Study Title: Leveraging CHWs to Improve COVID-19 Testing and Mitigation Among CJIs Accessing a Corrections-focused CBO
IRB Approval Date: 02/10/2025
Study ID: 2021-12976
NCT04878328

KEY INFORMATION FOR MOSAIC: MITIGATION THROUGH ON-SITE TESTING & EDUCATION AMONG FORMERLY INCARCERATED INDIVIDUALS AGAINST COVID-19

We are asking you to be a subject in a research study about the effectiveness of an onsite COVID testing and education intervention compared to standard testing in a clinic. We want to learn about providing onsite testing for COVID-19 infection at community-based organization that also provides reentry services. This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn whether providing onsite testing and education for COVID a corrections-based community-based organization is more effective than referral to clinics for testing. We will use knowledge gained to inform onsite testing strategies for other high-risk populations such as clients of homeless shelters or syringe exchange programs, and people living with other conditions, such as HIV or hepatitis C. Your participation in this research will last about up to 1 year and requires attending research visits every 3 months as well as web-based surveys every 2 weeks. For today's visit we will review your medical records. Subjects will be chosen at random to get onsite COVID testing or to have testing done at a medical clinic every 3 months for one year. In addition, there are in person and online questionnaires to complete.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The study will not give a benefit to you but may benefit other people have been recently released from the correctional setting in the future. For a complete description of benefits, refer to the Consent Document below.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

The study will not give a benefit to you but may benefit other people have been recently released from the correctional setting in the future. For a complete description of alternate treatment/procedures, refer to the Consent Document below.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dr. Matthew Akiyama. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is:

3300 Kossuth Avenue
Bronx, NY 10467
Telephone: +1 718 920 7175

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Einstein Institutional Review Board between the business hours of 9am and 5pm EST, Monday-Friday at 718-430-2253 or irb@einsteinmed.edu

ALBERT EINSTEIN COLLEGE OF MEDICINE

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to be a subject in a research study called **MOSAIC: Mitigation Through On-Site Testing & Education Among Formerly Incarcerated Individuals Against Covid-19.** Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Dr. Matthew Akiyama. You can reach Dr. Akiyama at: **Office Address: 3300 Kossuth Avenue** **Bronx, NY 10467** **Telephone #: 1 718 920 7175** For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.	The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einsteinmed.edu, or by mail: Einstein IRB Albert Einstein College of Medicine 1300 Morris Park Ave., Belfer Bldg #1002 Bronx, New York 10461
Support for this research study is provided by **National Institutes of Health (NIH),** **National Institute on Minority Health and Health Disparities (NIMHD)**	

Why is this study being done?

Jails and prisons have accounted for 10 of the largest U.S. outbreaks of COVID-19. Individuals are at an increased risk for contracting COVID-19 both while incarcerated and after release as many seek housing in settings such as shelters, converted hotels and halfway houses. The goal of this study is to test the effectiveness of an onsite COVID swab testing in a corrections-focused community-based organization.

Why am I being asked to participate?

You are being asked to participate in this study because you have been released from jail or prison within the last 90 days and access services at Fortune Society.

What will happen if I participate in the study?

If you participate in this study, you will be cared for by physicians and nurses in the usual way. If you are eligible for the study, we will assign you by chance (like a coin toss) to get COVID testing at the Fortune Society or at a nearby medical clinic. The choice will be made at random by a computer program - you and the study doctor cannot make the choice. You will have **an equal, 50-50, chance** of being assigned to each group. Either way, if you are found to have COVID-19 infection, the treatment that you receive is not study treatment, but the treatment that anybody may receive when starting treatment. What the study involves is obtaining information and nasopharyngeal swabs from you during this study to understand more about what COVID-19 transmission and prevention among people recently released from jail or prison.

If you do not have a smartphone or one that is compatible with our software, we will provide you with one. We will be using Ethica software to measure access to COVID testing and healthcare services, ability to socially distance, and knowledge translation from public health messaging, the questionnaires will be sent through this application. If you are provided a smartphone from the study, please keep in mind data collection via phone carrier may also be enabled in some instances. The research team will ask if you would like to share your location with the team. This will not be used to continuously check your whereabouts. The study team will only access the shared location feature in the event a participant contacts the study to inform them their phone has been lost or stolen. The research team agrees to not intentionally seek to identify a participants' whereabouts.

