CONSENT TO PARTICIPATE IN RESEARCH

ImmunoCARE: Rapid, Accurate COVID Testing to Reduce Hospitalization of Immunocompromised Individuals

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Institutional Review Board (IRB)	**Scripps Health**
Research Site(s):	**Digital Trial in MyDataHelps App**
Sponsor:	**The Scripps Research Institute (Scripps)**

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You are being invited to participate in the ImmunoCARE: Rapid, Accurate COVID Testing to Reduce Hospitalization of Immunocompromised Individuals Research Study.
This document informs you about the study so you can decide if you would like to participate. If you have questions about the study, ask us ImmunoCARE@scripps.edu. We are here to answer your questions.
Taking part in this study is entirely voluntary. You do not have to participate. If you decide to participate, you must sign this form to show that you want to take part.

Study Purpose

To examine whether a combination of at-home nucleic acid amplification tests, on-demand telemedicine, and delivery of prescriptions such as Paxlovid quickly after testing positive for COVID-19, can reduce severe outcomes such as hospitalization of immunocompromised patients. We will also analyze whether these efforts lower the cost of care compared to standard of care.

You should understand that:

- This is a research study. If you decide to participate, you can drop out at any time.
- The Cue Health Molecular COVID Test is FDA approved. Using the Cue telehealth services is optional.

- If you decide not to participate in this study, it will not affect your health care treatment or payment, enrollment in your health plan, or your eligibility for health care benefits.
- There are no plans to share any profits with you from potential scientific discoveries made using the information you donate.
- It is designed to help us learn about health and disease - in particular viral illnesses - for the benefit of immunocompromised people.

How long will I be in the study?

If you decide to join, we would like you to remain in the study for up to 8 months. Of course, you can stop participating at any time.

What will happen to me during the study?

ImmunoCARE will enroll 10,000 participants. Half of participants will test for COVID-19 and seek care as they normally would; the other half will receive at-home COVID-19 tests from Cue Health for themselves and others in their household. All participants will be asked to complete monthly surveys about COVID-19 exposure, infection, and hospitalization.

Surveys:

- You may skip any questions that you do not wish to answer.
- We will ask you to answer questions such as about your race, ethnicity, age, and sex at birth.
- We will ask you to answer questions about your health, including information about chronic disease diagnosis and symptoms you experience.
- We will ask you monthly about any COVID exposure and diagnosis.

Notifications:

- We will contact you via email, SMS and/or push notifications, based on your preference to remind you about different study activities.

Claims Data:

- We will ask you to share data from your health insurance claims. This will allow us to verify your immunocompromised status and study any care that you receive related to COVID-19.

What are the risks of participating?

The risks to participation in this study include risks to your privacy and minimal risk of physical harm with use of devices. These risks, although minimal, are outlined for your awareness below.

- **Privacy:**
    - We take your privacy very seriously. We use advanced technologies to protect it. But we cannot guarantee your privacy. If there is a data breach, someone who is not authorized could get information about you. This chance is very small, but it is not zero.
    - If you are asked to use Cue Health products, the information that you share with them is subject to their Privacy Policy and Terms of Service.
    - If you would like to learn more about the technology we use to protect your privacy, you can email us at ImmunoCARE@scripps.edu.
- **Discomfort:**
    - There may be a small risk for discomfort when using the Cue Health COVID Test. This risk is minimal, similar to other COVID-19 nasal swabs tests.

There may be other risks that are not known at this time. You will be told about any new information that might change your decision to be in this study.

What are the benefits of participating?

All participants will benefit by contributing to research and receiving compensation for completion of study activities. If you are in the group that receives Cue Health Products, you may benefit from that as well.

Will I be paid?

You will be eligible to earn up to $100 in Amazon gift cards.

Will it cost anything to be in the study?

There is no cost to participate in this study. There may be an indirect cost to participate in the study because transmitting the data collected for the study to the research team may use a part of your data plan. We do not expect this usage to be significant. You can configure your phone to have the study apps use WiFi connections to limit the impact data collection has on your data plan. You may receive charges for SMS messages. To avoid this, you can opt out of SMS notifications.

What if I don’t want to participate? What if I want to stop participating?

Your participation in this study is voluntary. You can decide not to join. If you decide to join, you can leave the study at any time.

You do not have to sign this consent form. If you do not sign the consent form, you will not be able to join in this research study.

If you leave the study, no new data will be collected. Data that has already been collected will still be used in the study.

What are my rights?

- You can email the ImmunoCARE study team to ask any questions about this study at ImmunoCARE@scripps.edu.
- You can decide not to be in this study. You can leave after starting.
- You still have all your legal rights whether you join the study or not.
- You have the right to be told about any new information that might make you change your mind about staying in the study.

Confidentiality and Data handling

Your contact information and data that directly identifies you will be separated from your study data and replaced with a random code that is unique to you before it is used for research purposes. All information used by this project will be protected in an effort to ensure it is only accessed by authorized people. No published scientific reports or presentations will identify you directly.

