Title: Community Collaboration to Combat COVID-19 (C-FORWARD)

NCT04673292

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Document: Informed Consent

WAIVER OF DOCUMENTATION OF CONSENT SCRIPT

Protocol Title: Community Collaboration to Combat Coronavirus (C-*FORWARD*): Testing

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KEY INFORMATION

Your home was randomly selected (by chance, like flipping a coin) to participate in a research study to understand how COVID-19 has affected our communities. We want to better understand the best strategies for providing COVID-19 testing to those who need it. We also want to understand the overall burden of COVID-19 in Baltimore City.

We are asking you to participate because you already participated in our survey or because someone in your home already completed a survey on COVID-19 and suggested that others in your home might be interested in the option for free and on-demand COVID-19 testing for 6 months. If you agree to participate, you and other members of the household, will be asked to answer questions once a month for 6 months. You will also be asked to tell us if you have any symptoms weekly.

Your household will be randomly assigned to one of three types of COVID-19 testing options and all tests results will be evaluated for COVID-19 at the Johns Hopkins Hospital laboratory.

- Option 1: testing at a Johns Hopkins testing site, based on your preferred location
- Option 2: a mobile van located within or near your community
- Option 3: a home collection kit delivered to your home

Once you enroll, we will schedule an initial test for COVID-19 based on the group you are randomized to. If you get symptoms or have any exposure while we are following you, we will offer to test you again. Testing includes collecting swabs from your nose and throat, spit from your mouth, and for Options 1 and 2 only, blood from your arm.

The entire study lasts for up to 6 months. The main risks are from the blood draw, the temporary discomfort from the collection of nose and throat swabs and that information may become known to people outside of the study.

PURPOSE

The purpose of this study is to understand the best ways to provide COVID-19 testing to people who need it.

You may join this study because you live in Baltimore City. We are enrolling 1,386 homes throughout Baltimore City.

PROCEDURES

We will ask you to do the following things:

- Complete COVID-19 testing by the option that you are assigned to.
- Conduct weekly symptom checks by phone/text/email or online, and conduct monthly visits by phone/text/email or online.
- Request, on demand, testing visits if anyone in the household develops COVID-19 symptoms.
- Each monthly study visit will occur online or via telephone and include a 20-30 minute survey for each person in the household who has enrolled and is 16 years of age or older.
- Surveys will ask about different things each month – including your race, age, sex, health history, COVID-19 symptoms, and the impact of COVID-19 on things like employment, healthcare access, and mental health.
- The first visit and any additional testing visits will include testing for COVID-19 for you and any members of your home who is 16 years and older.

You and the members of your household 16 years and older will complete the surveys in private, on the phone, via an email or text link, depending on your preference.

Will research test results be shared with you?
This study involves tests that may produce information that could be useful for your clinical care. We will share this information with you if the test has been approved by the Food and Drug Administration (FDA).

RISKS/DISCOMFORTS

Sample Collection
Nose and throat swabs, and collecting spit from your mouth may cause discomfort but are generally well tolerated. A Nasal PCR test included in the home kit (Option 3) from the company, Everlywell, will be used.

For all in person testing whether symptomatic or asymptomatic (Option 1 and Option 2), we will obtain approximately 50mL (almost 4 tablespoons of blood) at each visit. Taking blood may cause discomfort, bleeding, or bruising where the needle enters the body. In rare cases it may result in fainting. There is a small risk for infection. There is a risk of pain or irritation when samples are taken. If you are symptomatic and require an additional interim visits, we will only obtain 50mL over a 2 month period. The volume of blood collected from the adolescent will be reduced to a smaller volume based on the member's weight.

Results
A negative test for SARS-CoV-2 (COVID-19) does not guarantee that you are not infected. The test may be negative if your infection is just beginning or if the nasal swab does not contain an adequate sample of nasal secretions.

A positive antibody test for SARS-CoV-2 (COVID-19) does not guarantee you are protected from infection. The test may be negative if your infection is just beginning. You may have also have antibodies, but still go on to develop another infection.

Identifiable private information
There is some risk that information about you may become known to people outside the study. To minimize this, all information will be securely stored and only accessible to study team members.

Surveys
You may also get tired or bored when completing the surveys, but you do not have to answer any question you do not want to answer.

BENEFITS
There is no direct benefit from you being in this study. If you take part in this study, you may help others in the future.

VOLUNTARY PARTICIPATION
You do not have to agree to be in this study. If you do not want to join, it will not affect your care at Johns Hopkins.

PAYMENT
Each person in the household who completes the baseline survey will receive $50.

Each person that completes baseline testing will receive $50.

Every month, every household member will receive an additional $25 for completing 3 brief weekly questionnaires and $25 for a monthly questionnaire.

For testing at month 6, each household member will receive an additional $100 for completing a survey and testing.

Reimbursement for those under the age of 18 will be given directly to the adolescent member in the form of a

gift card.

Individual members of the household that receive over $599 in payment in a calendar year are required to report this income as taxable in the state of Maryland.

COSTS
There are no costs associated with your participation. You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet that will show you the procedures/tests that are part of this research and that will be paid for by the study (no cost to you).

