IRB APPROVED
AS CORRECTED
May 15, 2020

RESEARCH SUBJECT CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

TITLE: Usability Study of Home Collection and Mailing with SARS-CoV-2 Test Specimen Collection Materials

PROTOCOL NO.: 2020-06
IRB Protocol # 20201252

SPONSOR: Exact Sciences

INVESTIGATOR: [redacted]

STUDY-RELATED PHONE NUMBER(S): [redacted]

DETAILED RESEARCH CONSENT

What should I know about this research?

- 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.
- Enrollment may be opened to employees of Exact Sciences. An employee's decision about research participation will not affect (favorably or unfavorably) performance evaluations, career advancement, or other employment-related decisions made by peers or supervisors.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide if you would like to participate.

The sponsor is paying for this research study. Your Study Doctor owns significant stock with, and is employed by, the Sponsor of this study.

Why is this research being done?

The purpose of this research is to determine the usability of the SARS-CoV-2 Specimen Collection Materials for at-home collection and mailing of the of sample to the testing laboratory. During your study visit, you will be observed by a moderator as you follow the Instructions for Use, included with SARS-CoV-2 Specimen Collection Materials, for collecting and shipping of the study sample. The study sample is a self-collected nasal swab which is analyzed by the laboratory for the detection of SARS-CoV-2, the virus that causes COVID-19.

Approximately 30 subjects will take part in this research.

How long will I be in this research?

It is expected that your participation in this research will last up to 1 day from enrollment, the time you sign this form, to completion. Your study visit will last approximately 45 minutes.

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

If you decide to take part in this research study, you will sign this form before any study procedures are performed. After you sign this form, the moderator will request for you to complete a questionnaire which will include your name, date of birth and demographic questions, such as your sex, race and ethnicity, and information about your experience with prior COVID-19 self-collection.

You will then be provided with the SARS-CoV-2 Specimen Collection Materials and asked to follow the Instructions for Use for self-collection and shipping of the nasal swab sample. The moderator will observe you as you open the collection materials, self-collect the nasal swab sample by swabbing the inside of each of your nostrils, and ship the sample to the laboratory.

Upon completion, you will be requested to provide feedback on the usability of the Instructions for Use by completing a brief survey, answering several questions asked by the moderator and providing written feedback on your experience.

You will not be notified of your SARS-CoV-2 test results from the sample collected during your participation in this research study.

Your leftover samples may be retained for purposes such as additional testing in this or alternative SARS-CoV-2 tests. All samples will be destroyed 12 months after your study participation ends, or earlier.

Ask us if you have any questions about the tests and procedures for the study.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for doing the following:

- Provide private information, including your name and date of birth
- Follow directions provided by the moderator
- Complete the study questionnaires
- Make and keep your study appointment
- Provide the requested nasal swab sample
- Properly dispose of used nasal swab

Could being in this research hurt me?
During or after a nasal swab, you may experience sneezing, nasal redness, or a bloody nose. There is a potential for loss of confidentiality of your data. You may read below about how your medical information will be protected.

Will it cost me money to take part in this research?
You do not have to pay for study visits or tests that are part of the study.

Will being in this research benefit me?
There are no direct benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, there may be possible benefits to others in the future based on information learned from this study.

What other choices do I have besides taking part in this research?
This study does not involve treatment for any condition. You may choose not to take part in this study. If you choose not to take part in this study, it will not affect your current position in any manner. There will not be any penalty or loss of benefits to you if you decide not to take part or if you leave the study early.

What happens to the information collected for this research?
Your self-collected sample will be identified by your name and date of birth. The survey you complete will be identified by your name and contain your date of birth. Your private

information (name and date of birth) will be maintained by the Sponsor study staff for the purpose of overseeing the research study. Your informed consent form and private information will be kept in a secure electronic file storage area with limited access. The Sponsor will not present or publish the data in any way that might identify you as a participant in this study.

The Sponsor personnel responsible for executing this study will have access to your private information for a limited number of tasks, including conducting this informed consent process and sending appropriate study reminders.

Your private information and your medical record will be shared with individuals and organizations that conduct or watch over this research, including:

- The research Sponsor (Exact Sciences)
- People who work for the research Sponsor
- Government agencies, such as the U.S. Food and Drug Administration (FDA)
- The Institutional Review Board (IRB) that reviewed this research. The IRB is a group of scientists and non-scientists who review the ethics of research. The goal of the IRB is to protect the rights and welfare of study subjects.

