *for adult participants*:

Individuals who:

c) Do not speak English, Spanish, or Creole
d) Are under the age of 18

Study 2

Inclusion criteria:

a) Youth aged 4-21 years, including individuals who are pregnant.
b) Enrolled at one of the schools served by the University of Miami School Health Initiative (SHI; Arch Creek Elementary, Fulford Elementary, Greynolds Park Elementary, Sabal Palm Elementary, North Miami Middle School, J.F.K. Middle School, North Miami Senior High School, North Miami Beach High School, Booker T. Washington High School).
c) For testing data, participants must be clinic members, as defined as consent signed for SHI clinic. Other aggregate data is not defined as "consented." D
d) Were administered a COVID-19 test as part of standard care in the school health clinic.

Exclusion criteria:

a) Over the age of 21

5) **Procedures Involved***

Study 1

This is a cross-sectional study that employs the use of surveys and focus groups to create COVID-19 testing protocols and vaccine confidence initiatives for urban at-risk schools to provide realistic, feasible, and adequate levels of safety in this school community.

Specific Aim 1.1: Conduct a cross-sectional assessment of current COVID-19 knowledge and experiences of parents, school staff, and students (aged 14 and above) of the 9 schools who are part of the School Health Initiative (SHI; Arch Creek Elementary, Fulford Elementary, Greynolds Park Elementary, Sabal Palm Elementary, North Miami Middle School, J.F.K. Middle School, North Miami High School, North Miami Beach High School, Booker T. Washington High School). Parents and school staff at each respective school setting (elementary, middle, and high) will be recruited via flyers posted at their schools (see flyer attached), advertising at orientations, other school events, and via word of mouth by school champions, open house meetings and through the school messaging systems. Interested individuals that meet the inclusion/exclusion criteria will be invited to participate in a survey that includes measures from the Radx-UP 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 (please see attached measures).

Consent/assent will be obtained in writing at the school clinics or study sites or completed at home and returned to study personnel, or online via REDCap. Data will be collected via paper forms or electronic surveys accessed through a link or QR code. Upon completion of the measures, information on how to participate in the focus groups will be provided to those interested and available. Participants who complete the survey will have the option to provide their name and contact information in order to receive a $15 gift card for survey completion in-person,

via mail, or via email. Their personal information will be de-identified and unlinked from any study data.

Specific Aim 1.2: Engage youth, parents, and school staff in focus groups to learn about their current COVID-19 knowledge, hesitations about testing and vaccination, and how to implement testing and education programs in their specific school settings. At least six focus groups will be conducted, two per school level (i.e., elementary, middle and high schools). Additional focus groups may be conducted, based on availability of participants. Older students (aged 14 and above) will also be invited to participate in our high school focus groups. Guiding questions and a rapid analysis of the data will be conducted. Focus groups will be recorded and transcribed for data analyses. Basic demographic information will be collected as part of the focus group (see measures). Participants will be given a $25 gift card as compensation for focus group completion.

The quantitative and qualitative data gathered in aims 1.1 and 1.2 will be used to design COVID- 19 testing protocols and COVID -9 health and vaccine confidence initiatives. These initiatives will be presented to solicit feedback from our advisory board which will consist of a pediatric infectious disease expert, a representative from the local health department, school district operations leadership, the Children's Trust, parent representatives, school staff representatives, and "school champions." The COVID-19 health education program will have developmentally appropriate versions and a student versus teacher/parent component. Length and duration will be determined according to the recommendations from study 1.2. Potential formats include health education campaigns in school, townhall meetings with medical experts, and single or multiple session education groups. The school staff/parent version will include a vaccine confidence section.

Study 2

Data on absenteeism and quarantining are identified and collected by the MDCPS District and stored in their central database. The Department of Comprehensive Student Health Services of MDCPS will provide the University of Miami research team with deidentified weekly data from all study schools.

Data related to COVID-19 testing will be obtained from students accessing the clinics at all study schools. These data are collected by the school nurse. Data are entered into a data tracking spreadsheet and reviewed by the project manager as completed.

The sources of data are the following:

1. MDCPS Department of Federal Compliance Office Schools Data Base. De-identified data is extracted by a MDCPS representative and sent weekly to UM Research Team.
2. Individual school data is reported daily by the principal and shared with the school nurse and project manager. This information is de-identified and shared with the UM Research Team.

3. Positive cases are self-reported by students/parents and collected by the school nurses. Information is entered into the data tracking spreadsheet by the school nurse. The information is de-identified then shared with the UM Research Team
4. Clinic nurses which conduct testing of symptomatic students in the school clinics. The information is de-identified then shared with the UM Research Team

6) **Data and Specimen Banking***

☒ This section is not applicable. This research is not banking data or specimens for future use.

Study 1

Individual-level data will be collected in Specific Aims 1.1 and 1.2 during cross-sectional assessments and focus groups among school youth and their parents, and among school staff to gain an understanding of any vaccine hesitancy to design a vaccination promotion intervention.

