Cover Page

Official Study Title: Rapid Acceleration for Diagnostics in Underserved Populations: Home Testing

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Duke University Health System

Consent to Participate in a Research Study
ADULT
You and Me Covid Free 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.
- Text messages reminders will be sent out to all study participants automatically using Twilio, with REDCap as the backend. The messages will include a link to complete a short survey. Participant phone numbers will be provided to Twilio to facilitate the sending of text messages, and Twilio may store metadata about the delivery of the messages, such as successful or failure, and time and date stamps, but no other content will be stored. Messages for this study are one-way only and cannot be replied to.

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 You and Me Covid Free 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 *You and Me Covid Free 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.

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HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

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

WHAT IS INVOLVED IN THIS STUDY?

If you decide to join this study, we will gather data (information) about you. We will gather some of the data from you directly. We will gather some of the data from other places.

Examples of the information that we may collect from you or other places include, but not limited to:

- We will ask you for basic information such as your name, date of birth, address, contact information, race, ethnicity, gender, language, health insurance status, disability, job, and household information including address history.
- We will ask you information about COVID-19, including information about any symptoms (a change in your health) and test results. If you had a positive COVID-19 test, we may ask information about contact tracing (people who may have come in contact with you while you had COVID-19). We will ask about your medical history and if you have or have not had vaccines and why.
- We will ask you information about your health, education, family, home, relationships, and social life, among others.
- We may ask you to fill out questionnaires, surveys and other forms in order to collect the information above.

If you choose to take part in this study:

- You will be asked to complete surveys on a smartphone application. After taking each swab test, scan the QR code to answer survey questions. Combined, the three surveys (1 short survey, 1 detailed survey, and, 28 days later, 1 final short survey) will take about 20 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 with the study team who will enter your answers into the study database on your behalf.
- We will send you automated text messages throughout this study. To do this we use a web-based system, called Twilio, which uses your phone number to send you messages. We plan to use this feature to send you text message reminders. As long as you agree and are a member of the study, we will contact you this way approximately one to two times during the study. If you change your mind about the messages or if your contact phone number changes, please contact the study team. These messages are one-way only, so you cannot reply. If you have questions or concerns about information in a messages contact your study team.

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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 through completion of your final survey. 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.

Many companies and applications on your smartphone commonly use work with text platforms and cloud-based companies to send and receive information. We use Twilio to send you text messages. Text messaging does not provide a completely secure and confidential means of communication, and the messages are unencrypted. Twilio does encrypts your information on their servers, but no system is completely safe. If they decide to share these data, it may no longer be covered under the privacy protections. Information that identifies you, such as your phone number, may be sent to and permanently kept by Twilio and their business associates. Information disclosed to these companies or their business partners, it may no longer be covered under the privacy protections. Because text messaging does not provide a completely secure and confidential means of communication, if you wish to keep your communication completely private **<please let us know and we will communicate with you only through regular channels like Email> or <this study may not be appropriate for you and you should discuss with the study team>.**

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

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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.

HOW WILL MY DATA BE USED?

We will keep your data securely (which means with extra protection), along with the data from all the other people who take part in the RADx-UP program. Researchers will use the data to learn more about COVID-19 or other diseases and conditions.

The Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies.

The DCRI will build two RADx-UP databases (systems that hold electronic information).

The first database will only hold information that can identify you (called identifiable information). Examples are your name, address, email, and gender.

- These data will be kept at the DCRI. The DCRI will not share these data with the NIH.
- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- Only if you agree, by initialing below, the DCRI will keep information that can identify you in order to contact you for future research studies. If you do not agree, this information will stay with your study team, as applicable.
- These data will stay in a password-protected secure electronic system and only staff responsible for maintaining the security of your data at the DCRI will be able to see this information.

The second database will not hold information to identify you. It will hold all the non- identifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data in a secure database for COVID-19 research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- When using the data from this second database, researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.

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HOW WILL YOU PROTECT MY PRIVACY?

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 collectedduring this study may be accidentally released or seen by unauthorized persons. Here are a few steps we will take:

- Data will be stored on protected, secure computer systems. We will limit and keep track ofwho can see these data.
- Anyone who can see these data will have to use a password.
- We will take steps to protect your information from others that should not be able to see it.
- 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.

WHO WILL ACCESS MY DATA AND IN WHAT FORM?

DCRI Participant Research Operations 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 DCRI Participant Research Operations may contact you if needed during the project. DCRI Participant Research Operations 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 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.

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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?

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 and according to this schedule:

After you complete Survey 1	$25
After you complete Survey 2	$25

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

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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 DCRI Participant Research Operations at 1-844-665-2020.
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 You and Me Covid Free Research Study

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

- 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 1-844-665-2020.
SMS Opt-In In REDCap

Do you consent to opt-in to receive SMS reminders to complete the End of Study survey? (Standard text message charges may apply.)
Signature