These people may look at your records to make sure the study has been done the right way. They also want to make sure that your health information has been collected the right way, or for other reasons that are allowed under the law.

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.

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 an Institutional Review Board (“IRB”). An IRB is a group of people who perform independent review of research studies. You may talk to them at (888) 303-2224 or (800) 562-4789, irb@cgirb.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.

What if I am injured because of taking part in this research?
If you are injured or get sick because of being in this research, call the study investigator immediately. The study staff will provide emergency medical treatment or refer you for treatment. Your insurance may be billed for this treatment. The Sponsor will pay any charges that are not covered by insurance policy or the government, provided the injury was not due to your underlying illness or condition and was not caused by you or some other third party. No other payment is routinely available from the study investigator or Sponsor. You do not give up any legal rights by signing this consent form.

Can I be removed from this research without my approval?
The principal investigator or Sponsor can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- The research is canceled by the FDA or the Sponsor
- You do not follow the study procedures as instructed

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research. You may be asked to sign a new consent form if this occurs.

What happens if I agree to be in this research, but I change my mind later?
Taking part in this study is your choice. There will not be any penalty or loss of benefits to which you are otherwise entitled if you decide not to take part or if you leave the study early.

You may leave the study at any time. You are a volunteer in this study, and you have the right to change your mind about participating. You can decide not to participate and leave the study at any time without losing any of the medical benefits to which you are otherwise entitled.

If you decide to withdraw before the end of the study, there are no anticipated risks associated with this decision.

Will I be paid for taking part in this research?
You will receive a $25.00 gift card for taking part in this study.

Otherwise, you will receive no compensation for taking part in this study or for providing samples for Exact Sciences' use within the scope of this consent.

What if something is developed from this research?
It is possible that Exact Sciences will develop a commercial test for SARS-CoV-2. There are no plans to compensate you for the sales of this test.

STATEMENT OF CONSENT

I have read this form, and I have been able to ask questions about this study. The study staff has talked with me about this study. They have answered all my questions. I voluntarily agree to be in this study.

By signing this form, I have not given up any of my legal rights as a research subject. I have been told that I will be given a signed and dated copy of this consent form for my records , as well as a signed and dated copy of the Experimental Subject's Bill of Rights.

TO BE COMPLETED BY SUBJECT

_____

Printed Name of Subject

_____

Signature of Subject Today's Date

TO BE COMPLETED BY SITE STAFF

_____

Printed Name of Person Obtaining Consent

_____

Signature of Person Obtaining Consent Today's Date

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study doctor must obtain your authorization (permission) to use or release any health information that might identify you.

If you decide to be in this study, the study investigator and study staff will use and share health data about you to conduct the study. Except when required by law, you will not be identified by name, address, telephone number or other facts that could identify the health information as yours. Health data may include:

- Your name
- Address
- Phone number
- Email address
- Date of birth
- Medical history
- Information from your study visits, including all test results

Health data may come from your study records or from existing records kept by your doctor or other health care workers.

For this study, the study staff may share health data about you with authorized users. Authorized users may include:

- Representatives of Exact Sciences.
- Institutional Review Board that reviews this study.
- The U.S. Food and Drug Administration and other U.S. federal and state agencies.
- Government agencies to whom certain diseases (like HIV, hepatitis, and STDs) must be reported.
- Governmental agencies of other countries.
- Outside individuals and companies, such as laboratories and data storage companies, that work with the study staff and sponsor and need to access your information to conduct this study or perform

activities related to the study, such as reimbursement services if applicable.
- Other research doctors and medical centers participating in this study, if applicable.
- A data safety monitoring board which oversees this study, if applicable.

Your health data will be used to conduct, complete, evaluate and oversee the study and perform activities related to the study, including for instance:

- Development and evaluation of SARS-CoV-2 Specimen Collection Materials

Once your health data has been shared with authorized users, it will no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here. Further, authorized users may de-identify your health data and use and release de-identified data (i.e., data that does not identify you) for purposes unrelated to this study.

Your permission to use and share health data about you will end in 50 years unless you revoke it (take it back) sooner.

You may revoke (take back) your permission to use and share health data about you at any time by writing to the study investigator. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received unless you have a side effect related to the study. However, health data about you that has already been gathered may still be used and given to others as described in this form.

If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you can access your study health data.

You do not have to sign this form. If you decide not to sign and date this form, you will not be able to take part in the study.

Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are otherwise entitled.

STATEMENT OF AUTHORIZATION

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

TO BE COMPLETED BY SUBJECT

_____

Printed Name of Subject

_____

Signature of Subject Today's Date