University of California, San Diego
Consent to Act as a Research Subject
SASEA: Safer at School Early Alert system for K-12 schools

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?
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 this study and we will try to find a way to keep you safe from the virus that causes COVID-19 by looking at you, the surfaces in schools and daycare centers, and wastewater.

Why is this study being done?
The purpose of this study is to try to find a way to keep you safe from the virus that causes COVID-19 by looking at you, the surfaces in your school or daycare center and the wastewater from the building.
We are interested in looking at how viruses like SARS-CoV-2 (the virus responsible for COVID-19 disease) are transmitted to surfaces surrounding infected people, and how long it may remain as a source of infection. We will also sample wastewater from the school and compare it with the results we get from testing children and adults at your school or childcare site.

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

You will be provided with a sampling kit containing 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. Sampling and completion of the survey will take place by you at home.

Sample sites may include swabs from your nostrils, saliva by sampling your tongue or cheek, and saliva collected by spitting into a tube.

You will be asked to donate samples once a week for up to 12 weeks. We anticipate that each sampling session will last approximately 60-90 seconds, but no longer than 15 minutes.

We will use your samples to examine the microbial communities of your different body habitats. 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 analyzed as part of this or any future studies. At the conclusion of the study, the analyzed data can be made available to you through a public data repository.

If your 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 total time commitment, and how long will the study last?
We anticipate that each sampling time point will require no more than 60-90 seconds but 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 you from the sampling, which makes use of sterile cotton-tipped or polyester-tipped applicators that are self-applied. You 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, we will not identify any individuals who agree to participate in this study.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. The data will be de-identified with all care taken to ensure that you cannot be identified from a combination of the information you have provided. The code-key – relating the code to your 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 you have 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 fecal material, nasal mucus or saliva) collected from you for this study and/or information obtained from your 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 can choose not to participate.

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 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 at any time. If you decide that you no longer wish 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 will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?
The PI may remove you from the study without your consent if the PI feels it is in your best interest or the best interest of the study. You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?
You will not be financially compensated in this study.

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

What if you are injured as a direct result of being in this study?
If you are 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 you are injured. You 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 participate.

Name_____

_____ _____

Subject's signature Date

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

_____ YES _____ NO

(Please initial as appropriate for your response)