All data collected as part of the proposed study will be collected using paper forms or the REDCap service at the University of Miami. Upon recruitment, participants will be asked if they meet study criteria and to sign a consent form (see consent and assent details below). Participants will be assigned a unique identification (ID) number. All data will be entered on RedCAP or on 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 (DCRI; see "Confidentiality" section below for more details).

Study 2

Only de-identified data will be collected as part of Study 2. Research staff will not have access to participant's personal identifiers. All data will be entered on RedCAP or on University of Miami's Box and will be accessible only to research team members, who are CITI certified and approved by the University IRB. De-identified data will also be shared with the DCRI.

7) **Data Management***

Data Analysis Plan

Study 1 Data Analysis

We estimate we will recruit a minimum of 33 parents, 33 school staff, and 33 students (14 and older) per school for a total of approximately 300 parents, 300 school staff and 100 students. Descriptive analyses of individual questions and validated measures will be run using mixed models to account for clustering of individuals within school to summarize parent, school staff, and student feelings towards COVID.

Study 2 Data Analysis

Several important COVID-19 milestones will be used to demarcate time points during the academic year. Individual-level absentee days and quarantined days (counts) will be analyzed using generalized linear mixed models to examine change over time. Covariates will include: presence of school-based testing, school, grade, and gender/race/ethnicity. Power calculations using PASS 2020 estimated over 80% power using an alpha of .05 to uncover a difference in proportion of students absent or quarantined between 10 and 20% among schools with differential access to school-based testing or among time points with differential access to school-based testing.

Data Management

Study 1 and General Data Management:

The proposed study team will meet regularly to discuss project implementation, including data and safety monitoring. All human data collected during the course of this study will be de-identified, encoded and encrypted when entered into the research databases, CDCC and NIH RADx Data Hub. All identifiers will be stored separately in encrypted files on a password-protected computer and/or on University of Miami approved data storage hubs such as Box and REDCap, and 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.

Study 2-Specific Data Management:

The following data will be collected as a part of our chart review (study 2):

1. Aggregate data at school and grade level collected from the MDCPS central database weekly:
    a. Total number of absences
    b. Number of quarantined students
    c. Number of quarantined students who resulted in positive
    d. Number of positive cases
    e. Number of students who have been identified as being exposed
    f. Number of exposed students whose parents have elected to have them quarantine
    g. Number of exposed students whose parents have elected not to have them quarantine
2. De-identified individual-level data extracted by SHI staff:
    a. Number of absences between important time points (time points to be determined by local infection rates, changes in vaccine availability, changes in testing access, school policy changes)
    b. Number of quarantined days between important time points (as above)
3. Individual-level data collected at school clinics at time of testing:
    a. Gender
    b. Race
    c. Ethnicity

d. Age
e. Grade
f. Staff/Student
g. Symptoms
h. Reason for testing
i. Vaccination status
j. Test result

Data Sharing

Study 1 Data Sharing

Data will be shared with Duke University, or Duke will be given access to de-identified research subjects' information that constitutes Protected Health Information ("PHI"), as defined in the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), 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/HIPAA authorization ("Subject Authorization"), 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"). PHI, Discloser Confidential Information and Duke Confidential Information shall be collectively referred to hereinafter as "Information".

Study 2 Data Sharing

De-identified data will be shared with Duke University. These data will not include any PHI, as defined by HIPAA.

8) **Risks to Subjects***

Study 1

The potential risks in this study are minimal. It is possible some subjects may experience discomfort while answering questions about or discussing COVID-19. We will welcome stakeholder feedback on most acceptable (i.e., culturally sensitive, addressing their concerns) methods to discuss COVID-19 testing, diagnosis, and vaccination with children and families participating in this study.

Study 2

All information will be de-identified prior to sharing with the research team. Given the retrospective nature of gathering the data, we don't foresee any risks to the participants.

9) **Potential Benefits to Subjects***

Studies 1 and 2

No direct benefits.

10) **Vulnerable Populations***

Study 1

This research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research. Therefore, we have followed the HRP-416 checklist to ensure we have followed recommended safeguards to protect their rights and welfare. These safeguards include: 1) soliciting the permission of a parent or guardian; 2) soliciting the assent of the children, if they are capable. They will also be verbally explained the study; and 3) documenting both parental/guardian consent and child assent.

Study 2

The retrospective chart review nature of this study does not directly involve the participation of individuals.

11) **Setting**

Studies 1 and 2

This study will take place at 9 Miami Dade County Public Schools which are served by the UM School Health Initiative: Arch Creek Elementary, Fulford Elementary, Greynolds Park Elementary, Sabal Palm Elementary, North Miami Middle School, J.F.K. Middle School, North Miami High School, North Miami Beach High School, Booker T. Washington High School.

12) **Resources Available**

Studies 1 and 2

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.

13) **Prior Approvals**

Study 1

Study 1 has been approved by UM IRB and MDCPS IRB.

Study 2

Study 2 will be submitted to MDCPS once it is approved by the UM IRB committee.