IDENTIFIABLE INFORMATION IN FUTURE RESEARCH
We may use the information or biospecimens collected through this study for future research including research with external collaborators. Specifically, the Duke Clinical Research Institute (DCRI) is a research group chosen by the National Institute of Health (NIH) to combine data collected from everyone taking part in a group of studies that are part of the Rapid Acceleration in Diagnostics (in) Underserved Populations of the RADx-UP program. The RADx-UP program supports this project and as part of this RADx-UP program, data collected from everyone taking part in RADx-UP studies. We will study the data from all who participate to understand how to help more people at risk for or with COVID-19.

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.

For future research using biospecimen, the biospecimen is de-identified. Only the PI will have a code to link the biospecimen data to the participant for the purpose of inclusion of demographics and covariates in the analysis. When sharing information or biospecimens for future research we will take precautions to remove any information that could identify you (like your name or medical record number) before sharing. The only personal data that will be shared with the DCRI and NIH is your zipcode of residence.

HIPAA DISCLOSURE
We will collect information about you in this study. People at Johns Hopkins who are involved in the study or who need to make sure the study is being done correctly will see the information.

People at Johns Hopkins may need to send your information to people outside of Johns Hopkins (for example, government groups like the Food and Drug Administration) who need to make sure the study is being done correctly. These people will use your information for the purpose of the study.

Your Authorization for the collection, use, and sharing of your information does not expire. We will continue to collect information about you until the end of the study unless you tell us that you have changed your mind. If you change your mind and do not want your information to be used for the study, you must contact the Principal Investigator by using the contact information provided in this document. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

We try to make sure that everyone who needs to see your information uses it only for the study and keeps it confidential - but, we cannot guarantee this.

CERTIFICATE OF CONFIDENTIALTIY
Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

CONTACT INFORMATION:
If you have any questions regarding the study or information on this form, please contact us at the C-*FORWARD* study at this number 1-855-6C4-WARD.

For urgent questions or issues regarding study procedures, please feel free to contact the Principal Investigator Jason Farley, PhD, MPH, NP at 410-258-4506.

The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

By agreeing to participate it means, you have reviewed the information in this form, and have had a chance to ask questions, and agree to join the study. You will not give up any legal rights by agreeing to participate.

I agree to participate.

We would like your permission for our research team to contact you in the future. Please note that your decision does not prevent other researchers at Johns Hopkins from contacting you about other research. *Your answer to this question does not impact your participation in this study*.

I agree to future contact.

I agree to let the DCRI collect my zip code.

Biospecimens: Will you allow us to collect and store these biospecimens (blood, saliva and viral samples of COVID-19) for use in future unplanned research? These specimens will not include your personal identity. *Your answer to this question does not impact your participation in this study*. The blood, saliva and viral samples, may be shared with researchers both inside and outside of Johns Hopkins, including commercial partners to assist in developing and validating tests for COVID-19. If you join this study, you will not own the data and/or biospecimens collected from you as part of this research study. If researchers use them to create a new product or idea, including those that may have commercial value, you will not benefit financially from this.

I agree to have biospecimens collected and stored.

Genomic Data Sharing: Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions. As part of this study, we will collect information about your health and your individual genes. This information will be sent to a National Institutes of Health (NIH) designated data repository that includes genomic and other data from studies funded by the NIH.

The aim of collecting this information is to look for genetic connections that may:
Increase the likelihood of getting a certain disease (such as asthma, cancer, diabetes, heart disease or mental illness) or a condition (such as high blood pressure or obesity); affect the progress of a certain disease or condition; affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others. We or our collaborators will remove direct identifiers (such as your name or date of birth) and instead code your information before sending it to the repository. The NIH will never receive this code or the identifiers we have removed.

The repository is a controlled-access repository. This means that your individual de-identified data is only available to researchers who apply to the NIH. The NIH will review data requests for scientific merit, and for methods to protect data and ensure it will be used for the approved purpose. We will not always know what

types of health-related research will be done with the data that are sent to the repository.

Information from Johns Hopkins participants that is sent to the repository will only be shared with researchers at other not-for-profit organizations (for example, other academic institutions).

Genomic summary results (GSR) data for non-sensitive studies may be made available by NIH without controlled-access. GSR data does not include information about you as an individual, but consists of statistical information calculated using your data combined with data from other people. *Your answer to this question does not impact your participation in this study.*

I agree to have blood collected for genetics.

We would also like to review some of your medical records from the Chesapeake Regional Information System for our Patients [CRISP] to obtain information on any COVID-19 testing outside of the study, health care visits and hospitalizations for COVID-19 as well as other related health conditions.

I agree to my medical record review through the CRISP.

I agree to let the DCRI collect my zip code.

Assent Statement: The research study has been explained to my child / children (16 - 17 years of age) for whom I am the parent or primary guardian in my presence in language my child can understand. He/She/They have been encouraged to ask questions now and at any time in the future, and have assented/agreed to join the study.

My child / children assent(s) to participate (Please place initials for each childbelow)
INITIALS: _____
INITIALS:_____
INITIALS:_____
INITIALS: _____