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Optimization of a New Adaptive Intervention to Increase COVID-19 Testing
Informed Consent
July 26, 2021

Informed Consent to Participate
Optimization of a new adaptive intervention to increase COVID-19 testing among people at high risk in an urban community

PROTOCOL NUMBER	CWCOVIDSUPP-UIUC-NJCRI 102497-18274-267805 version 1.0
TITLE OF THE STUDY	Optimization of a new adaptive intervention to increase COVID-19 testing among people at high risk in an urban community
NAME OF PERSON(S) IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):	Ellen Benoit, PhD
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WHAT IS THE PURPOSE OF THIS FORM?

You are being asked to participate in a research study. The purpose of this consent form is to help you decide if you want to participate in this study. It is important that you read the following explanation of the proposed study procedures. This form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes alternative procedures that are available to you and your right to withdraw from the study at any time.

Please ask as many questions as you need to before you decide if you want to be in the study. You should not submit this form if you have any questions that have not been answered. Once you fully understand the study, you will be asked if you agree to take part in it. If you agree, then you will be asked to submit this consent form. You can download a copy of this consent from the e-mail invitation you received with the link to the survey.

You may show this consent form to family, other professionals, and friends before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study.

This research is being funded by the National Institute on Minority Health and Health Disparities (NIMHD) in the National Institutes of Health (NIH) in Washington, DC. The Principal Investigators are Liliane C. Windsor of the University of Illinois at Urbana-Champaign and Ellen Benoit of NJCRI. The NIH is part of the United States Department of Health and Human Services. The NIH's purpose is to find new knowledge that will lead to better health for everyone. This study is part of the RADx-UP program. The NIH funded (provided support for) the RADx-UP program. RADx-UP stands for Rapid Acceleration in Diagnostics (in) Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. If you join RADx-UP, we will gather some data (information) about you. We will send the data to The Duke Clinical Research Institute (DCRI), a research group chosen by the National Institute of Health (NIH) to combine the data collected from everyone taking part in RADx-UP studies. Your data will be combined with data from other people who join RADx-UP. Researchers will study the data from all who join to understand how to help more people at risk for or with COVID-19.

You must be honest with the investigators about your health history or you may harm yourself by participating in this study.

You are being asked to be in this study because you told us that you may be at high risk of contracting COVID-19 or experiencing complications from it.

WHY IS THIS STUDY DONE?

The purpose of this research study is to develop an intervention that increases COVID-19 testing and adherence to New Jersey public health recommendations (e.g., wearing masks, practicing social distancing). This study seeks to test if three

different interventions work. We want to develop the best program we can by identifying interventions that work best for different people at different times.

TO BE IN THIS STUDY

To be in this study you must be 18 years of age or older, at high risk of contracting COVID-19 or developing complications from it and able and willing to provide consent.

HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY?

If you agree to participate in this study you may complete up to 7 research interviews (each lasting between 5 minutes and 60 minutes) and attend one group meeting (approximately 1 hour) or three 15 to 30 minute phone calls or in-person sessions. Some people will complete the study after the baseline interview. For others, it will take approximately 6 months to complete the meetings and all of the interviews. Your participation may occur online, over the phone, or in person, as long as it is safe to do so. Different people will be randomized (picked by chance or luck) to complete different activities. We expect to recruit a total of 670 people to be in this study. All participants will be adults at high risk of being exposed to the COVID-19 virus or developing health complications from a COVID-19 infection.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to participate, we may ask you to complete a COVID-19 test, and participate in up to three phone or in-person sessions with a peer navigator or a licensed clinician lasting up to 30 minutes. The number of sessions you will be asked to attend will depend upon which version of the program you are randomly selected to join. Thus you will not be able to choose which group you will be joining. This means you could be randomized to join a peer navigation group, an informational brochure group, a brief individual counseling group or a group intervention called Critical Dialogue that meets once for 1 hour. Your participation in the study may take 6 months, regardless of which group you were randomly selected for.

