INFORMED CONSENT FORM AND HIPAA AUTHORIZATION

TITLE: Asymptomatic novel CORonavirus iNfection (ACORN) Study

PROTOCOL NO.: 2020-9174
IRB Protocol # 20200829

SPONSOR: Eli Lilly and Company

INVESTIGATOR: David Bradley Woodward
Lilly Corporate Center
893 Delaware St
Indianapolis, Indiana 46225
United States

STUDY RELATED PHONE NUMBER(S): 877-393-8504 (ACORN STUDY CALL CENTER)

1-800-545-5979 (24 hours) The Lilly Answers Center (TLAC) number is available for those who are enrolled in the study. If you have a problem or have a question regarding a Lilly product, please contact TLAC.

Eli Lilly and Company ("Lilly") is conducting a research study, "Asymptomatic novel CORonavirus iNfection (ACORN) Study". The purpose of this study is to investigate the occurrence of COVID-19 among people who do not have symptoms. There is little information about COVID-19 available as this is a new virus. This study will help us understand more about COVID-19, the characteristics of people that do not have symptoms, and provide key information for future research. Your active participation in this study could range from three (3) days to three (3) weeks. The broader study activities will run for approximately ten (10) weeks. This is an observational study. Approximately 3000 patients will participate in this study. Your treatment and medical care will not change because you are participating in this study. Your health care provider will continue to make all decisions regarding your proper treatment and care.

The sponsor is paying for this research study. The study doctors are employees of the sponsor.

Your active participation in this voluntary study will require screening, consent, questionnaire completion and testing for COVID-19. For those who test positive, the study team will require follow-up phone calls following the test. Lilly will collect information regarding you, your current health status, and your medical history. The study is not intended to, and does not, provide medical advice. You should seek medical advice from your physician.

You will first participate in a phone call where your eligibility for the study will be assessed. The call center staff will discuss the requirements for participating in the study and explain the procedures for the study. The call center will verbally confirm that you understand this Consent Form and the Notice of Privacy Practices, and you will electronically confirm your consent via email. You will then complete a questionnaire over the phone. You will then schedule an appointment for testing and receive an accession number for the test. When you come to your scheduled appointment, you will bring your accession number. You will be tested for COVID-19 with a nasal swab. The results will be available for you to access on a secure website, one (1) to three (3) days after you are tested. If the results are positive you will also receive telephone notification and follow up calls. The first phone call will occur within approximately two (2) to three (3) days and will confirm that you received the result. The second phone call will occur within approximately fourteen (14) days and you will be asked questions about your health status. The results of your COVID-19 test will be kept confidential and disclosed only as required by law. In the event that your nasal swab sample cannot be evaluated in the laboratory, you will be notified that the sample was "invalid". You will then receive a telephone call asking if you would like to return and provide a second nasal swab for testing. This retest will not be included in the study, but for your own personal knowledge of results. The information you share and the results of the test may be used and disclosed consistent with this Consent Form and the Notice of Privacy Practices provided to you.

ARE THERE ANY BENEFITS?

You will not receive any benefits for providing this information or participating in this study.

Your participation will provide information about COVID-19. This might benefit others in the future.

WILL I BE PAID TO TAKE PART?
You will not receive any payment for providing this information or participating in this study.

ARE THERE ANY COSTS?
You do not have to pay for study visits or tests that have to be done for the study. You or your insurance company will have to pay for routine care you would receive whether or not you are in the study, including care if you test positive for COVID-19. You may talk to the study staff and your insurance company about what is covered.

WHAT ARE THE RISKS OR DISCOMFORTS OF THE STUDY?
There are risks inherent in the Testing Program and in any COVID-19 testing. Before continuing in the Testing Program, you should consider the following:

- If you are having trouble breathing or are suffering severe distress, you should call 911 or go to your nearest emergency room.
- There are still many uncertainties about the transmission of COVID-19. Lilly has incorporated into the Testing Program common medical practices and reasonable safeguards designed to, among other things, prevent transmission of the virus based on current understandings of the virus and how it is transmitted. However, Lilly cannot guarantee your health or that you will not become infected with COVID-19 during or as a result of your participation in the Testing Program.
- The nasal swab procedure used to obtain the sample may be uncomfortable.
- The sample you provide will be tested as described above so that Lilly may share results with you, in part, to prevent the potential spread of the virus to others. In addition, your sample may be re-tested one or multiple times in conjunction with efforts relating to COVID-19, including for research, scientific, public health, or related purposes and information regarding such testing may be published in connection with these efforts; provided, however, that (except as described herein) we will not publish information that allows identification of your specific identity.
- The COVID-19 testing is not 100% reliable, and there is a possibility that the test will indicate you have been infected with COVID-19 when you have not been (a “false positive”), or that you have not been infected with COVID-19 when you have been (a “false negative”).
- If your test result is positive, Lilly may be required by law to report that result to certain public health agencies, including the Indiana State Department of Health and the Centers for Disease Control and Prevention. In addition, the information you share may be used and disclosed consistent with the Notice of Privacy Practices provided to you.
- Lilly has incorporated into the Testing Program reasonable safeguards designed to protect the confidentiality of your health information. However, Lilly cannot guarantee that your information will remain confidential; it is possible that it could inadvertently

be disclosed to others.
- Lilly cannot provide treatment for COVID-19 or your symptoms and is not providing you with medical advice. You are and will remain responsible for seeking appropriate treatment based on the results of your test. It also is possible that your physician or other health care professional may want to conduct a second test.

