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NYU NEW YORK COMMUNITY ACTION PROJECT (NCAP) STUDY

Research Subject

Informed Consent Form – Enrollment into NCAP Study

May 2, 2023

PID _____

Title of Study:	Using the multiphase optimization strategy (MOST) to optimize an intervention to increase COVID-19 testing for Black and Latino/Hispanic frontline essential workers – PILOT STUDY Study #: FY2022-6023
Field name	NYU New York Community Action Project (NCAP)
Trials registration number	ClinicalTrials.gov Identifier: NCT05139927
Principal Investigator:	Dr. Marya Gwadz NYU Silver School of Social Work 1 Washington Square North New York, NY 10003
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1. About volunteering for this pilot research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects.” Before you can decide, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. If you have any questions about the study or about

this form, please ask us. If you decide to take part in this study, we will note your consent for our records. We will give you a copy of this form for you to keep.

Your decisions about your health will be respected in this study and we will not judge any of the decisions you make or pressure you to do anything with respect to COVID-19 testing or vaccination that you do not wish to do.

If you do not wish to be tested for COVID-19, we understand, and we hope you will stay enrolled in the NCAP study so we can learn from you.

2. Brief description of the study

You have been invited to take part in a study to learn more about the various factors that help people make health decisions about COVID-19 testing, from the perspectives of Black and Latinx frontline essential workers. If you join the study, we will stay in touch with you for about 3 months and ask you to engage in different activities with us over that period.

This study focuses on people who have not recently been vaccinated for COVID-19 and who therefore may not be fully vaccinated for COVID. This study is interested in occupations where people are possibly exposed to COVID-19 because they must work in person, but where the work setting doesn't generally provide or require COVID-19 testing or vaccination. The occupations of interest are:

- food preparation and serving (e.g., deli, bodega, restaurants, fast food)
- retail and sales (e.g., grocery, drug, and convenience stores)
- building and grounds cleaning and maintenance
- building and home construction
- personal care and service (e.g., in-home childcare workers, barbers, nail technicians, cosmetologists)
- in-home health care services (e.g., home health aides)

If you agree to be in this study, you will be asked to do the following:

1. Provide more information that will help us keep in contact with you over time

2. Conduct three structured surveys on a computer lasting about 40-60 minutes each about your thoughts and experiences with COVID-19 and other aspects of your life

3. Receive a health education session and discussion lasting 30-40 minutes on COVID-19 and COVID-19 testing

4. Be randomly assigned to receive 1 to 4 other intervention components

5. Show proof of COVID-19 testing and/or COVID-19 vaccination, at the two follow-up surveys, if you so choose

6. Some participants will be asked to engage in an in-depth semi-structured interview

Participation in this study will generally involve 4 total visits. Three of these visits are to carry out surveys and the other visit is for you to engage in the intervention program that you are randomly assigned to receive. The first visit will usually be carried out in-person, but it is possible to carry it out virtually. The other visits can be held in-person or virtually.

The main risk to you would be loss of confidentiality and we have procedures in place to protect your confidentiality, as we will explain. You may find it helpful to talk about your health decisions and other aspects of your life. Your participation may inform services for other people at risk for exposure to COVID-19.

Participation in this study is voluntary. You may refuse to participate or withdraw at any time without penalty. Please read the rest of this consent form for more information about the study.

3. What is the purpose of this study?

This is a research study testing different ways to boost COVID-19 testing rates among frontline essential workers from African American/Black and Latino/Hispanic racial or ethnic backgrounds. The study will test different ways to increase awareness of COVID-19 testing, increase interest in testing, and provide better access to testing. You do not need to be tested for COVID-19 to enroll in or stay in the study. It will be your decision.

The study is called the New York Community Action Project (NCAP).

You have been chosen to participate because you received a flyer, were asked to participate in the community, or saw an advertisement on social media or in a newspaper.

4. How long will I be in the study? How many other people will be in the study?

Participants will be enrolled in the study for approximately 12 weeks. A total of 448 participants will be enrolled in the study.

5. What will I be asked to do in the study?

This study has a number of parts. These parts are confidential, which means we will keep all the information you provide private. We will create a code number for you that will help us keep track of your participation in the different parts of the study. Your participation is voluntary, which means you do not have to participate. Your personal choices and decisions will be respected in every part of the project.