Study Visit
If you agree to join the study, you will sign on this form; we will then ask you some questions about your medical history and review your test results from your medical record.

Nasal Passage (NP) sample collection
All participants will have swabs collected at each research visit, every three months for one year, for a total of five times. These swabs will be used to assess for COVID infection. If collected at the Fortune Society, specimens will be collected via self-swab under the supervision of the community health care worker and we will record results of those tests in your study record. The cartridges used to conduct the SARS-CoV-2 analysis at Fortune Society may also simultaneously test for infection with influenza A, influenza B, and RSV.

Follow-up visits
Between today's study visit and 1 year from now, you will complete a survey with a study coordinator either in person or by phone every 3 months. You will also receive a prompt through Ethica every two weeks to complete a web-based survey, there will be 26 in total.

A description of this clinical trial will be available on 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.

As part of this study, we will review your medical records and put the information we collect in our research records.

How many people will take part in the research study?

You will be one of about **250** people who will be participating in this study.

Genetic Testing

This study will not involve genetic research or genetic testing.

Specimen Banking (Future Use and Storage)

Specimens will be used to analyze circulating variants of the coronavirus. We will destroy the specimens when the study is complete. Information about you will be kept as long as required by regulations and institutional policy but will not be used for future studies.

Will I be paid for being in this research study?

You will receive up to a total of **$605** for participating in this study. This includes receiving **$40 reimbursement for your time for each of the 5 study visits** you complete (as well as an additional $5.80 to cover the cost of roundtrip transportation to and from the study visit if opting for an in-person visit). You will also receive $**10 for each of the 26 web-based surveys** you complete. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits or surveys you complete.

Retention procedures:

In addition to the payments listed above you are eligible to receive retention incentives.

1. You will also receive **$5 for completing a 4-week check-in** with the study coordinator to confirm/update your contact information.
2. You can receive up to **8 additional $5 payments (up to $40)** for contacting MOSAIC staff and providing updated locator information between in-person visits. You will only be compensated for one contact per month between each in-person visit. For example, if you enroll in January and your next visit isn't until April, you may reach out to the research staff once in February and/or once in March to inform them your contact information has changed or remained the same and you will receive $5 on your clincard per contact made.
3. You will also receive **$50 for completing BOTH the Month 3 and Month 6 visits (to be paid at the completion of the Month 6)** and an additional **$50 for completing BOTH the Month 9 and Month 12 visits (to be paid at the completion of the Month 12).**
4. Finally, if we become unable to reach you for a study visit, we may incentivize your emergency contacts to help us get back in touch with you. This is only to make sure that we don't lose track of individuals whose contact information changes. If we need to reach out to your contacts, we will only be disclosing that we are calling from Einstein/Montefiore and share with them that you are part of a program. We will not share any of your personal information or details about the nature of the study.
    - Contacts will receive **$25 via electronic giftcard** if they are able to successfully reconnect you with the MOSAIC team and you complete the study visit we were contacting you for. There will only be one compensation per study visit.

Some researchers may develop tests, treatments or products that are worth money. You will not receive payment of any kind for your specimens and information or for any tests, treatments, products or other things of value that may result from the research.

Will it cost me anything to participate in this study?

There will be no cost to you to participate in the study.

Confidentiality

The researchers and study staff follow federal and state laws to protect your privacy. This part of the consent form tells you what information about you may be used and shared in the research described in this form. You do not have to sign this form but, if you do not, you may not participate in the research.

The health information that we may use or disclose for the research described in this form includes information from your entire medical record, such as your name, phone number, email, medical diagnoses, dates, test results, social security number, medical record numbers, etc.

Your information and research records will be kept confidential. Your study information will be kept as long as they are required by regulations and institutional policy or are useful for the research described in this form.

The only people who can see your research records are:

- Researchers and other individuals who work with the researchers.
- Organizations and institutions involved in this research, including those that fund the research, if applicable.
- Groups that review research such as central reviewers, Institutional Review Boards, the Office for Human Research Protections, the US Food and Drug Administration, data coordinating centers, and domestic and foreign agencies that regulate research.
- As part of this study, we may provide updated contact information or other needs you express to the research team to Fortune Society in an attempt to enhance the services you receive

The purposes of these uses and disclosures are to (1) conduct the study and (2) make sure the study is being done correctly. The information covered under this form may no longer be protected by federal privacy laws (such as HIPAA) once disclosed, and those persons who receive your health information may share your information with others without your additional permission. All of these groups have been asked to keep your information confidential.

