Study Title	Rapid Acceleration for Diagnostics in Underserved Populations: Home Testing (Say Yes! COVID Test)
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Duke University Health System

Consent to Participate in a Research Study
ADULT
Say Yes! COVID Test Research Study

CONCISE SUMMARY

- This study will collect information to help us understand if COVID-19 testing you do at home on yourself can affect social behaviors and reduce the spread of the virus.
- You will be asked to complete surveys and questionnaires about your health, COVID-19 testing and symptoms, social interactions, knowledge of prevention strategies, infection risk, and attitudes towards vaccines.
- The risks for this study are minimal.
- You can choose to withdraw at any time.

Please review the information below for more details about this study.

You are being asked to take part in this study because you are 18 years of age or older, live in a community that is participating in the Say Yes! COVID Test At-Home Testing Challenge and have indicated that you're interested in participating in the related research study.

This study is funded by the National Institutes of Health (NIH). This study is part of the RADx-UP program. RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations, and it is a health research program to learn more about COVID-19 disease. This study specifically looks at the impact of at-home COVID-19 testing.

This study is run by Dr. Christoph Hornik at Duke University and Dr. Giselle Corbie-Smith and Dr. Gaurav Dave at the University of North Carolina.

WHY IS THIS STUDY BEING DONE?

The *Say Yes! COVID Test Research Study* is a study that collects information from people who live in a community with an increased risk of COVID-19. The purpose of the study is to see if at-home testing affects social behaviors, knowledge on preventing the virus, rates of hospital visits, and thoughts towards vaccination. A study like this one will be helpful in understanding how public health strategies such as at-home testing can be useful in decreasing the spread of the COVID-19 virus.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We expect that up to 300,000 people will take part in this study.

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WHAT IS INVOLVED IN THIS STUDY?

If you choose to take part in this study:

- You will be asked to complete surveys on MyDataHelps, a smartphone application. The survey questions will ask about your social behaviors, knowledge on preventing the virus, any hospital visits, and your thoughts on COVID-19 vaccination. The surveys will be weekly for the first 5 weeks and then monthly for 4 months. Each survey will take about 10 minutes to complete. Your responses are very important and will help researchers answer important questions about issues related to COVID-19 testing and spread.
    - For those who do not want to take part using the app, you will have the option of answering the questions through phone calls from the study team
- You will be asked to report your COVID-19 test results via the app and/or the surveys. The test results will be collected and shared with the study team.

Taking part in this study is voluntary. You can choose to stop at any time without any penalty. If you decide to no longer take part in this study, we will still use the data you provided until then.

HOW LONG WILL I BE IN THIS STUDY?

The study will continue for up to 25 weeks. Your participation could end at any time without your permission. Reasons your participation could end may be:

- The study ends
- You do not agree with consent updates
- The principal investigator or team who oversees research recommends you no longer take part
- The sponsor ends the study

There may be other reasons not listed here. If your participation ends without your permission, you will be notified of the reason.

If you agree to take part, a copy of this signed consent form will be available to you through the mobile application.

WHAT ARE THE RISKS OF THE STUDY?

Even though we will not share your name or other identifying information in reports and analyses, your personal information could be lost or stolen. We will take steps to prevent this by keeping information in restricted areas and on secure computer networks.

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ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There is no direct benefit to you. Researchers hope to learn more about community spread of COVID-19. This is not a treatment study for COVID-19. There is no direct medical benefit to participating in this study.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Your privacy is very important to us. We will take great care to protect your privacy. However, there is always a chance that, even with our best efforts, your identity and/or information collected during this study may be accidentally released or seen by unauthorized persons.

MyDataHelps is an NIH-supported tool for confidentially collecting and storing information for research through the internet. All information collected by this study will be stored on a secure third party system with many layers of protection. We will protect your data by:

- Keeping it in a secure, encrypted database with restricted, monitored access
- Complying with applicable state and federal laws that protect the privacy and security of your health information
- Anyone who can see these data will have to use a password
- When your data are shared with other researchers, they will not have information that can identify you.

This project has a Certificate of Confidentiality from the United States government. Certificates of Confidentiality protect your privacy by blocking the release of identifiable, sensitive research information to anyone not connected to the research except when you agree or in a few other specific situations.

HOW WILL MY DATA BE USED?

The information you share will be combined with information from others. Your name will not be provided.

Your data may be used to:

- Contact you about updates regarding this study.
- Conduct and publish research on health and disease.
- Contact you about future studies. If you do not want to be contacted for future studies, you may select the opt-out option at the end of this consent form.

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WHO WILL ACCESS MY DATA AND IN WHAT FORM?

The Call Center at the Duke Clinical Research Institute (DCRI) will have access to your contact information. They will need your name, phone number and email address so the DCRI Call Center can contact you as needed during the follow up period. The DCRI Call Center might call, email or text you in order to remind you to complete surveys or for other study-related reasons. They will also need the name and phone number of a family member in case they are unable to reach you. They will also need your contact information in order to send your study payment. This contact information is confidential and will only be available to representatives of the DCRI.

Your de-identified data (data that does not include your name or other details to specifically identify you or other individual participants) will be shared by CareEvolution (the MyDataHelps app developer) with the Study Data Coordinating Center for the purposes of this research study only to verify that the data transfers work correctly.

We will share summary information very broadly, which may include making that information public. This information will not include your name or other details to specifically identify you or other individual participants.

We will study basic factors about participants and how they relate to test results and survey responses. These factors will include things like age, gender, race/ethnicity, and zip code. This information will not include your name or other details to specifically identify you or other individual participants.

We will share your de-identified information with qualified researchers through large research databases such as the NIH COVID-19 Data Hub for general research use.

A description of this study will be available on https://clinicaltrials.gov/. This Web site will not include information that can identify you.

Your name, contact information, and test results will be shared with public health departments if you test positive for COVID-19.

The Institutional Review Board (IRB) or other regulatory agencies may use your data to monitor research conduct and ethics, or in a way that is required by law.

By consenting to take part, you agree to allow access to your data for these reasons.

WHAT ARE THE COSTS TO YOU?

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There are no costs to you to join this study. If you access the study using a mobile device you will be responsible for any data usage or other charges from your wireless service provider.

WHAT ABOUT COMPENSATION?

For your time, we will provide a gift card up to $50 per participant. You will be paid according to which study time points you complete. You will receive the total amount of $50 if you complete the entire study. You will be paid according to this schedule:

After you complete week 1 surveys	$20
After you complete week 2, 3, 4 & 5 surveys	$15
After you complete month 2, 3, 4 & 5 surveys	$15

Your name, address, phone number and email may need to be shared with companies and individuals involved in processing the payment for participation.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected other than data needed to keep track of your withdrawal. Your decision to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled. Information that you have already provided to the study will not be removed unless you specifically request it. To withdraw from the study, you must select the withdrawal option in the mobile application or contact the study team by phone.

WHOM DO I CONTACT IF I HAVE QUESTIONS OR PROBLEMS?

If you have concerns about your participation, you may contact the Call Center at 1-888-757-0166.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

NOW IT'S TIME TO CONSENT TO THE Say Yes! COVID Test Research Study

Please confirm the following statements and check the box to provide your consent. Providing consent confirms that you:

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- Are at least 18 years of age
- Have a primary residence within one of the pre-identified communities
- Have read and understood the information provided
- Have had enough time to think about the information and get answers to any questions
- Understand that you don't have to take part, and confirm that you are giving your consent freely

☐ I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time.

☐ Please check this box if you do not want to be contacted for future studies.

You can review this information as many times as you'd like. You can reach out to us with questions at 1-888-757-0166.