IRB APPROVED
AS MODIFIED
Mar 02, 2022

RESEARCH SUBJECT CONSENT FORM

TITLE: Human Saliva Data Collection for COVID Modeling

PROTOCOL NO.: PCI-HS002-V.2
IRB Protocol #20217097

SPONSOR: Pattern Computer, Inc.

INVESTIGATOR: Jim Rhodes, BA
3516 Ocean View Boulevard
Glendale, CA 91208
USA

STUDY-RELATED PHONE NUMBER(S): 818-209-5936 (24 hours)

Participant's Name: _____ Date:_____

If you are an adult that will decide whether to take part in this study, the "you" refers to you. If you are a parent or legal guardian of a child that may be enrolled in this research study, then the "you" refers to your child. "We" refers to the staff performing the study.

RESEARCH CONSENT

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

In this consent form "you" generally refers to the research subject. If you are being asked as the parent, or guardian to permit the subject to take part in the research, "you" in the rest of this form generally means the research subject.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand something, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to generate data to refine a model that identifies active infections from saliva, particularly COVID, and to explore potential variations in collection (e.g., with and without a mouthwash rinse), and explore usability of various saliva collection regimes.

We expect that between 1,000 and 10,000 subjects will take part in this research at all participating study sites.

How long will I be in this research?

We expect that your taking part in this research will last less than 10 minutes, though in some cases we may request additional samples, or supplemental information.

What happens to me if I agree to take part in this research?

You will be asked to read this document and consent to its terms. If you agree, we will ask you to respond to a brief series of questions regarding your medical history, current symptoms you may be experiencing and some demographic data.

Once you sign the consent form and complete the questionnaire, you will be asked to provide a small amount of saliva. We will test your saliva with our system and the specimen will be discarded afterward. The site is also testing you via other, FDA authorized PCR methods as per routine care. If you are tested by the site multiple times via other, FDA authorized PCR methods, we will ask to test your saliva with our system on each occasion, which you are free to decline without consequences.

Data from the results of the research saliva testing will be shared with the study sponsor. Your identity will be assigned a code, and your name will not be released to the sponsor. The code to your identity will be kept by the researchers at the testing site.

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

If you take part in this research, you will be responsible to provide a saliva sample according to the directions provided and to answer a few questions.

Could being in this research hurt me?

There are no known risks or discomforts associated with providing a saliva sample.

There could be a risk the information you provide us could be accidentally shared with others, but information will be kept as confidential as possible, as required by law. Please read the section of this consent form describing how information about you will be kept private.

Will it cost me money to take part in this research?

There is no cost to you to participate in this research. You will not be paid for participating in the research.

Will being in this research benefit me?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

Information learned from your saliva may help researchers learn more about COVID infections and may result in the development of fast and accurate tests for COVID and other viral infections.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

Your participation is voluntary, and you may refuse to allow participation or may discontinue at any time and for any reason without penalty or loss of benefits to which you are otherwise entitled.

What happens to the information collected for this research?

The information we collect, which includes your underlying medical conditions, will be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor, Pattern Computer, Inc.
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- WCG IRB, the Institutional Review Board (IRB) that reviewed this research. This is a group of people who work to protect the rights and welfare of people who take part in research studies.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Data collected in this research will be deidentified and may be used for future research or distributed to another investigator for future research without your further consent.

CONFIDENTIALITY AND AUTHORITY TO RELEASE MEDICAL RECORDS

By agreeing to participate in this study, you are agreeing to authorize Jim Rhodes and his research staff to review your PCR test results. Information regarding your involvement in this research study will also be collected. These records will be kept confidential and will be reviewed only by necessary medical personnel.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

SIGNATURE FOR CONSENT: A member of the research team has answered my questions and I agree to participate in this research study. I HAVE READ THE INFORMATION PROVIDED ABOVE. I VOLUNTARILY AGREE TO ALLOW MY CHILD TO PARTICIPATE IN THIS STUDY. AFTER IT IS SIGNED, I WILL RECEIVE A COPY OF THIS CONSENT FORM AND A COPY OF THE RESEARCH SUBJECT'S BILL OF RIGHTS.

_____
Participant's Name

_____ _____
Adult Participant's Signature Date

I certify that under state law I am the parent or guardian of the Participant named above and that I am authorized to sign this form.

_____
Printed Name of Parent/Guardian

_____ _____
Signature of Parent/Guardian Date

Relationship to Participant: _____

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form will be given to the participant or his/her representative.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

INTERPRETER STATEMENT: I interpreted for the above Investigator or Research Staff, who explained this consent form to the Participant, Parent or Guardian.

_____
Printed Name of Person Interpreting Consent

_____ _____ _____
Signature of Person Interpreting Consent Date Language of Interpretation

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Assent instructions:

- All children are required to assent, unless the investigator determines that the capability of the child is so limited that the child cannot reasonably be consulted
- If assent is obtained, have the person obtaining assent document assent on the consent form. Subjects can sign the assent statement below but it is not required.

Child Assent

We want to tell you about a research study. We are testing to see if an infection can be detected in a very short period of time. To perform the test, you would put a small amount of saliva from your mouth into a tube. The results from this test will be compared to the regular test being done to see if you have an infection. These results will be shared with the study sponsor, Pattern Computer, but the information will not contain your name, or any information that identifies who you are. We will replace that information with a code number. The study team will keep the code that identifies you separate from the study data.

Being in this study is your choice. You don't have to be in the study, and no one will be mad at you if you decide not to participate. Please ask any questions you might have.

- ❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study. OR
- ❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

- ❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

Signature of person obtaining assent | Date

I asked and got answers to my questions. I know that I can ask questions about this study at any time. I want to be in the study at this time.

Subject's Printed Name

Signature of subject

Date