Consent to Act as a Research Subject

Community Survey - Consent Form

Study Title: Safer at School Early Alert HUB

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?

Rebecca Fielding-Miller, Ph.D. is an Assistant Professor of Public Health at UC San Diego. She is conducting a research study to learn more about the effectiveness of the Safer at School Early Alert system (SASEA), a program to reduce COVID-19 in preschools and K-12 schools. You have been asked to participate in this study because you are a parent of a student at one of the approximately 40 sites across San Diego County that are participating in the SASEA project. We are asking parents and staff members at these schools to fill out a brief survey to help us understand COVID-19 risks, needs, and priorities in your community There will be up to 33,000 survey participants, and 2628 participants total in this study.

Why is this study being done?

We are working with your school district to create systems that we hope will reduce COVID-19 risk in preschools and elementary schools. We are talking to parents, families, and staff to understand how we can create tools that are most useful to your community.

What is the NIH and RADX-UP?

Our study is funded the RADx-UP program. RADx-UP stands for Rapid Acceleration of Diagnostics - Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. RADx-UP is funded by the National Institute of Health (NIH). The NIH is part of the United States Department of Health and Human Services. The NIH's purpose is to find new knowledge that will lead to better health for everyone.

The SASEA project is funded by the RADx-UP program to conduct this research. If your child joins RADx-UP, we will gather some data (information) about your child. We will combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

What will happen to you in this study?

You will be asked to complete the following brief (15-20 minute) survey.

What will you ask me?

If you join this study, we will gather data (information) about you from your responses to our survey questions. You do not need to answer any question you are uncomfortable answering. Examples of the data that we will ask about may include, but are not limited to:

- Your name and contact information
- Race, ethnicity, gender, or languages spoken
- Medical history
- Your health insurance status, disabilities, or job
- COVID-19 symptoms, test results, vaccination, and treatments
- Your schooling, family, home, and social life

How much time will each study procedure take, what is your total time commitment, and how long will the study last?

The survey will take approximately 15-20 minutes of your time. The SASEA HUB study will take place from July 2022 to June of 2023.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include the following:

1. A potential for the loss of confidentiality, however we will not ask you any personally identifiable or sensitive information as part of this survey. Research records will be kept confidential to the extent allowed by law. Research records may be reviewed by the UCSD Institutional Review Board.

Because this is a research study, there may also be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

What are the alternatives to participating in this study?

The alternative to participation in this study is to not participate.

What benefits can be reasonably expected?

There is no direct benefit to you from participating in this study. The investigator, however, may learn more about how to implement an early alert system for COVID-19 in schools and childcare settings, and society may benefit from this knowledge.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?

Participation in research is entirely voluntary. You may refuse to participate or withdraw or refuse to answer specific questions at any time. If you would like to request that your input not be used, you may email Dr. Rebecca Fielding-Miller any time at rfieldingmiller@health.ucsd.edu.

Are there any costs associated with participating in this study?

There will be no cost to you for participating in this study.

Will you be compensated for participating in this study?

To thank you for your participation, you will be entered into a raffle where you will have the chance to win $100 gift card. Any individual who is asked to participate in this research study but declines, who consents or assents to enroll in the study, or who fails to complete the study, will be given equal opportunity to enter into a raffle for a chance to win a $100 gift card. Individuals who do not wish to participate in the survey but would like to be included in the raffle can enter their email address on the online survey platform without completing the survey for a chance to win the gift card. An email will be randomly selected via our online survey platform REDCap, and will be notified via email that they have won the $100 gift card. Participants will have 1/250 chance of winning the raffle.

What will you do with my data?

Data for this study will be collected using REDCap or Colectiv. REDCap is a secure data collection tool that meets HIPAA compliance standards. Colectiv is a web-based data collection system. Colectiv is hosted at Duke University. If Colectiv is used, your data will be stored at Duke. However, Colectiv will only be accessible by:

1. Staff who are approved by a research ethics committee to work on this study;

2. Duke staff who maintain the system.

We will keep your data securely in Colectiv. This means with extra protection. Some or all data from Colectiv will be sent to the Duke databases described below. Duke was chosen by the NIH to hold the data from all RADx-UP studies. Duke will keep your data securely. This means with extra protection. Researchers will use the data to learn more about COVID-19. Duke will build two RADx-UP databases. Databases are systems that hold electronic information.

The first database will only hold data that can easily identify you. These data are called identifiable data. Examples include your name, address, email, and phone number, among others. Duke will not share your identifiable data with others. Your data will be stored securely. Only study staff approved by a research ethics committee will be able to see your data.You will initial below if you would like to share identifiable data with Duke. This will allow researchers in the future to contact you about other kinds of research studies.

The second database will not hold data that can easily identify you. It will hold all of your other data. Your data will be assigned a study code. Your data will only be identified in this database by this study code. Your data may be linked with other data using your zip code. This linked data will tell us more about the area where you live. We will transfer these data to a secure NIH database. These data will not be able to identify you. Other researchers may use these data for future studies. We will not ask your permission before sharing these data because they are non-identifiable.

I agree to let Duke University collect my identifiable information. This includes name, address, and contact information.

_____ *Yes* _____ *No*

_____*Initials* _____*Initials*

I agree to let the DCRI collect my zip code.

_____ *Yes* _____ *No*

_____*Initials* _____*Initials*

I agree to be contacted for future research.

_____ *Yes* _____ *No*

_____*Initials* _____*Initials*

How will you protect my privacy?

Your privacy is important. We will take great care to protect your privacy. But, privacy cannot be guaranteed. Below are a few steps we will take to protect your privacy.

- Data will be collected via secure applications.
- Data will be stored on secure computer systems.
- We will limit and keep track of who can see your data.
- Your data will be protected by a password and multi-factor authentication.
- We will take steps to protect your data from others that should not be able to see it.
- We will not share data that can identify you.

This project has a Certificate of Confidentiality (CoC) from the NIH. A CoC protects your identifiable data from all legal proceedings. Data from this study that identifies you will not be shared outside this research unless you consent. No one can be forced to share your identifiable data for a lawsuit. This is true even if there is a court order.

Who can you call if you have questions?

If you have other questions or research-related problems, you may reach Rebecca Fielding-Miller at (858)900-3247.

You may call the Human Research Protections Program Office in San Diego at +1858-246-HRPP +1(858-246-4777) or email hrpp@ucsd.edu to inquire about your rights as a research subject or to report research-related problems.

Signature and Consent

You have received a copy of this consent document.

You agree to participate.

_____ _____

Signature of Participant Date