University of California, San Diego
Assent* to Act as a Research Subject (Ages 13-17 years)
*(*Giving your assent means that you agree to participate in the research study)*

COVID-19 Testing of Adolescents

Dr. Louise Laurent and her colleagues from UCSD are conducting a study on COVID-19 and asking for your consent to participate. This study is a collaboration between UCSD, San Ysidro Health, and a National Institutes of Health (NIH) program called RADx-UP which stands for Rapid Acceleration in Diagnostics in Underserved Populations.

The most important points to remember are:

- Being part of this study is voluntary – it is your decision to join the study or not. You can discuss your decision with others (like family, friends, or your doctor).
- You can say yes now but change your mind later.
- If you say no, that will not affect the care you receive from your doctor or the clinic.
- You can say no even if the person inviting you is part of your healthcare team.
- Please ask questions or let someone know if you have concerns anytime, before, during or after the study.

The purpose of this study is:

To offer testing for COVID-19 in a new, more convenient way and to understand how this new testing program affects the spread of the SARS-CoV-2 virus (the virus that causes COVID-19) in children and close contacts.

This study will directly benefit you because you will be able to find out if you have the virus that causes COVID-19, but the major purpose of this study is to gain new knowledge that may help others.

If you sign up for the study, you will be asked to fill out a questionnaire and will be offered a COVID-19 test. Once enrolled, you can return to test multiple times, at a maximum frequency of 2 times a week, and no more than 55 tests/visits per year. The COVID-19 test will be performed on samples collected either by swabbing your nose or from spit collected in a tube.

The alternative to this study is not to participate.

Why have you been asked to participate, and what is the approximate number of participants in the study?

You have been asked to participate in this study because you are a child who lives, works, goes to school or has connections to the San Ysidro community or to the San Ysidro Maternal and Child Health Center. There will be approximately 44,000 participants in this study, including 2,800 pregnant subjects, 31,600 non-pregnant adult subjects, and 9,600 children.

What will happen to you in this study?

We will ask you to fill out a questionnaire about yourself that will include questions about your race, ethnicity, gender, language, contacts, exposure, symptoms, living situation, health insurance status, your work, and other questions related to COVID-19. We will also ask you questions about how you feel about vaccines and testing for COVID-19. If you prefer not to answer one or more of these questions,

you can skip them. If you are a patient at San Ysidro Health, we may also collect data from your San Ysidro Health medical record.

We will show you how to collect a nose swab or saliva sample on yourself and watch you collect it. We will send your sample to be tested and will look for the virus that causes COVID-19 in the saliva or nose swab material you provide. The results of this test will be given to you in your preferred method: email, text, phone call, or postal mail and your doctor. The results will also be reported, as required, to the County of San Diego. You can choose to be tested up to a maximum frequency of 2 times a week, and no more than 55 tests/visits per year during the study period. If you choose to be tested again, the questionnaire we will ask you to fill out will be much shorter and will focus on your symptoms, possible exposures, previous testing, and persons you have had close contact with.

Any left-over samples will have your personal identifying information removed and will be stored and may be used for other research purposes, including looking at your genetic code (if you give your consent) or the genetic code of the SARS-CoV-2 virus.

How much time will each study procedure take and how long will the study last?
It will take approximately 30 minutes to enroll in the study, answer questions about yourself and collect the sample to be tested for COVID-19. If you choose to be tested again in the future, it will take approximately 10 minutes to answer a shorter set of questions about your symptoms and contacts, and to collect your sample for testing. You may choose to be tested for COVID-19 up to a maximum frequency of 2 times a week, and no more than 55 tests/visits per year over the study period. If you choose to be tested 55 times, we expect the total time you spend filling out the questionnaires and collecting your samples to be 9 hours and 40 minutes per year.

What risks are associated with this study?
Participation in this study is not expected to involve any physical risks. For some people, it can be uncomfortable to swab the nose. Because this is a research study, there may be some risks that are currently unknown.

What does it mean if my test comes back negative?
A negative test result means that the virus that causes COVID-19 was not found in your sample at the time it was collected. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause the symptoms. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test result is negative. If this is the case, your healthcare provider will consider the test result together with your symptoms and possible exposures, to decide how to care for you.

What does it mean if my test comes back positive?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be requested to isolate to avoid spreading the virus to others. Study staff will provide you information about COVID-19. This study will not provide treatment for COVID-19 but if you choose, study staff will set up an appointment with your healthcare provider at SYH or will send your COVID-19 results to your healthcare provider if they are not part of SYH. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider can work

with you to determine how best to care for you based on the test results, your medical history, and your symptoms.

