UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

Note: In this consent the word "you" refers to the person being considered for enrollment in the study described. This may be you as the reader of this document, a person for whom you are serving as the Legally Authorized Representative (LAR) or surrogate, or your child.

1. **Study Title and Number**

Title: CO-CREATE-Ex: Community-engaged Optimization of COVID-19 Rapid Evaluation and Testing Experiences

Study # 806121

2. Principal Investigator

Dr. Louise Laurent, MD PhD, Professor, OB/GYN & Reproductive Sciences Department at UC San Diego

3. Principal Investigator Phone Number, Research Team Number, and Emergency Contact Number

Principal Investigator Phone Number: 858-255-1117

Research Team Number/ Emergency Contact Number: 858-945-4553

4. Study Sponsor

This study is a collaboration between UC San Diego (UCSD), San Ysidro Health (SYH), the Global Action Research Center (Global ARC) and Duke Clinical Research Institute (DCRI). The study is funded by the National Institutes of Health (NIH) under a COVID-19 research program called RADx-UP, which stands for Rapid Acceleration in Diagnostics in Underserved Populations.

5. Study Overview

This research study is being conducted to refine, specify, implement, and evaluate an implementation strategy bundle that optimizes COVID-19 testing.

We are inviting you to participate in a research study because you live, work or have connections to San Ysidro Health or the surrounding communities, and/ or you are seeking a COVID-19 test at a San Ysidro Health establishment for yourself or a child under 18.

This form explains the research so that you may make an informed decision about participating.

- Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends, or another physician).
- You can say yes but change your mind later.
- If you say no, we will not hold your decision against you.
- You can say no even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care or other benefits you may be entitled to.
- Please ask the study doctor or study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.
- You will be given a copy of this consent form and the Participant's Bill of Rights.

The purpose of this research study is to offer sustainable COVID-19 testing at your convenience in the greater San Diego community. This will be a flexible and sustainable approach that promotes responsiveness to both the needs of the community and the changing pandemic context while reducing COVID-19 testing disparities.

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 free COVID-19 test.

The most common risks or discomforts of this study are experiencing discomfort when swabbing your nose.

The most serious risks include the loss of confidentiality in the case of a security breach or the risk that information about you could be released to an unauthorized party.

A complete listing of possible risks and discomforts associated with this study can be found in Section 9 of this document. Because this is a research study, there may be some risks that are currently unknown.

The alternative to being in this study is not to participate. If you decide not to participate, we will provide you with a list of COVID-19 testing resources.

More detailed information about this research study is provided below.

6. Whom can I talk to if I have questions?

If during your participation in the study you have questions or concerns, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form. You should not agree to participate in this study until the research team has answered any questions you have about the study, including information contained in this form.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

- UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

7. How many people will take part?

We plan to include up to 7,500 people in this study. The research will include people who are seeking COVID-19 testing in underserved communities in Central and South San Diego at a San Ysidro Health clinic location.

8. What happens if I take part in the research?

Here is what will happen to you if you agree to be in this study:

1. You will be asked to register as a research participant either in person at a testing site or by accessing a website. When you register, we will ask you for your name, date of birth, address, phone number, email, race, ethnicity, gender, and preferred language. We will also ask you about your symptoms, if you have received any COVID-19 vaccines, and if you have been previously tested for COVID-19.
2. You will be offered a free COVID-19 test from either a person or a vending machine at one of testing sites. After receiving your free COVID-19 test, you may leave the testing site or vending machine.
3. You will then be asked to fill out a questionnaire about yourself that will include questions about your exposure, living situation, health insurance status, your work, and other questions related to COVID-19. If you prefer not to answer one or more of these questions, you can choose not to answer.
4. After you perform the COVID-19 test, we will ask you to send the result to the research team by text.
5. You may return to test with either the testing site or vending machine as often as needed. If you choose to be tested again, you will not be asked to complete the registration questions. You will be asked to report any symptoms, changes in vaccine or test history to receive your free COVID-19 test. After completing your test, we will ask you to complete a shorter questionnaire and send your result to our research team by text.

As you read this form, ask questions if something is not clear.

9. What are the risks and possible discomforts?

Participation in this study may involve risks or discomforts. Participation in this study is not expected to involve any physical risks. For some people, it can be uncomfortable to swab their nose. Risks also include the potential for the loss of confidentiality.

Risks of Loss of Confidential Information: There is also a risk that information about you could be released to an unauthorized party. To minimize this risk, all protected health information will be kept in locked and/or password protected files. Research records will be kept confidential to the extent allowed by law. Research records may be reviewed by the regulatory and funding agencies, such as the UCSD Office for Human Research Protections, FDA, and NIH.

Risks of Collection of Sensitive Information: Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study.

Possible Unknown Risks: In addition, there might be risks that we cannot predict at this time. These unknown risks may be temporary, mild, and last only while you are actively participating in the research, or they may be serious, long-lasting, and may even cause death. You will be informed of any new findings that might affect your health or welfare or might affect your willingness to continue in the research.

10. How will information about me be protected?

While we cannot guarantee complete confidentiality, we will limit access to information about you. Only people who have a need to review your information, documents, or specimens will have access. These people might include:

- Members of the research team and other staff or representatives of UCSD whose work is related to the research or to protecting your rights and safety.
- Representatives of the study sponsor.
- Representatives of Federal and other regulatory agencies who make sure the study is done properly and that your rights and safety are protected.