To maintain the integrity of this research study, you generally will not have access to your research-related personal health information. If it is necessary for your care, your research-related health information will be provided to you or your physician.

Certificate of Confidentiality

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study were requested or subpoenaed by government agencies or the courts, we would use the Certificate to attempt to legally refuse to provide that information. These requests are rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations to which the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Are there any risks to me?

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy – see the Confidentiality section above for details.

Your research records will be kept confidential, and your name will not be used in any written or verbal reports. To protect your privacy, we will replace your name with a code. We will only use this code on your sample and any written information we collect about you for this study. We will do our best to keep the code private. The form that links your name to the code number will be kept in a locked file cabinet and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information and specimens will be kept if they are useful for this study.

Questionnaire
You may feel uncomfortable answering questions about your demographic and clinical information, including sex, age, ethnicity, measures of socio-economic status, criminal justice involvement, relevant medical history, substance use behavior, knowledge about COVID-19, testing experiences and social distancing impacts. You can choose not to answer questions that make you feel uncomfortable.

Ethica
Data collected via Ethica measures location to understand your risk of having been exposed COVID-19. To protect your privacy, you can turn on or off location data at any time. Any location data collected will also be de-identified and every effort to ensure your anonymity will be taken. The research team will not intentionally seek to re-identify your individual information.

New Findings
If we learn any significant new findings during the study that might influence your decision to participate, we will contact you and explain them.

If information is published as a result of this study, your name and any personal information will not be included in the publication(s).

The study team would like to contact you by social media, if they are unable to get in contact with you through your phone. However you may say “no” to receiving these messages and still participate in this study. If you say “yes”, messages may be sent or received by the study team’s personal electronic devices or in a method that is not able to be encrypted (protected) and there is the risk your information could be shared beyond you and the study team. This information may include information such as reminders and notifications to contact the study team.

If you wish to stop receiving unprotected communication from the study team or have lost access to your device, please notify the study team using the study contact information on the first page of this consent form. After the study is complete and all research activities finished, or you withdraw from the study or request to stop receiving unprotected communication, you will no longer receive un-encrypted (un-protected) messages specific to this study.

_____ Yes, I consent to the study team utilizing the following social media accounts to send communication (include account name or handle):
Facebook:_____ Instagram: _____ Snapchat: _____
Twitter: _____ WhatsApp: _____ Other: _____

_____ No, I do not consent to receive un-protected communication from the study team.

Are there possible benefits to me?

You will not experience any direct benefit from participating in this study. We hope you will participate because the study will generate important information about COVID testing and reducing its transmission in people like you.

What choices do I have other than participating in this study?

You can refuse to participate in the study. If you decide not to participate, the medical care providers at this facility will still give you all of the standard care and treatment that is appropriate for you.

Are there any consequences to me if I decide to stop participating in this study?

No. If you decide to take part, you are free to stop participating at any time without giving a reason. This will not affect your care and you will continue to be treated at this facility. However, some of the information may have already been entered into the study and that will not be removed. The researchers and the sponsor may continue to use and share the information they have already collected.

To revoke (take back) your consent and authorization, you must contact the Principal Investigator in writing at the address on page 1 of this form. However, you may first call or speak to the Dr. Akiyama and he will stop collecting new information about you. If you take back your consent and authorization, you will not be allowed to continue to participate in this research study.

Can the study end my participation early?

We will not let you participate in the study any more if you are unwilling to comply with all study procedures and availability for the duration of the study. This may include: (1) When Fortune Society has notified the study team that the participant is no longer permitted on-site at Fortune's locations; (2) Moving out of the NYC area (one of the five boroughs) during the course of your participation in the study; or (3) Exhibiting disruptive behavior or acting inappropriately toward the study staff. If the participant isn't following the study procedures, that would be grounds for removal from the study. In addition, your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

I have read the consent form and I understand that it is up to me whether or not I participate. I know enough about the purpose, methods, risks and benefits of the research study to decide that I want to take part in it. I understand that I am not waiving any of my legal rights by signing this informed consent document. I will be given a signed copy of this consent form.

Printed name of participant	Signature of participant	Date
Printed name of the person conducting the consent process	Signature	Date