What happens if you change your mind about participating?
If in the future you decide that you no longer wish to continue in this study, you will need to let the principal investigator, Dr. Laurent (contact information provided at the end of the consent form) know that you no longer want to participate. We will destroy all remaining samples collected from you and your genetic or other information. However, if your samples or the information collected from you are already being used in an active research project, it may not be possible to remove them. Your decision will not result in any penalty or loss of benefits and you will still be able to receive care from UCSD and San Ysidro Health.

Can you be withdrawn from the study without your consent?
You may be withdrawn from the study for the following reasons:

1. Your doctor believes that it is in your best medical interest.
2. You may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel.

Will you be compensated for participating in this study?
Participants who agree to participate in the study and complete the surveys will receive $20 for the initial visit survey and $10 for the completion of each return visit surveys.

Are there any costs associated with participating in this study?
There will be no cost to you to participate in this study. The cost of the COVID-19 test will be covered by the research study and will not be charged to you or your insurance.

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-HRPP (858-246-4777) for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality and use of your information?
Research records will be kept confidential to the extent allowed by law. 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 study information to anyone not connected to the study except when you agree, or in a few other specific situations.

All protected health information will be kept in locked and/or password protected files. When we use your data to conduct research, we will remove personal identifying information including your name, street address, email, date of birth, and telephone number from the data and samples we collect from you and will assign you study code. You will only be identified in our database by this study code. Your data, that **does not contain your name or other information that could easily identify you** will be combined with data from 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 is a research group chosen by the National Institutes of Health to combine the data collected from everyone taking part in RADx-UP studies.

What about your confidentiality and use of your samples?
Dr. Laurent will be responsible for deciding how the samples (such as nose swabs or saliva) collected from you will be used after they have been tested for the virus that causes COVID-19. Your samples may be used to examine the genetic code of the virus that causes COVID-19 and they may be used to examine your DNA, which carries the genetic code or instructions for the cells that make up your body.

Federal and State laws generally make it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: a) Health insurance companies and group health plans may not request your genetic information that we get from this research. b) Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. c) Employers with 5 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you. Be aware that these laws **do not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Additionally, these laws do not apply if you are a member of the United States Military, or if you are receiving health care through the Veteran's Administration or the Indian Health Service.

It is your choice to have your genetic code examined in your sample. *(please check yes or no below)*
We are asking your permission to look at your DNA in the sample you provide. You can choose to not have your genetic code examined but still participate in this study.

___ **Yes** You may look at my genetic code in the sample you collect from me.
___ **No** You may NOT look at my genetic code in my sample.

What about future use of samples and information?
The information and specimens collected from you and/or the information from your samples may be kept indefinitely and used in this research or other research and shared with other organizations. Other researchers may also use these data for studies, other than the ones described in this consent form. 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 these other researchers. Your information and samples will only be shared with researchers who apply for and get permission to use the information for a specific research project. Your genomic data (if you have provided permission) and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the database have agreed not to attempt to identify you.

The samples and information collected during this study may be used in future studies in ways that are not currently planned yet. For example, if there is a technological breakthrough in the future for analysis of saliva, scientists may apply this new technology to study your samples. You will not share in any commercial value or profit resulting from the use of your samples and/or information obtained from them.

What about participation in future studies?

In the future, we may wish to re-contact you to collect information about you or to offer participation in future studies. *(please check yes or no below)* You can choose to not be contacted in the future about other studies or to answer more questions but still participate in this study.

___ **Yes** You may contact me to ask me more questions or to see if I am interested in participating in future studies.

___ **No** I do NOT want to be contacted to answer more questions or to see if I am interested in participating in future studies.

If you agree to be contacted, please provide one or more of the following:

Phone number: _____

E-mail address: _____

Mailing address: _____

Will you receive any results from participating in this study?

Yes, you will receive the results of the COVID-19 tests that will be performed as part of this study; you will not receive any other results from participating in this study.

Who can you call if you have questions?

If you have other questions or research-related problems, you may reach Dr. Louise Laurent at 858-336-6882.

You may call the Human Research Protections Program Office at 858-246-HRPP (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.

Verbal Consent Agree to Participate:

___ Yes

___ No

_____ _____

Subject's Name Date

_____ _____

Signature of the person conducting the informed assent discussion Date