WHAT ARE THE ALTERNATIVES?
Your alternative is to not allow us to collect and use this information for research purposes.

HOW WILL MY INFORMATION BE PROTECTED?
As part of the conduct of this research study, it will be necessary to share your medical information with persons other than you or your health care provider. This Consent Form explains how your personal health information will be used and to whom it will be given ("disclosed") for this research study. It also describes your privacy rights, including your right to see your personal health information.

You also have privacy rights according to a federal government rule that has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Additional information about your privacy rights is contained in the Notice of Privacy Practices for Lilly's Employee Health Services (EHS). This Notice of Privacy Practices describes how the study doctor may use or release any health information that might identify you.

The study doctor and study staff will use and share your health information as part of this research 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.

Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records, medical history, including health information (paper or via electronic media) needed for this study and new information created or collected during the study.

Your personal health information will be handled by the health care provider and staff in a confidential manner. Your personal health information will be stored in limited-access databases. Your health information will be used and disclosed in accordance with this Consent Form. Access to all information is limited and accessed only as indicated in this document. Steps are taken to reduce the risk of your personal health information being misused or accessed by unauthorized people. However, these risks cannot be eliminated.

By signing this Consent Form for this study, you give permission ("authorization") for the uses and disclosures of your personal health information that are described in this Consent Form. If you do not want to allow these uses, you should not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- Lilly will use your information (paper or via electronic media) and information created or collected during the study to conduct the study.
- Lilly is the sponsor of the study, and because the sponsor conducts business related to clinical research in many countries around the world, this may involve sending your study data outside of this country.
- The initial test results will be held in an accession database and identified by a code that is known by you and the study investigator.
- The test results are taken out of the accession database and linked to your questionnaire data (the study data) only by a code number. Thus, the study data do not include your name, address, or other information that directly identifies you. Instead, the study health care provider assigns a code number to the study data. Some study data sent to the sponsor may contain information that could be used (perhaps in combination with other information) to identify you (for example, date of birth). If you have questions about the specific health information that will be transferred, you should ask the study investigator.
- The sponsor will use the study data for research purposes to support the scientific objectives of the study described in the consent document, to better understand the disease(s) included in the study, or to improve the design of future studies.
- The study doctor and study staff will share your study data, either alone or combined with data from other studies, may be shared with:

    - the sponsor, including persons or companies working for or with the sponsor
    - the U.S. Food and Drug Administration (FDA),
    - Department of Health and Human Services (DHHS) agencies,
    - other regulatory authorities in this country and other countries including the United States
    - and also with health care providers
    - and 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.

- The sponsor works with business partners in drug development. The sponsor may share your study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners sign a contract that requires them to protect your study data in the same way as the sponsor.

- Your health information may be further shared by the groups above. Your personal health information may no longer be protected under the HIPAA privacy rule once it is disclosed to these other parties.
- You have the right to see and copy your personal health information related to the research study for as long as this information is held by Lilly. However, your access to this information may be delayed until the study is complete.
- You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.
- You may cancel your authorization at any time by providing written notice to the Lilly Principal Investigator. If you cancel your authorization, the sponsor will no longer use or disclose your personal health information in connection with this study, unless Lilly needs to use or disclose some of your personal health information to preserve the scientific integrity of the study or unless you have a side effect related to the study. The sponsor will still use and disclose study data that was collected before you canceled your authorization. If you cancel your authorization, you will no longer be able to participate in the study. However, if you decide to cancel your authorization or not to participate, you will not be penalized or lose any benefits to which you are otherwise entitled. The study team may attempt to reach out to you after your participation in the study is complete.
- If you provided a name of your primary healthcare provider, we will also share your results with your healthcare provider.
- If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.
- If you do not withdraw this Authorization, it will remain in effect. ‘This authorization will expire on 31Dec2070.

DO I HAVE TO TAKE PART IN THE STUDY?
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.

COULD I BE WITHDRAWN FROM THE STUDY?
Your doctor or the sponsor, may withdraw you from the study without your consent for the following reasons:

- if you have a side effect from the study,
- if you need a treatment not allowed in this study,
- if you do not follow the study procedures as instructed,
- if the study is canceled by the FDA or the sponsor.

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(s) 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.

STATEMENT OF CONSENT

If, after considering the information contained within this Consent Form and Notice of Privacy Practices, you want to participate in the study, please provide your acknowledgement that you understand and accept its terms.

To become a part of this study and to authorize use and disclosure of your personal health information, you must provide informed consent.

I acknowledge the following:

- that I should review and receive a copy of this consent form electronically.

By providing consent, I am confirming the following:

- I have read all of the information in this Consent Form Notice of Privacy Practices, and I have had time to think about it.
- All of my questions have been answered to my satisfaction.
- I am volunteering to be part of this research study, and I understand that I may freely choose to stop being a part of this study at any time.
- I allow the sponsor to use and disclose my personal health information as described in this document.
- I have received a copy of this Consent Form to keep for myself.