We may also ask you to complete up to 5 online surveys (baseline, then follow-ups at 2 weeks, 5 weeks, 3 months and 6 months) and grant us permission to access your results from the COVID-19 test. Some of the questions in the surveys will ask you for information about yourself (e.g., gender, race, ethnicity), about your health and living situation, about vaccines and about COVID-19, including your experiences during the pandemic. For the COVID test, a sample will be taken from the inside of your nose with a swab. You may do the swab yourself or have a member of the clinical study team do it. The sample will be analyzed by a machine at NJCRI and results should be available within 15 minutes. A licensed clinician or your peer navigator will tell you your results in private. If you are assigned to navigation, your peer navigator will call you to discuss your results. If your results are positive, you will receive information on how to quarantine and get medical care and we will ask you about people who may have been around you recently (called contact tracing). If your results are negative, you will receive information on how to stay safe and avoid infection.

A total of 35 participants will also be randomly selected to complete a 60-minute phone interview about their experience with the study interventions and their feelings about COVID-19 testing and public health recommendations. The information you give us, including results from the COVID-19 test, will be kept private. Your answers to any questions that will be asked in this study will be completely confidential. If, at any time, you do not want to answer a question or participate in a certain part of the study, you may refuse without penalty.

WHAT WILL YOU DO WITH MY DATA?

Our research team and the Duke Clinical Research Institute (DCRI) 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 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.

- 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.

Please select the permissions you are willing to give DCRI:

1. I agree to let the DCRI collect only my ZIP code and no other identifiable information as stated above

2. I agree to let DCRI contact me for future research as stated above

WHAT ARE THE POSSIBLE RISKS?

The main risks of this study include accidental loss of confidentiality and potential emotional discomfort. The prospect of testing positive for COVID-19 may cause fear and anxiety and receiving a positive test result can be distressing. Some people may find the content of intervention sessions disturbing. If you agree to be tested for COVID, you will discuss your results - positive OR negative - with a licensed clinician or your peer navigator. If you are assigned to the Critical Dialogue group, discussion will be moderated by a licensed clinician. You always have the right to stop participating in the research study and program at any time without penalty. If you feel upset during any part of the study, for example, during the group session or during an interview, you may stop participating. At that time we can let you speak with our project manager or a trained counselor at NJCRI. If necessary, or if you request it, we will refer you to affordable services in the community that can help address emotional issues that may arise during your participation in this study.

While we will take several steps to protect your identity and the confidentiality of your responses (see details below), there is a small chance that confidentiality may be lost. If you participate in the Critical Dialogue group discussion, peers who participate in your group will learn information about you that you choose to share. Group members will make a pledge in the group meeting to maintain confidentiality. We hope that people will abide by this pledge, but it is possible that group members will share information about you with other individuals.

It is possible that data could be stolen if our server is hacked. We will take every precaution to prevent this from happening, and we will use locked files and password protected secured servers to safeguard your information. The only instance where the researcher will reveal information you provide is if during an interview you tell us about child abuse or about yourself or someone else being in danger that is about to happen. In these circumstances, the researcher will notify the appropriate authorities. If you begin to reveal this information during an interview, the researcher will remind you that such information cannot be kept confidential or secret.

ARE THERE POSSIBLE BENEFITS OF THE STUDY?

We cannot guarantee that being in this study will have any positive effects. However, we hope that this study will be helpful to you and members of your community by detecting and treating cases of COVID-19 and preventing further transmission of the disease. We also hope that participants will benefit from referrals to resources related to housing, food and other basic needs that help to maintain health. In addition, if participants express a need for mental health assistance at any time, the project team is well equipped to either provide service or make appropriate referrals.

ARE THERE ALTERNATIVES TO BEING IN THIS STUDY?

Participating in this study is completely voluntary. It is your choice to participate in this study and all of its components. Choosing not to be part of the study will not involve any penalty or loss of benefits to you. Your participation or nonparticipation in this study will not have any effect on your relationships with providers in the community, the University of Illinois at Urbana-Champaign or at NJCRI.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

There will be no cost to you for participating in the study.