During data analysis, your study data will be labeled with a code instead of your name or other information that can easily identify you.

The results of this study may be published once the study is completed. However, we will keep your name and other identifying information confidential. We expect this study to be completed in 2 years. This is only an estimate and the actual time to complete the study may be longer or shorter depending on a number of factors.

Information about you is protected by a federal Certificate of Confidentiality. This means that we cannot be forced to release your specimens or information about you for any legal proceeding, even if a court of law asks.

The Certificate allows us to use *your* information about you for the purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect information we share with them.

There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).
- A federal agency audits or evaluates research that it funds.
- Researchers are required to report possible intent to harm yourself or others, child abuse, elder abuse, or infectious disease cases.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect.

11. Will I need to pay to participate in the research?

There will be no cost to you for participating in this study. The COVID-19 test will be supplied at no cost to you while you take part in this study.

12. What if I agree to participate, but change my mind later?

You can stop participating at any time for any reason, and it will not be held against you. Your choice will not affect any treatment relationship you have with healthcare providers at UC San Diego Health, San Ysidro

Health or any services you receive from them. No matter what you decide, there will be no penalty to you. You will not lose medical care or any legal rights.

If you stop participating, we may not be able to remove the information we have already collected from you.

In addition, the study doctor or sponsor may stop the study or take you out of the study at any time, even if you would like to continue. This could happen because you do not follow the instructions given to you by the study personnel or your doctor believes that it is in your best medical interest.

13. What will happen to the information collected from me?

The data we collect from you as a part of this study may be used to answer other research questions or may be shared with other investigators for other research. Some of the data we collect from you will include identifiable information (for example, your name or date of birth).

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 a study code. You will only be identified in our database by this study code.

Once identifiable information has been removed, the remaining de-identified data will not be able to be used to identify you, and we will not ask for your consent for the use or sharing of your de-identified data in other research.

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 Institue is a research group chosen by the NIH to combine the data collected from everyone taking part in RADx-UP studies.

While your privacy and confidentiality are very important to us and we will use safety measures to protect it, we cannot guarantee that your identity will never become known.

14. What are my responsibilities if I take part in this research?

If you take part in this research, you will be asked to fill out a questionnaire and report COVID-19 test results to our team. Once enrolled, you can return to test multiple times. It will take approximately 30 minutes to enroll in the study, answer questions about yourself and obtain a COVID-19 test kit. Repeat visits are expected to be shorter.

15. Will I be compensated for participating in the research?

We will not pay for any out-of-pocket expenses related to your participation, such as travel costs. Participants who agree to participate in the study and complete the survey will be offered a $20 gift card

16. What else is important for me to know?

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 with information about COVID-19. 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.

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 Office of IRB Administration at 858-246-4777 or irb@ucsd.edu for more information about this, to inquire about your rights as a research participant, or to report research-related problems.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

17. What are my rights when providing electronic consent?

California law provides specific rights when you are asked to provide electronic consent:

- You have the right to obtain a copy of the consent document in a non-electronic format.
- You have the right to provide consent in a non-electronic format.
- If you change your mind about electronic consent, you have the right to request your electronic consent to be withdrawn and you can then provide consent in a non-electronic format; however, a copy of your electronic consent will be maintained for regulatory purposes. If you wish to withdraw your electronic consent, please tell the study team.

This agreement for electronic consent applies only to your consent to participate in this research study.

18. Additional Choices to Consider

The study team would like your permission to contact you about participating in future studies. You may still join this study even if you do not permit future contact. You may also change your mind about these choices at any time. Please select your choices below:

I agree to be contacted for future research. (You may still join this study even if you do not permit future contact.)

_____ Yes, you may contact me

_____ No, you may NOT contact me

For Adults Able to Provide Consent

Participant

I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I agree to participate in the research described in this form.

____Yes

____No

_____ _____

Electronic Consent Print Name Date

For Adults Unable to Provide Consent

Participant

I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I give my permission for the named person below to participate in the research described in this form.

_____ Yes

_____ No

Electronic Consent Print Name of Participant Date

Electronic Consent Print Name of Legally Authorized Representative Date

For Parent(s)/Guardian(s) of Child Participants

Participant

I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I give my permission for the named child below to participate in the research described in this form.

_____ Yes

_____ No

Electronic Consent Print Name of Participant Date

Electronic Consent Print Name of Parent/Guardian Date

The person providing the information above is: (Choose One)

- ❑ Parent
- ❑ Individual legally authorized to consent to the child's general medical care (See below note)

If consent of second parent not obtained, indicate why: (Choose One)

- ☒ The IRB determined that the permission of one parent is sufficient
- ❑ Second parent is deceased
- ❑ Second parent is unknown
- ❑ Second parent is incompetent
- ❑ Second parent is not reasonably available
- ❑ Only one parent has legal responsibility for the care and custody of the child

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CONSENT TO PARTICIPATE IN RESEARCH

Experimental Participant's Bill of Rights

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.

2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.

5. Informed about of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. Told of the types of medical treatment, if any, available if complications should arise.

7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.

9. Provided a copy of the signed and dated written consent form and a copy of this form.

10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study, contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

- UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777