Nurse-Community-Family Partnership

You have been invited to take part in a study to learn more about how COVID-19 has impacted you, your family, and the Mott Haven community. If you agree to be in this study, you will be randomly selected to be a part of the *intervention group* or *non-intervention group*. The group you are placed in will determine if you participate in some *or* all of the following study procedures.

All Participants

(1) **Assessments:** We will ask you to fill out monthly assessments that will take about 60 minutes to complete. These assessments ask questions about COVID-related events that may have taken place in your household over the prior 30 days.

(2) **Contact Form:** We will ask you to fill out a contact form that will take about 10 minutes to complete. You will be asked to provide us with the contact information of at least three persons who will know how to reach you in the future.

Randomly Selected Participants

(3) **Family Interviews:** Some participants will be randomly selected to complete an evaluation that will take approximately 1.5 hours to complete. These interviews will discuss several topics, including barriers & facilitators of uptake of COVID-19 testing, control measures, and vaccines. The interviews will be completed with a trained interviewer who does not personally know the participant.

Non-Intervention Group

(4) **COVID-19 Testing:** You will be offered information about locations in your community where you can get tested for COVID-19.

Intervention Group

(5) **House Visits from Nursing Staff:** Nurses will visit your home on a monthly basis. During the visit, nurses will discuss the importance of infection control measures and create an infection control plan with you that addresses the unique circumstances of your household. Nurses will also deliver training on infection control skills necessary for optimal implementation of household plans.

(6) **COVID-19 Testing:** You will be offered in-home COVID testing once per month, after completing your monthly survey assessment. This test can be self-administered.

Time: Participation in this study will involve you taking part in monthly sessions over a 9-month study period. These sessions will take approximately 1 ½ hours to complete.

Risks: Some participants may feel discomfort or embarrassment while answering assessments or completing interviews. There are no known risks associated with nasal swabs or collecting saliva samples.

Benefits: There may be benefits to being part of the Nurse-Community-Family Partnership. You will have increased access to COVID-19 testing, PPE, pulse oximeter assessments, culturally appropriate health information and public health guidance, as well as referrals to other local social service and medical programs, as needed.

Voluntary: Study participation 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.

Introduction: Who is Doing What and Why?

The Nurse-Community-Family Partnership is the name of our health intervention taking place in Mott Haven. Our project seeks to partner with families as a way to understand what we can do to support the Mott Haven community. Too often, communities like Mott Haven are not asked what they need or what can be done to support them during emergencies like COVID-19. Community members like you are also not asked how they respond to these emergencies. We believe that your opinion matters. There is no way to know what is best for Mott Haven without asking Mott Haven.

We want to learn a little more about COVID-19 prevention and response in the Bronx, and how COVID-19 has impacted you, your family, and the Mott Haven community. We would like to invite you and your family to participate in our study. This study will be conducted by Dr. Holly Hagan from New York University and Dr. Vincent Guilamo-Ramos from Duke University.

Procedures: What Will You Be Asked to Do?

For this study there is an *intervention* group and a *non-intervention* group. The decision of which group you are placed into is random, like the lottery, and happens completely by chance. Attendance at every meeting for both *intervention* and *non-intervention* groups is important so we can better understand how to best support Mott Haven families during the pandemic.

The group you are placed in will determine if you participate in some *or* all of the following study procedures.

All Participants

All Mott Haven families who join this study will be doing the following:

(1) **Contact Form:** We will ask you to fill out a contact form after you consent to participate in this study, that will take about 10 minutes to complete. You will be asked to provide us with the contact information of at least three persons who will know how to reach you in the future. There will be a staff member available to help you with any questions you may have.

(2) **Assessments:** We will ask you to fill out monthly assessments that will take about 60 minutes to complete. These assessments ask questions about COVID-related events that may have taken place in your household over the prior 30 days. The first assessment will occur at baseline and monthly thereafter, through month 9. You will complete this assessment using a tablet. If you need assistance, a data collection staff member will be available to review the questions and record your responses onto the tablet for you. You will be asked to go in a separate room to fill out each assessment for privacy purposes.

Randomly Selected Participants

If you are randomly selected then you will also be asked to complete the following *Family Interview*:

(1) **Family Interview:** Some participants will be randomly selected to complete an evaluation with a trained interviewer who does not personally know the participant. This interview will take approximately 1.5 hours to complete. The interviews will discuss either of the following topics: (1) COVID-19 testing, safety precautions, vaccines, and contract tracing; (2) your family's thoughts about the acceptance of their household safety plan; (3) household views about our nurse-CHW-family intervention (for the *intervention group*) or household views about local COVID-19 testing opportunities (for the *non-intervention group*). These interviews will be held in a private space that ensures participant confidentiality.

