NYU SILVER SCHOOL OF SOCIAL WORK

Marya Gwadz, PhD
Professor and Associate Dean
for Research

Silver School of Social Work
One Washington Square North
New York, NY 10003-6654
marya.gwadz@nyu.edu
www.socialwork.nyu.edu

NYU NEW YORK COMMUNITY ACTION PROJECT 2 (NCAP2) STUDY

Research Subject

Informed Consent Form – Enrollment into NCAP2 Study

February 25, 2025

PID _____

Title of Study:	Community-based behavioral intervention to increase COVID-19 and influenza vaccination for African American/Black and Latino persons: An optimization randomized controlled trial Study #: IRB-FY2025-9851
Field name	NYU New York Community Action Project 2 (NCAP2)
Trials registration number	ClinicalTrials.gov Identifier: NCT06614361
Principal Investigator:	Dr. Marya Gwadz NYU Silver School of Social Work 1 Washington Square North New York, NY 10003
Emergency Contact:	Dr. Marya Gwadz 212-998-5965 917-863-2125 MG2890@NYU.EDU

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 “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.

This study is about COVID-19 and flu vaccination. 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 or flu vaccination.

If you do not wish to be vaccinated for COVID-19 or flu, we understand, and we hope you will stay enrolled in the NCAP2 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 and flu vaccination, from the perspectives of Black and Latine New Yorkers. If you join the study, we will stay in touch with you for about 12 months and ask you to engage in different activities with us over that period.

This study focuses on people who have gotten at least one dose of the COVID-19 vaccine but who have not recently been vaccinated for COVID-19 or flu. This study is interested in Black and Latine New Yorkers, who typically have more barriers to getting good health information about COVID and flu and who may have more barriers to vaccination than other groups/

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

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

2. Receive a health education session and discussion lasting about 30 minutes on COVID-19 and flu vaccination

3. Be randomly assigned to receive 0 to 4 other intervention components

4. Show proof of COVID-19 vaccination at the two follow-up surveys and at 12 months after you enroll, if you so choose

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

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

The first study visit will usually be carried out in-person, but it is possible to carry it out virtually over Zoom. The other visits can be held in-person or virtually over Zoom.

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 in the future.

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 inform people about COVID-19 and flu vaccination and increase vaccination rates in communities. It focuses on New Yorkers from African American/Black and Latino/Hispanic racial or ethnic backgrounds. The study will test different ways to increase awareness of COVID-19 and flu vaccination, increase interest in vaccination, and provide better access to vaccination.

You do not need to be vaccinated for COVID-19 or flu while you are in the study or stay in the study. It will be your decision.

The study is called the New York Community Action Project 2 (NCAP2).

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 and were found eligible in the screening process.

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 months. A total of 560 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 an identification number for you that will help us keep track of your participation in the different parts of the study. All the interviews you engage in will use the same identification number.

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 45-60 minutes.

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 your health, family, home, relationships, and perspectives on vaccination, among others. You can decline to answer any question you do not wish to answer.

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 and flu vaccination. 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, a health education session. Most people will be randomly assigned to participate in 2 or 3 of the other 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 via phone, text, or email or over the next few months.

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.

The components are:

C. Health Education Session (Core session)

You will be asked to attend a meeting that will last about 30 minutes. In that meeting, we will first review a health education on COVID-19 and flu vaccination. We will review topics such as COVID-19 and flu vaccination guidelines. We will also provide referrals to no-cost COVID-19 and flu vaccination 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 other intervention components you may receive, depending on the random assignment

The components are:

A) one **counseling session called shared decision making** (lasting about 60 minutes or less) with a **study nurse** to answer any questions you have about COVID and flu vaccination, and discuss what you might plan to do about COVID-19 and flu vaccination. We may audio-record these sessions for supervision purposes with your permission. You can say no to audio-recording and still continue with the shared decision making meeting.

B) receiving **text messages** with information about COVID, flu, vaccination, and general health. During the study, we will explain this component to you and put the study phone number in your phone. It will take about 5 minutes or less to explain this component and then you will receive text messages twice a week for 12 weeks, then once a week for 8 weeks. There are 32 messages total. You can stop receiving text messages at any time.

You will be asked to respond to each text message with a "1" to let us know you receive it. You will have four hours to respond. You will receive compensation ($1) for each response we receive. You will receive the compensation in a lump sum at the end of the component.

C) **a prize** awarded six months after starting in the study if you have been vaccinated for COVID-19 and can show documentation such as My Vaccine Record.

The prize will be a gift bag with a $25 gift card and some other items.

You will also receive 3 reminder messages during intervention period about the prize.

D) **peer navigation** from someone with ties to the community, to assist you accessing COVID-19 and flu vaccination if you wish to do so.