14) **Recruitment Methods**

Study 1

Parents and school staff at each respective school setting (elementary, middle, and high) and students from high schools (aged 14 and older) will be recruited to complete measures about COVID-19 via flyers posted at their schools, advertising at orientation, other school events, and via word of mouth by school champions, open house and through the school messaging systems. Please see attached recruitment flyers for study 1.

Those who complete the surveys for study 1.1 will receive a gift card incentive in the amount of $15.00. Those who participate in the focus groups as part of specific aim 1.2 will receive $25.

Study 2

Study 2 is a retrospective chart review. No participants will be actively recruited.

15) **Local Number of Subjects**

Study 1

For study 1 we estimate about 800 adults (parents and school staff) and 200 students (age 14 and above) will complete study measures. For the qualitative focus groups we plan to

conduct at least 6 groups of about 10 individuals each, so 60 participants (parents, school staff, and students aged 14 and above).

Study 2

Due to the retrospective nature of this study, there are no goals for recruitment or specific number of subjects. We will review data of 9 schools for a specific time frame of 6 months.

16) **Confidentiality**

Confidentiality and privacy of participant data is a major priority of research. Students, families, and staff might have concerns about health data privacy and sharing information with the school and/or classmates. Therefore, confidentiality and privacy procedure will be clearly outlined and communicated so that the school or school district can follow to maintain confidentiality of all student and staff health data.

Study 1

All information taken from the study will be coded to protect each subject's name. No names or other identifying information will be used when discussing or reporting data. Data will be aggregated via the Redcap reporting function. The investigator(s) will safely keep all files and data collected in a secured locked cabinet in a locked office. Once the data has been fully analyzed it will be destroyed.

Participants can report adverse events to research staff in person, or by email or phone. When an adverse event is reported, the PI will report all appropriate information to the University of Miami IRB office. Research staff will monitor participants for any undesirable subject outcomes or experiences and follow all protocols developed by the IRB offices for cases of adverse events. All staff will be briefed on this plan. Notification of any problems will be directed immediately to the PI. All research staff participating in this protocol have completed and/or will renew the Human Subjects Research Training established by the University of Miami (i.e., CITI Program and the Responsible Conduct of Research course) before they interact with subjects or handle any subject data. Further, the critical importance of subject and data confidentiality will be reinforced prior to data collection with research staff.

The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies. The DCRI will build two RADx-UP databases (systems that hold electronic information). The first database will only hold identifiable information (i.e. name, address, email, and gender). These data will be kept at the DCRI. The DCRI will not share these data with the NIH. This information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and participant electronic health record, among others. These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of the data at the DCRI will be able to see this information. The second database will not hold any identifiable data. Participants will be assigned a study code and they will only be identified in this database by this study code. That data will be transferred and kept in a secure database for COVID- 19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in the consent form.

Study 2

No identifiable data will be collected in Study 2; therefore, all data are confidential.

Studies 1 and 2

The data obtained in this project will be published as manuscripts in peer-reviewed scientific journals and available in the format of Open Access publications following NIH-funded research publication guidelines. We will also adhere to the NIH Grant Policy on Sharing of Unique Research Resources including the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources issued October 29, 2020. In addition, we will provide relevant protocols upon request. Should any intellectual property arise which requires a patent, we will ensure that the technology (materials and data) remains widely available to the research community in accordance with University of Miami policies and the NIH Principles and Guidelines document. Most importantly, the rights and privacy of human subjects who participate in this NIH-sponsored research will be protected at all times.

Study 1

Choose the statements below that are applicable to this research:

16(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)

16(b). Data collected:

☐ Will not include Protected Health information or Personally Identifiable Information

Will include Protected Health information or Personally Identifiable Information

16(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: Paper forms will be stored in a locked filing cabinet in a locked office.

Study 2

Choose the statements below that are applicable to this research:

16(b). Data collected:

X Will not include Protected Health information or Personally Identifiable Information

Will include Protected Health information or Personally Identifiable Information

16(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:

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.

16(d). **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)

17) **Provisions to Protect the Privacy Interests of Subjects**

Study 1

Participants inquiring and discussing matters related to the study will be able to do so in clinic, privately. Clinic operation in schools adhere to standards for protecting the privacy and confidentiality of procedures rendered. During consent process for e Study 1, subjects will be reminded that information regarding the study will be respected as private and kept confidentially. Data will be collected in a private setting and confidentiality will be kept regarding responses to all questions.

Study 2

Not applicable due to the retrospective chart review nature of the study. All data will be de-identified.

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

Study 1

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

Study 2

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***

19) **Consent Process**

Study 1

All participants will provide either consent or assent 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. Parents/legal guardians will provide consent for participants who are under the age of 18. All participants will have sufficient time to consider their participation. Those participants will also provide assent.

Study 2

Consent does not apply because de-identified data is not considered human subjects research.

Rights and welfare:

This study will not adversely affect the rights and welfare of the subjects. The purpose of the study is largely to identify factors that could aid deploying supportive and preventive interventions in the near future.

20) **Process to Document Consent in Writing**

Please see attached consent and assent and refer to consent process.

21) **<u>References</u>**

None