Non-Intervention Group

If you are randomly assigned to the *non-intervention* group then you will receive the following information:

(1) **COVID-19 Testing:** If you are put in the *non-intervention* group, study staff will provide you with an information sheet that lists locations in your community where you can get tested for COVID-19. The information provided will be consistent with NYC DOH recommendations and guidelines. The information sheet will be available in both English and Spanish.

Intervention Group

If you are randomly assigned to the *intervention* group then you will also be asked to participate in the following activities:

(1) **Home-Visits:** If you are put in the *intervention* group, nurses will visit your home on a monthly basis. During the visit, nurses will discuss the importance of infection control measures and create an infection control plan with you that addresses the unique circumstances of your household. Nurses will also deliver training on infection control skills necessary for optimal implementation of household plans. For example, nurses will train you on the safe and correct use of PPE, and offer in-home point-of-care (POC) SARS-CoV2 testing to all members of your household. Lastly, nurses will conduct triage, medical case management, monitoring, and follow-up with you if you are identified to have COVID-19 or any other acute health emergencies.

(2) **COVID-19 Testing**: If you are put in the *intervention* group, you will be offered COVID-19 testing once per month, after completing your monthly survey assessment. Nurses will offer in-home point-of-care (POC) testing to all members of the household. The test we are using can be self-administered by participants. We will ask you to provide a saliva sample or perform a nasal swab, and provide you with instructions on how to do so. COVID-19 testing is voluntary. Your decision to accept or decline COVID-19 testing will be documented. Your decision will not impact your eligibility to remain in the study or participate in any other study activities.

Audio-Recording

Your interviews will be audio recorded. This helps researchers ensure that your interview responses were accurately documented. You may review the audio recordings and request that any portion of them be destroyed.

How Much Time Will Participation Involve?

Participation in this study will involve you taking part in monthly sessions over a 9-month study period. These sessions will take approximately 1 ½ hours to complete.

Risks or Discomforts

Surveys: Some of the questions we ask on the survey may be sensitive. If any of the questions we ask on the surveys make you feel upset or embarrassed, you can decide not to answer. If at any time during your participation in an activity you should feel uncomfortable, you may choose not to participate in the activity. If you want to stop, you can just let us know. We do not want to make you feel upset.

If you feel that you need to talk about any discomfort you may experience, you should tell a staff member so that we may help you. We can talk to you about how you are feeling and answer any questions you may have.

Distress during COVID-19 Testing: It is possible that participants may experience psychological distress during or after COVID-19 testing. The study is designed to address and reduce these types of reactions, and study staff, including the PIs, will be available to aid participants in dealing with these feelings.

The COVID-19 test results contain sensitive information. You will be told if you have a negative or positive COVID-19 test result. If your COVID-19 test is positive, a nurse will perform an oximeter assessment and provide you with infection control guidance. Should you require medical assessment or treatment because of severe COVID-19 symptoms, respiratory distress, or other acute medical conditions, the PIs and clinicians (e.g., doctors and nurses) on the study team will be contacted immediately and our nurse staff or team member will be instructed in how to respond. Referrals made to Montefiore Medical Center, Bronx, will be determined on a case-by-case basis.

Adverse reactions to COVID-19 Testing: There are no foreseeable risks associated with performing nasal swabs or saliva testing.

Infection Control Guidelines

We care about your safety, as well as ours. That's why, when we visit your home our study staff will wear gloves, a face mask, eye protection, and sometimes a gown. You will also be asked to wear a face mask while we are at your home. If you don't have a mask, don't worry. We will give you one.

Staff will remove gowns immediately prior to leaving households and will remove other PPE after leaving the household as appropriate. All of these policies and procedures will be continually updated based on current evidence, recommendations and requirements by authoritative bodies (NYCDOMH, NYSDOH, CDC and as required by the primary study institution (NYU) and its IRB).

Benefits

There may be benefits to being part of the Nurse-Community-Family Partnership. You will have increased access to COVID-19 testing, PPE, pulse oximeter assessments, culturally appropriate health information and public health guidance, as well as referrals to other local social service and medical programs, as needed. You might also find it useful to talk to our nurses and community health workers about health, COVID-19 risk, and COVID-19 stigma and misconceptions in your community. Your participation is also helping to develop a program that can help underserved populations reduce COVID-19 transmission and COVID-19 disparities in the United States. We want to come up with the best program possible and you can help us do that.