A. Baseline survey

We will ask you to complete a baseline survey. This will last approximately one hour. We will also ask you to show your COVID-19 vaccination card at this time, if you have one. We will enter the information about your COVID-19 testing dates and type of vaccine into the confidential study database.

In the survey, 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 that may include, but will not be limited to: information about any symptoms (a change in your health), test results, vaccination, and treatments. If you had a positive COVID-19 test, we will 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, including if you have or have not had vaccines and why, among others.

We will ask you information about your health, education, family, home, relationships, and social life, among others.

B. Random assignment to an intervention condition made up of different components

We will also ask you to engage in some of our intervention programs (also called components) focused on COVID-19 testing. You will be randomly assigned to a "condition" that includes 1-4 of these components. Each condition has a different combination of specific components, some of which are short and some of which are longer. There are 16 possible intervention conditions.

Being "randomly assigned" means that you and every person in the study have an equal chance of being placed in one of the intervention conditions.

Everyone gets at least one component. Most people will be randomly assigned to participate in 3 or 4 of the components. Some of the components are short and do not require a lot of your time, and some have activities that will take place independently or over the next 6 weeks. You can engage in all the components you are assigned to receive at the same time, if your schedule allows.

When you are randomly assigned to your condition, we will explain which components you are eligible to receive.

Of course, if you are randomly assigned to an activity you do not wish to engage in, you can skip it, and still remain in the study. It's your choice.

C. Health Education Session (Core session)

You will be asked to attend a meeting that will last about 20 to 40 minutes. In that meeting, we will first review a health education on COVID-19 testing. We will review topics such as COVID-19 testing guidelines, types of tests, prevention and recommendations about what to do if you test positive for COVID. We will also provide referrals to no-cost COVID-19 vaccination sites in addition to testing sites. We may audio-record these sessions for supervision purposes with your permission. You can say no to audio-recording and still continue with the session.

D. Description of the 4 intervention components you may receive

The components are:

A) one **counseling session** (lasting about 60 minutes) with a study counselor to discuss your health decisions, and discuss what you think about COVID testing and what you plan to do about COVID-19 testing. We may audio-record these sessions for supervision purposes with your permission. You can say no to audio-recording and still continue with the session.

B) receiving **text messages** with information about COVID and COVID-19 testing, along with quiz questions for which you earn 10 points for a correct answer and 5 points for an incorrect answer. During the study, we will explain this component to you and put the study phone number in your phone. It will take about 10-15 minutes to explain this component and then you will receive text messages followed by quiz questions automatically twice a week for 6 weeks. You can stop receiving text messages at any time.

You will receive compensation based on your points at the 6-week point (the time of your first follow-up assessment).

You also have a chance to spin a prize wheel and win a **lottery prize** if you have been tested for COVID-19 and you show us evidence of the result such as a photograph or doctor's note at the first survey point (the 6-week assessment).

C) training on **peer education** (15-20 minutes), where you will be trained to educate peers on core messages about the importance of COVID-19 testing, and you will be given the opportunity to educate three of your peers on these core messages. These peers will contact the study and participate in a brief interview that includes some true-false questions about COVID, based on your peer education. Your peer will receive compensation for carrying out the interview.

You do not need to educate peers if you do not wish to. You will receive compensation when the peer contacts the study and a bonus if the peer answers at least 50% of the true-false questions correctly (that is, answers at least 5 questions correctly).

D) **navigation** guidance to assist you accessing COVID-19 testing if you wish to do so (**a brief meeting** lasting less than 20 minutes) OR you will be randomly assigned to receive two **FlowFlex rapid COVID test kits** which can be picked up or mailed to you, along with instructions on conducting the test and interpreting results (in a brief meeting lasting less than 20 minutes).

Half of the participants in the study will be randomized to an intervention condition that provides you with COVID-19 self-test kits that you can take home.

You do not need to participate in any of the components you are assigned to receive if you do not want to.

E. Two Follow-up Surveys

We will contact you 6 and 12 weeks after participating in first survey for follow-up surveys. We will also you to provide documentation that shows the result of any COVID-19 testing you may have carried out.

With your permission, we will want to **confirm your COVID vaccination status**.

- If you have a **CDC vaccination card** or other forms of documentation of COVID vaccination and are willing to show it to us during this brief interview, we would appreciate that. If you don't have one, or don't have the documentation handy, that is OK and you can continue with this interview.