CONFIDENTIALITY

To make sure that your privacy and confidentiality are protected, your name will not appear on any research records or results. We may ask you for contact information (e.g., phone number, address) so that we can reach you to schedule follow-up interviews, but that information will be kept in a locked file cabinet in the project manager's office or a password-protected file. There will be a code number placed on all of the documents related to your interviews and test results and you will use a code name during interviews and if you are assigned to group sessions. Only the project manager and Dr. Benoit will have access to the only document that links your name to your code number. Your comments will be kept confidential. Only researchers working on this study will have access to the information you provide, and only to the extent needed to schedule appointments. Things that you say throughout the study will be reported in ways that will protect your identity. If we use specific things you say, we will not refer to you by name or number. For example, we might report that during one group session, "four people mentioned needing help finding housing."

Once the study is completed, other researchers may ask to use the data. Sharing data is an important way to create opportunities for new discoveries. Thus we will make every effort to make the data available to others, but only if we believe your identity and privacy are protected. In order to share the data, we will require an agreement that provides for the following conditions at minimum: (1) a commitment to use the data only for research purposes and not to identify any individual participant; (2) a commitment to secure the data using appropriate tools and computer technology; and (3) a commitment to destroy or return the data after analyses are completed. We will remove all personal identifiers from the data before we will allow it to be used by other researchers.

To help us protect your privacy, we obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate of Confidentiality to resist any demands for information that would identify you, with the following exceptions:

1) The certificate cannot be used to resist a demand for information from personnel of the agency sponsoring the project and that will be used for auditing or program evaluation of agency-funded projects.
2) You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.
3) If you give another person or organization your written permission to receive research information, then we may not use the Certificate to withhold that information.
4) Mandated reporting of ongoing child maltreatment or imminent danger.

All project staff will be trained in how to protect confidentiality and will sign a pledge of confidentiality. Utmost care will be taken when contacting participants about enrollment and participation. Only study staff will talk with you directly unless you ask another authorized staff person to leave a message. In general, we will not tell anyone any information about you. When this research is discussed or published, no one will know that you were in the study.

PAYMENT FOR BEING IN THE STUDY

You will receive compensation for each interview activity you participate in, including $30 for the baseline interview and $40 for each of the four follow-up interviews. If you are randomly selected for an in-depth individual interview and you complete that interview, you will receive an additional $50. Thus you have the opportunity to receive a minimum of $30 and a maximum of $240 if you are eligible and choose to participate in all possible research interviews over the period of 6 months.

LEGAL RIGHTS

You will not lose any of your legal rights by submitting this consent form.

CONTACT INFORMATION

If you have questions or suggestions about the study or the procedures, you may contact Dr. Benoit at (973) 483-3444 (e.benoit@njcri.org) or Dr. Liliane Windsor at (217) 300-1782 (lwindsor@illinois.edu). If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research participant, including questions, concerns, complaints, or to offer input, you may call NJCRI IRB Liaison Corey DeStefano at 973-483-3444 ext. 205, or James Oleske, MD, Chairman of NJCRI's IRB, at 201- 704- 3281.

You will receive a copy of this information in your email but feel free to download a copy using the link below for your records.

AGREEMENT TO BE IN THE STUDY

I have read this entire form and I understand it completely. All of my questions regarding this form or this study have been answered to my satisfaction. I understand that my participation in this research project is voluntary. I know that I may quit the study at any time without harming my future medical care or losing any benefits to which I might be entitled. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study.

I agree to receive testing and medical services from NJCRI and to have my information added to the electronic medical records.

___ Yes

___ No

By clicking the **Yes** button below I am agreeing to participate in this study and I have not waived any of my legal rights.

___ Yes

___ No

CONTACT FOR FUTURE STUDIES

NJCRI and The University of Illinois often engage in health related studies that seek research participants. Would you like for us to add your name and contact information to our study participant bank? If you agree, we will periodically send you invitations to join studies whenever these are available.

Please check your corresponding choice:

☐ I consent to study staff to add my contact information to a recruitment list for future studies.

☐ I am not interested in being contacted about future studies.