University of California, San Diego
Parent Consent for Child to Act as a Research Subject

SASEA: Safer at School Early Alert system for K-12 schools

Who is conducting the study, why your child been asked to participate, how your child was selected, and what is the approximate number of participants in the study?
Dr. Rob Knight is conducting a research study to find out more about how we can detect and stop COVID-19 outbreaks early to prevent the spread of COVID-19 in school and childcare settings. There will be approximately 3,000 participants in the study and we will try to find a way to check for the virus that that causes COVID-19 by looking at your child, the surfaces in schools and daycare centers, and wastewater from the sewer.

Why is this study being done?
The purpose of this study The purpose of this study is to try to find a way to check for the virus that causes COVID-19 by collecting nasal swab samples and/or diapers (if appropriate) from your child, the surfaces in the school or child care center and the wastewater from the building. We are interested in looking at how the viruses like SARS-CoV-2 (the virus responsible for COVID-19 disease) is transmitted to surfaces surrounding infected people, and how long it may remain as a source of infection. We will also sample wastewater from the facility to see if that can be used to rapidly detect infection at the facility and limit the spread of the virus.

What will happen to your child in this study and which procedures are standard of care and which are experimental?
If you agree to allow your child to participate in this study, the following will happen to your child: You will be asked to sign this consent form and then complete an initial survey at home. The types of questions in this survey include things such as your child's age and ethnicity and possible exposure to people who are or have been infected with the COVID-19 virus.

Children younger than 12 years will be assisted with sampling by the research health care provider. Children older than 13 will have the option of sampling themselves under supervision of the research staff or may request assistance. The sampling kit will contain polyester-tipped sterile swabs or cotton-tipped swabs with a sterile buffer (phosphate buffered saline) that will facilitate sampling. The collection device may also include 95% ethanol or VTM (viral transport medium) to preserve the sample and/or make it non-infectious. Alternatively, your child may receive a tube to collect saliva (spit).

Sample sites may include swabs from your child's nostrils, saliva by sampling their tongue or cheek, saliva collected by spitting into a tube. If your child uses diapers, we will also use fecal samples by collecting used diapers from your childcare provider.

Your child will be asked to provide a nasal or saliva sample once a week for up to 12 weeks. We anticipate that each sampling session will last approximately 2 minutes, but no longer than 15 minutes.
We will use your child's samples to examine the microbial communities of different body habitats over time. DNA and RNA will be extracted from the sample and amplified by PCR

(polymerase chain reaction) and then sequenced to see what micro-organisms (including viruses like SARS-CoV-2) are present and in what proportion in your sample. You will receive results of the test for SARS_CoV-2 and a referral to the county for contact tracing should the results of the test be positive. We may also use the remaining sample to look at the metabolites like proteins or chemicals present that are derived from the bacteria, or to look more carefully for specific bacteria that may be interesting to us. Please be aware that **no human DNA** will be sequenced as part of this or any future studies. Data may be published in a scientific article and then will be deposited in a public data repository.

If your child's sample shows infection with the COVID-19 virus you will be informed and referred to San Diego County for contact tracing and further investigation. The school or daycare center will also be informed.

How much time will each study procedure take, what is your child's total time commitment, and how long will the study last?
We anticipate that each sampling time point will require approximately two minutes and no more than 15 minutes. The total time commitment depends on how many times you provide samples.

What risks are associated with this study?
We anticipate no risks to your child from the sampling, which makes use of sterile cotton-tipped or polyester-tipped applicators that are applied by you or your child. Your child may experience some discomfort at the site of application of the swab but this is usually not significant. It is possible that there may be some loss of privacy from participating in the study, e.g. if the study is reported in the news media with schools identified. However our team will not share the names or any other identifying information of any study participants.

What about your confidentiality?
Research records will be de-identified kept confidential to the extent allowed by law. The data will be de-identified with all care taken to ensure that your child cannot be identified from a combination of the information you have provided. The code-key – relating the code to your child's personal identity - will be retained by the PI Dr. Rob Knight. The data (including the data derived from the samples) will be stored on a password protected server located at the San Diego Supercomputer Center (SDSC) at UCSD. Access to SDSC is controlled by biometric marker identification only. Research records may be reviewed by the UCSD Institutional Review Board

The investigation personnel have taken precautions to ensure that there is minimal risk of loss of confidentiality. If confidentiality is compromised, there is a risk that somebody could learn that your child has participated in this research study.

Personal identifiers will be removed from the information and biospecimens collected as part of the research. After such removal, the information could be used for future research studies or distributed to another investigator without your additional informed consent.

Biospecimens (such as nasal mucus, saliva and fecal) collected from your child for this study and/or information obtained from the biospecimens may be used in this research or other

research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

Because this is a research study, there may 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?
You may elect not to consent to your child participating.

What benefits can be reasonably expected?

There is no direct benefit to you for participating in this study. We hope that the information we learn from this study will contribute to helping school and childcare communities like yours minimize the risk of COVID-19 outbreaks.

Can you choose to not to have your child participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to allow your child to participate or withdraw your child at any time without penalty or loss of benefits to which you or your child are entitled. If you decide that you no longer wish your child to continue in this study, you will be requested to contact the PI, Rob Knight 858-246-1184 or by email: robknight@ucsd.edu). You and your child will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can your child be withdrawn from the study without your consent?
The PI (Rob Knight) may remove your child from the study without your consent if the PI feels it is in your best interest or the best interest of the study. Your child may also be withdrawn from the study if you or your child does not follow the instructions given you or your child by the study personnel.

Will you be compensated for participating in this study?
You and your child will not receive financial compensation for taking part in the study.

Are there any costs associated with participating in this study?
There will be no cost to you or your child for participating in the study and all sampling materials will be provided to you.

What if your child is injured as a direct result of being in this study?
If your child is injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if your child is injured. You or your child may call the Human Research Protections Program Office at (858) 246-4777 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

Who can you call if you have questions?

Dr. Rob Knight and/or_____ has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Rob Knight at 858-246-1184.
You may call the Human Research Protections Program Office at (858) 246-4777 to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent
You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to allow your child to participate.

Please print your child's name: _____

_____ _____
Parent/Guardian Signature Date

I consent to future use of my child's sample/s in other studies:

_____ YES _____ NO
(Please initial as appropriate for your response)

_____ _____
Parent/Guardian Signature of Second Parent Date
(if required by IRB)

I consent to future use of my child's sample/s in other studies:

_____ YES _____ NO
(Please initial as appropriate for your response)