Payment

If you agree to be part of the study, you will fill out several assessments. You can receive up to **$270** for your participation over a 9-month period: this includes $60 for the baseline assessment, and $30 for each of the monthly follow-up assessments. Compensation for each follow-up assessment does not require completion of the prior month's assessment. Participants who are selected at random for a qualitative *Family Interview* will be compensated an additional **$30**. Compensation will only be given for study visits, not COVID-19 testing. Your decision to accept or decline COVID-19 testing will not impact your eligibility to remain in the study or participate in any other study activities. If medical treatment is needed based on the results of the COVID-19 test a nurse staff or team member will respond as advised. If needed, a referral to Montefiore Medical Center Bronx will be made. The cost of treatment will not be covered by this project. We appreciate that you have given your time to the Nurse-Community-Family Partnership program.

Confidentiality

Data will be collected by trained and supervised staff members on tablets and audio tapes and will be uploaded using encryption software to a secure, password protected server. You may review the audio recordings and request that any portion of them be deleted. Your answers and anything you write will be kept private. Your name will not appear on any of the assessments, reports, or COVID-19 test results. We will not tell anyone what you wrote on the assessments. Each study participant will get a code number. Only project staff will have access to your name and code number. We will keep all of the data in a locked file cabinet in a locked office that only select staff will have access to. All data will be used strictly for research purposes.

Future Research

We will destroy identifiable data when we have completed the data analysis portion of the study. Your information from this study may be used in future research, shared with other researchers, or placed in a data repository without your additional consent. However, this information will not contain any identifiers.

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.

The following are exceptions:

(1) To protect the safety and well-being of those under 18, we are required under New York State law to report any information to authorities (police and/or child protection services) if we think a minor has been, or is in immediate danger, of being abused or neglected.

(2) All identified COVID-19 cases will be reported by name to the NYC DOH, consistent with COVID-19 POC test reporting regulations. NYC DOH can offer you additional support and services to help keep you and your family safe.

(3) Your explicit approval for the researchers to release your name and/or personally identifiable information.

Your Right to Refuse or Withdraw

You are free to join this study or not. For assessments and interviews, you have the right to skip or not answer any questions you prefer not to answer. If you are randomly selected to be a part of the intervention group, you may choose to accept or decline COVID-19 testing. Your decision will not impact your eligibility to remain in the study or participate in any other study activities. You may leave the study at any time without any penalty. If you wish to leave the study, you can tell a staff member or contact one of the Principal Investigators, Dr. Holly Hagan at (212)-998-5221 or Dr. Vincent Guilamo-Ramos at (833)-774-1799.

Our Right to Withdraw

The investigator may withdraw you from the study without your consent if unsafe conditions in your home have been identified (e.g., someone in your home not adhering to infection control protocols.)

For More Information

A description of this project will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website may include a summary of the results, but will never include information that can identify you. You can search this website at any time.

Questions or Concerns

If you have any questions or concerns related to the study, please call Dr. Holly Hagan at (212)-998-5221 and/or Dr. Vincent Guilamo-Ramos at (833)-774-1799. If at any time you have comments related to the conduct of this research or questions about your rights as a research participant, you can contact New York University's Institutional Review Board at (212)-998-4808 or ask.humansubjects@nyu.edu.

How to Get Involved

(1) Please sign the consent form.

(2) Talk with your family about joining this study.

(3) Contact Dr. Holly Hagan at (212)-998-5221 and/or Dr. Vincent Guilamo-Ramos at (833)-774-1799 with any questions you have.

Do you want to take part in the Nurse-Community-Family Partnership study? If you want to join, please check the first line below. Then print your name and sign your name with today's date.

If you do NOT want to take part in the study, please check the second line.

THANK YOU FOR TAKING THE TIME TO READ THIS!

Adult Informed Consent Form

I have read this consent form. All my questions were answered. All parts of the Nurse-Community-Family Partnership study are clear to me.

Please check one:

_____I consent to be part of the Nurse-Community-Family Partnership study, and I have received a copy of this consent form.

_____I DO NOT consent to be part of the Nurse-Community-Family Partnership study.

_____
Adult Name – Please Print

_____ _____
Adult Signature of Consent Date

I observed the process of consent. The prospective participant read this form, was given the chance to ask questions, appeared to show understanding and to accept the answers, and agreed to participate in the Nurse-Community-Family Partnership study.

_____ _____

Witness Signature Date