This will start with a **brief meeting** lasting less than 30 minutes to talk about COVID-19 in our communities and check with you about whether you wish to be vaccinated for COVID and/or flu at this time. If yes, the navigator can help you make appointments.

Also, your peer navigator will reach out to you bi-weekly with personal phone calls, texts, or emails over 5 months to see if we can help make appointments. You can stop receiving messages and calls at any time.

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 and check of vaccination at 12-months

We will contact you 3 and 6-months after participating in first survey for follow-up surveys. We will also ask you to provide documentation that shows any COVID-19 vaccines you may have carried out.

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 vaccinated for COVID-19 or flu.

At 12-months after you enroll, we will contact you to document whether you got any COVID and flu vaccinations in the past year, using My Vaccine Record or some other medical documentation and asking you about that.

F. Recruiting peers, friends, family, and acquaintances

We will ask you if you are interested in referring your peers to the study who are also Black and Latino New Yorkers not recently vaccinated for COVID-19 and flu. If yes, we will give you some recruitment coupons and explain the process to you.

G. Contact information

We will ask you for some ways to stay in touch with you over the next year, using a locator form.

H. 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. The identification number 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 such as the names of family members or organizations you attend 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 and flu vaccination rates among Black and Latino/Hispanic people.

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 people. This study may help us develop better services to manage and prevent COVID-19 and flu.

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:

- $60 for the initial baseline survey
- $50 for each follow-up survey
- $20 bonus for bringing or showing evidence of COVID-19 vaccination such as the NYC Health Department My Vaccination Record website at the follow-up surveys
- $25 for the health education session (core session)
- Depending on which NCAP2 study condition you are randomly assigned to, you will receive:
    A. Shared decision making session with a nurse: $25 for the meeting
    B. Text messages: up to $32 ($1 for each text message you respond to)
    C. Prize: $25 gift card and other gift items

D. Peer navigation: $25 for the initial meeting

- $25 at 12-months when we call you to check your vaccinations over the past year, if any
- $50 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

Compensation will be provided using a refillable debit card called a Clincard.

11. Tax forms

You might receive more than $250 in a calendar year from participating in this study. We will ask you to complete a W-9 tax form, which will include your name, physical mailing address, and social security number.

Then, if you participate in other studies at New York University (NYU) this year and receive **more than $600** in compensation from NYU within the calendar year, NYU will report the compensation to the IRS and will issue you a 1099 form.

If you receive less than $600 this year from all the studies you participate in at NYU, no report on compensation will be made to the IRS by NYU. (You will not receive more than $600 from the NCAP2 study.)

If you do not complete the W9 at this time, we will ask you to track all payments made to you by NYU for your participation in any research studies for this calendar year. Please let us know immediately if/when the total research payments you receive equal or are likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. At that point, you will need to provide your Social Security number or Alien Registration number and will be asked to complete a IRS W9.

12. 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.

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

We may end your participation in the study if we find you have already participated, you are unable to follow the study protocol, or there are changes to who is eligible to be part of the study.

If you leave the study or you are withdrawn from the study, you will no longer have access to the surveys/interviews or intervention component activities. 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.

In this study, you may be asked to provide information that could be used to identify you personally. This information will be kept confidential. Only researchers and others that will keep the information confidential (e.g., regulatory agencies or oversight groups) may access information that could personally identify you.

All your information will be labeled with your identification number and stored in a secure and confidential database that is protected by a password. If we audio-record your sessions or semi-structured interviews, the audio-file will be labelled with your identification number and stored on a secure site called NYU Box. The audio-files will be destroyed after the study ends.

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 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-FY2025-9851 when contacting the IRB (UCAIHS).

14. 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.

15. Sharing data that does not identify you

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.

Our project, NCAP2, will send some of the information collected from our study participants to a professional data sharing site used by researchers. **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.

The data sharing site will keep your data securely (which means with extra protection). Researchers could use the data to learn more about COVID-19 as well as other diseases and conditions.

Some ways we and the data sharing site will protect your privacy.

- You will be assigned a study code ID and you will only be identified in this database by this study code.
- The information in the database will not contain your name or other information that could easily identify you.
- When researchers use 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, no one will not contact you to inform you or ask your permission before sharing the data with researchers.

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 website will include a summary of the results. You can search this website at any time.

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

ADDITIONAL CONSENT ITEMS

A. I agree to have my sessions (Core session, Nurse-led shared decision making, peer navigation) audio-recorded **for supervision purposes**. (You can say no and continue in the study)

_____ Yes _____ No

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B. I agree to have my in-depth interview audio-recorded. (You can say no and continue in the study)

_____ Yes _____ No

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C. I agree to be contacted for future research.

_____ Yes _____ No

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