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Grant Title: Maximizing Child Health and Learning Potential: How to Promote A School Culture of Safety in the era of COVID-19

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Title of Study: Maximizing Child Health and Learning Potential: Promoting A School Culture of Safety inthe era of COVID-19
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Sponsor: National Institutes of Health

Detailed Information
The purpose of this study is to gather information from parents/guardians on COVID-19 knowledge and experiences. This information will be used to inform COVID testing and vaccination protocols in school settings.

This research is a part of a larger health research program called, Rapid Acceleration in Diagnostics (in) Underserved Populations, or RADx-UP for short, which aims to learn more about COVID-19. RADxUP is being funded by the National Institutes of Health (NIH) whose mission is to find new knowledge that will lead to better health for everyone.

What will you ask of me?

If you decide to participate in this study, you will be asked to complete a survey at two time points about yourself and experience during the COVID-19 pandemic, including:

- Basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, and language.
- Information about your health, education, and family.
- Information about COVID-19, including information about any symptoms and test results, your medical history, and your vaccination history.

This survey will take approximately 20 minutes to complete. You will be asked to complete the survey today and again in three months.

What should I think about before I enroll in this research?
You should ask any questions you may have and obtain answers before you decide.

Do I have to be in this research?
No. Your participation in this study is voluntary. You do not have to be in this study if you do not want to, and you can leave the study at any time. You will not lose any services, benefits, or rights you would normally have if you choose not to be in the study or if you leave the study early.

Is there any way being in this study could be bad for me?
The potential risks in this study are minimal. Some subjects may experience discomfort while thinking about their response to questions regarding COVID-19.

What are the benefits to being in this study?
No direct benefits are promised for your participation.

What happens to the information collected for the research?
Your privacy is **very** important to us. We will take great care to protect your privacy. The information you share with us will be stored in a secure location. Any paper consent forms or measures will be stored in a locked cabinet within a locked office. All electronic files containing identifiable information will be password-protected. Only select members of the research team will have access to the data. At the end of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Your information may be reviewed for research or regulatory purposes by:
- The sponsor;
- Department of Health and Human Services (DHHS);
- Other University of Miami employees for audit and/or monitoring purposes; and
- Other organizations collaborating in the research

This project has a Certificate of Confidentiality from the United States government. Certificates of Confidentiality protect your privacy by blocking the release of identifiable, sensitive research information to anyone not connected to the research except when you agree, or in a few other specific situations. The CoC does not prevent some disclosures, including:
- Requests from those funding this research. The NIHmay need information to assess this project.
- Suspected child abuse andneglect, harm to self or others. As required by law, researchers must disclose these things.
- You are free to share information about yourself and freely discuss your involvement in this study. The information you share will no longer be protected by the CoC.

What will you do with my data?

We will keep your data securely (which means with extra protection), along with the data from all the other people who take part in the RADx-UP program. Researchers will use the data to learn more about COVID-19 or other diseases and conditions. 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 information that can identify you (called identifiable information). Examples are your name, address, email, and phone number. Agreeing to provide this information is **optional**.
- These data will be kept at the DCRI. The DCRI will not share these data with the NIH.
- By checking the “yes” box below, you agree to share your identifiable information with the DCRI and your information may be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- By checking the “yes” box below, the DCRI will keep information that can directly identify you and be used to contact you for future research studies. If you do not agree (indicated by checking the “no” box), your information will not be shared.

- These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data at the DCRI and IRB approved study staff will be able to see this information.

The second database will not hold information that can easily identify you. It will hold all the non-identifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data 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 this consent form. Researchers will not be able to link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.

Optional:

I agree to let the DCRI collect the following identifiable information: Name, address, contact information, and date of birth, as stated above.

_____Yes_____No

I agree to let the DCRI collect **only my zip code** and no other **identifiable** information, as stated above.

_____Yes_____No

I agree to be contacted for future health research.

_____Yes_____No

Payment

If you agree to be in this research study, we will pay you with a $20 debit card for completing the first survey and an additional $25 debit card for completing the follow-up survey after three months (up to a total of $45).

The research team will give you a "ClinCard" debit card under your name. The research team will show you how to use the card. As you complete the study components, the team will load funds on the card. The company providing the card requires the team to enter your name, address, and birth date on a website. If you want to receive messages about the study, the team can also include your cellphone number and/or your email address. This information will only be used for payment and messaging purposes. Your information will not be given to another company or linked to any of your study data.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 305-243-3440.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). The Human

Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs. Please call the HSRO at 305-243-3195 if you are a participant in any research being conducted by UM, and

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study description.*
- *If I have questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I can request a copy of this consent form after I sign it (or I can print it from the computer screen).*

_____

Printed Name of Adult Participant

_____ _____

Signature of Adult Participant Date

_____

Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date