We will do our best to ensure that your data is kept private and secure. Your data will be stored and transmitted using high-security systems. The data will be securely stored in the United States. We will NOT access your personal contacts, other applications, text or email message content, or websites visited. We will never sell, rent, or lease your contact information.

Data sharing

Funding for the study comes from Cue Health and they are a scientific collaborator on this study. We may share the study data with researchers outside of Scripps and Cue Health. Before we do so, we will ensure that nothing in the data can identify you directly.

What if I get hurt while in this study?

We do not expect anyone to be hurt as part of participating in the ImmunoCARE Study. However, if you are hurt, you should seek medical care.

You or your medical insurance will be responsible for the costs of any treatment given. No money is available to pay you for time off from work. You are not giving up any of your legal rights by being in this study.

If you feel you have been hurt as part of participating in this study, please contact us at ImmunoCARE@scripps.edu.

Will Scripps, the study doctor, or sponsor benefit from this study?
Scripps and the study doctors are not being paid for the number of people who enroll. Researchers hope the knowledge gained from this study will help to improve the health of immunocompromised people in the future.

I agree to participate.

I have read and understood the explanation of the study. I have had a chance to ask questions and have them answered to my satisfaction. I agree to take part in this study. I have not been forced or made to feel obligated to take part. I am free to withdraw my consent at any time.

If I want to participate, I must sign this consent form. If I would like a copy of this document, I am able to save it and keep it for my records.

By providing my name below and selecting next, I am authorizing this document and agreeing to participate in this study.

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Printed Name of Subject

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Date

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

If I am asked to consent to be a subject in a research study involving a medical experiment, or if I am asked to consent for someone else, I have the right to:

Learn the nature and purpose of the experiment (also called "study" or "clinical trial").

Receive an explanation of the procedures to be followed in the study, and any drug or device to be used.

Receive a description of any discomforts and risks that I could experience from the study.

Receive an explanation of any benefits I might expect from the study.

Learn about the risks and benefits of any other available procedures, drugs or devices that might be helpful to me.

Learn what medical treatment will be made available to me if I should be injured as a result of the study.

Ask any questions about the study or the procedures involved.

Quit the study at any time, and my decision will not be used as an excuse to withhold necessary medical treatment.

Receive a copy of the signed and dated consent form.

Decide to consent or not to consent to a study without feeling forced or obligated.

If I have questions about a research study, I can call the contact person listed on the consent form. If I have concerns about the research staff, or need more information about my rights as a subject, I can contact the Scripps Office for the Protection of Research Subjects, which protects volunteers in research studies. I may telephone the Office at **(858) 678-6402**, 8:00 a.m. to 4:00 p.m. weekdays, or I may write to the Scripps Office for the Protection of Research Subjects, 4275 Campus Point Court, CPB200, San Diego, CA, 92121.

By signing this document, I agree that I have read and received a copy of this Bill of Rights.

______________________________________	_________________
Signature of Subject or Legal Representative	Date

**California Health & Safety Code, Section 24172*

Authorization to use your Private Health Information for Research

Name of Study: ImmunoCARE: Rapid, Accurate COVID Testing to Reduce Hospitalization of Immunocompromised Individuals

Principal Investigator: Eric Topol, MD
Julia Moore Vogel, PhD

What is private health information?

Private health information is any information that can be traced back to you. We need your authorization (permission) to use your private health information in this research study. The private health information that we will use and share for this study includes:

- *Health claims information pertaining to my medical history, mental or physical condition, and treatment received*

Who else will see my information?

In addition to the Principal Investigator, this information may be shared with:

- The sponsor of the research study, Scripps Research, our technical partner CareEvolution,, and any groups or companies that work with the sponsor, such as Cue Health
- government agencies, such as the US Food and Drug Administration and agencies like it in other countries, or agencies of the Department of Health and Human Services, and
- Scripps committees that review research to help protect people who join research studies.

Once we have shared your information we cannot be sure that it will stay private. If ***you*** share your information with people outside the research team, it will no longer be private. Your name will not be used in any report that is written.

How long will Scripps use and share my information?

- Your information will be used and shared until the research is completed, which we think will be in December 2025

What if I change my mind about sharing my research information?

If you decide not to share your information anymore:

- The sponsor and the research team can continue to use any of the private information that they already have.
- You will no longer be a part of the research study.
- Select to withdraw from the study within the participant portal or via email at ImmunoCARE@scripps.edu

Do I have the right to see and copy my research information?
You cannot see all of your research information while the study is going on. Once the study is over, you can access research information in the participant portal or from your email.

If you agree to share your information you should sign this form below. You will be given a copy of this form.

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I agree to share my information as described in this form

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Print your name

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Sign your name Date

If you have questions or concerns about your privacy and the use of your personal medical information, contact the investigator at the telephone number listed in the consent form.