- Or, if you were vaccinated in New York City, we will ask you to check the **"My Vaccine Record"** site on the NYC Health website and show it to us. But if you don't want to access My Vaccine Record for any reason, that's OK and you can continue with this interview.

- Otherwise, we will ask you some questions about whether you have been vaccinated or not.

The surveys will last 40-60 minutes or less and take place in-person at a NYU field site or virtually. We will ask you to do the follow-up survey, even if you did not get tested for COVID-19.

F. In-depth interview

We may ask you to take part in an open-ended interview with a study staff member (not on the computer) lasting 60-90 minutes. We will ask you about your experiences with health and services and perspectives on COVID. We will ask if we can audio-record this interview. You can do the interview even if you do not want it recorded, and you can choose not to do the interview and stay in the study.

6. What are the possible risks or discomforts?

One risk to you is loss of confidentiality. The study will do everything possible to protect your confidentiality. Confidentiality of your research records will be strictly maintained by the research team. Participants will receive an identification number (IN). The IN will be used on all forms, transcripts, and materials. Activities will take place in a confidential location at a NYU study field site, or over the phone or on Zoom/Facetime.

Audio recordings will be professionally transcribed and identifying data will be removed. Audio recordings will be destroyed six months after the completion of the study.

All forms and transcripts will be kept on a computer that is double password protected and only study personnel will have access to the files.

Some of the questions in the interviews or intervention components may make you feel uncomfortable. All answers you give will be kept confidential. You do not have to answer any questions or engage in any activity at any time for any reason.

The study may involve other risks that are unknown at this time.

7. What are the possible benefits of the study?

This study may help us learn how to find efficient and effective ways to increase COVID-19 testing rates among Black and Latino/Hispanic frontline essential workers.

You may experience personal benefits from participating in the study. These might include finding it useful to reflect on your personal health decisions in the interviews and intervention components. You may learn useful or interesting things about yourself and see your decisions in new ways. Some or activities may feel supportive to you, or be helpful to you.

There may be benefits to others as well. This study may help us learn about the various factors that influence the health care behavior of Black and Latinx frontline essential workers. This study may help us develop better services to manage COVID-19.

But, you may or may not get any direct benefit from being in the study.

8. What other choices do I have if I do not participate/alternatives to participation?

You are free to choose not to participate in the study without any loss of services or benefits to which you may otherwise be entitled.

9. Will I be compensated for being in this study?

There is no cost to you for participating in the study. You will receive compensation as follows:

- $30 for the initial baseline survey
- $40 for each follow-up survey
- $5 bonus for showing evidence of COVID-19 vaccination such as your CDC vaccination card or the NYC Health Department My Vaccination Record website at screening, if you have a card or are OK with checking the website, and at each follow-up survey
- $30 for the health education session (core session)
- Depending on which NCAP study condition you are randomly assigned to, you will receive:
    A. **Session: $30** for the counseling session with a study counselor
    B. **Text messages: Up to $75** depending on your engagement with the text messages and quiz questions you receive. You earn points for responding to the quiz questions. The maximum number of points you can earn is 120.
        - **Compensation based on points**: At the 6-week mark, you will receive $25 if you have 60-120 points and $10 if you have less than 60 total points
        - **Lottery prize:** You can spin a prize wheel at the first follow-up survey. If you were tested for COVID (and evidence is provided), there is a 3/10 chance of winning $50 and 7/10 chance of $25, if not tested or no evidence provided, $15 participation bonus is provided.
    C. **Peer education**: Up to **$75** depending on how many peers contact the study (maximum 3 peers)**,** broken down as follows
        - **$15** when you peer contacts the study

        - **$10 bonus** if your peer receives a score of 50% or higher the true/false knowledge quiz (that is, 5 or more questions correctly answered out of 10)
        - Your peer will receive $25 when contacting the study and completing a brief interview
    D. **Access: $20** upon receiving the component that helps with access to testing, either through navigation to testing appointments or being provided with self-test kits
- **$35** for the in-depth interview
- You will also receive a **MetroCard** or funds for round-trip public transportation for these activities if they take place in-person

11. When is the study over? Can I leave the study before it ends?

This study is completely VOLUNTARY. You are not giving up any legal claims or rights for being a part of this study. If you agree to participate, you are free to quit at any time. You may refuse to answer any question or engage in any activity.

We may decide to withdraw or pull you out of the study for certain reasons. Some reasons would be that you have already participated in this study or the study has been stopped. If we learn that you have been incarcerated after you have agreed to take part in this study and as a result you will not be able to take part in study activities, we may need to stop your participation in the study.

11. What happens if I leave the study or am withdrawn from the study.

If you leave the study or you are withdrawn from the study, you will no longer have access to the surveys/interviews, intervention component activities, or free COVID self-test kits from the study. You will only be compensated for the activities you engage in.

Participants should not do the interviews or other activities more than once, and if this occurs, compensation will not be received more than once.

12. How will my information be protected?

The NYU Silver School of Social Work is committed to protecting the privacy and confidentiality of the information you provide to us.

The information you provide to us will be used by the research team and others involved in the study to conduct and oversee the study.

If there is anything about the study or your participation that is unclear or that you do not understand, if you have questions or wish to report a research-related problem, you may contact Dr. Marya Gwadz at 212-998-5965, marya.gwadz@nyu.edu, 1 Washington Square North, Room 303, New York, NY 10003.

For questions about your rights as a research participant, you may contact the University Committee on Activities Involving Human Subjects (UCAIHS), New York University, 665 Broadway, Suite 804, New York, New York, 10012, at ask.humansubjects@nyu.edu or (212) 998-4808. Please reference the study IRB-FY2022-6023 when contacting the IRB (UCAIHS).

13. Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. Researchers with this Certificate will not disclose or use information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, even if there is a court subpoena.

Exceptions include:

- A federal, state, or local law requires disclosure.
- Your explicit approval for the researchers to release your name and/or personally identifiable information.

14. Sharing data that does not identify you with the RADx-UP team

This study is funded by the National Institutes of Health (NIH). 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. The NIH funded (provided support for) the RADx-UP program.

RADx-UP stands for Rapid Acceleration of Diagnostics - Underserved Populations. RADx-UP is a health research program to learn more about COVID-19 disease. If you join this study, you are also joining RADx-UP. RADx-UP will combine the information we collect from you with other people across the country who join RADx-UP. RADx-UP will study the data from all who join to understand how to help more people at risk for or with COVID-19.

Our project, NCAP, will send <u>some of the information</u> collected from our study participants to RADx-UP. We will not send any information that could identify you (e.g., your name or address). We will only send information that could not be used to identify you. You will be identified only by your participant identification number.

RADx-UP 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 as well as 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.

We will not send the DCRI information can easily identify you.

- You will be assigned a study code ID and you will only be identified in this database by this study code.
- The information will not contain your name or other information that could easily identify you.
- The DCRI plans 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 particular database, researchers will not be able to link the data back to you.

- Because the data cannot be linked back to you, the DCRI will not contact you to inform you or ask your permission before sharing the data with researchers.

15. How will RADx-Up and the DCRI protect my privacy

Your privacy is **very** important to NYU and DCRI. 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. Here are a few steps we will take:

- Data sent to RADx-UP/DCRI will be stored on protected, secure computer systems. They will limit and keep track of who can see these data.
- Anyone who can see these data will have to use a password and multi-factor authentication.
- They 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.

16. Clinicaltrials.gov

A description of this clinical trial will be available on https://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

17. Other ways to get tested for COVID-19

There are other ways you can obtain tests for COVID-19 other than enrolling in this study.

You can access free COVID-19 test options here: https://www.covid.gov/tests

You can find local testing options here: https://www1.nyc.gov/site/coronavirus/get-tested/covid-19-testing.page

If you do not wish to enroll in the study but would like information about how to get testing for COVID-19, we will provide you with a handout.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

ALTERNATE: OBTAIN VERBAL INFORMED CONSENT IF ENROLLING VIRTUALLY.

You will receive a copy of this consent document to keep.

Do you agree to participate in this research study?

_____	_____	_____
Name of Subject (Print)	Signature of Subject	Date

_____	_____	_____
Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

I agree to have my sessions (Core session and Component A) audio-recorded **for supervision purposes**. (You can say no and continue in the study)

_____ Yes _____ No

Initials Initials

I agree to have my in-depth interview audio-recorded.

_____ Yes _____ No

Initials Initials

I agree to let RADX-UP/the DCRI collect **only my zip code** and no other **identifiable** information.

_____ Yes _____ No

Initials Initials

I agree to be contacted for future research.

_____ Yes _____ No

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