

**Leveraging Social Networks to Increase COVID-19 Testing Uptake: A Comparison of Credible
Messenger and Chain Referral Recruitment Approaches**

Consent Forms

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**Informed Consent for Participation in a Study,
Leveraging Social Networks to Increase COVID-19 Testing Uptake: A Comparison of
Credible Messenger and Chain Referral Recruitment Approaches (Phase 2)**
(Katherine Elkington PhD, 646-774-6965)

CONSENT SUMMARY PAGE

Overview

Below is a summary of the study that you are asked to participate in. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The consent form contains detailed information about the study and about the risks which you will need to consider before making your decision. Read the consent form carefully and discuss it with others before deciding to take part. And remember that, even if you agree to participate, you can change your mind at any time

Voluntary

As with all research, this is a voluntary study, and you do not have to participate if you do not want to. Also, you may stop participating at any time.

Procedures

- Participate in 1 survey
- You will be offered an opportunity for COVID-19 testing – it is voluntary

Risks and Inconveniences

This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). These include loss of confidentiality related to your responses and possible discomfort because of the types of questions we ask.

Benefits

This research study is not meant to benefit you directly.

Questions

You may contact the study principal investigator, Dr. Kate Elkington at 646-774-6965 with any questions.

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WHAT IS THE PURPOSE OF THE STUDY?

We are asking you to participate in *Leveraging Social Networks to Increase COVID-19 Testing Uptake: a Comparison of Credible Messenger and Chain Referral Recruitment Approaches*, which is a RADx-UP program to increase COVID-19 testing uptake among people who use opioids and other substances in New York City. The goal of *Leveraging Social Networks* is to encourage people who use opioids and other substances to get tested regularly for COVID-19. We will explore the potential for two peer recruitment strategies, chain referral and credible messenger, to identify which can achieve greater reach and uptake of COVID-19 tests among individuals who use opioids and other drugs. We are asking you to complete a survey and participate in COVID-19 tests. You are being asked to participate in this study because you reside in New York City and use opioids or other substances. There will be 500 participants in the program.

WHAT IS the NIH and RADx-UP?

This study is funded by the NIH as part of the RADx-UP research program. The NIH stands for the National Institutes of Health. 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 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 combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

WHAT WILL YOU ASK OF ME?

If you decide to join this study, we will gather data (information) about you directly through a survey. We will also ask you to get a series of COVID-19 tests with us. 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 also ask you information about COVID-19, including information about any symptoms (a change in your health) and test results. We will ask about your medical history and if you have or have not had vaccines and why, information about your health, education, family, home, relationships, and social life, among others. We will also ask you to participate in COVID-19 testing.

WHAT ARE THE ALTERNATIVES TO STUDY PARTICIPATION?

Your participation is voluntary. You do not have to participate in this study in order to get services that are otherwise available to you through Alliance for Positive Change. The alternative to participating is simply not to take part; if you do not take part in this study, you will still receive all services as usual through Alliance for Positive Change. Study participation will not affect anything related to your status at Argus Community Inc, either positively or negatively.

WHAT IS THE STUDY PROCEDURE?

We will conduct the survey as described above when you arrive at the research site. A research assistant will conduct the brief survey with you, which will take about 30-40 minutes, and will record your responses to the questions in a computer.

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After we conduct the survey, you will receive COVID-19 testing. We are using Abbott's rapid antigen test, BinaxNOW. You will be taken to the designated testing area by research staff while wearing a surgical or N95 mask(s), seated, and given a tissue and asked to blow your nose and discard the tissue in the trash. You will then be instructed to sanitize your hands. Research staff or peer workers will explain the testing procedure to you and demonstrate the appropriate technique to collect the specimen. You will self-collect the sample and give the sample to the research staff member or peer worker who will label the sample with your name and date of birth and then immediately process the sample. Test results will be communicated directly to you by the research staff member or peer worker who supervised the collection and processing of the sample. We will ask you to return to the research site to receive COVID-19 tests twice a week for four weeks.

If you test positive for COVID-19, you will be referred to the NYC Test and Trace Corps for contact tracing. Contact tracing involves finding people who tested positive or were exposed to COVID-19 and asking them to safely separate from other people until they can no longer spread the virus. New York State law and the New York City Health Code requires us to send positive test results to the NYC Health Department. The NYC Health Department will securely share your information with the Test & Trace Corps in compliance with privacy laws that allow this type of information to be used to protect public health and stop the spread of disease.

The NYC Test & Trace Corps is committed to protecting the privacy and security of New Yorkers' personal health information as required by federal, state and local law and in keeping with the NYC Health + Hospitals' and the City Health Department's long-time experience in guarding such information. The information that the NYC Test & Trace Corps receives through contact tracing is confidential and protected under the New York City Health Code.

The NYC Test & Trace Corps will not ask about anyone's immigration status. The Corps database will not be linked to any law enforcement databases. Any information the NYC Test & Trace Corps obtains will be stored securely and used by authorized staff for the limited purpose of protecting public health.

A Contact Tracer will call you to:

- Ask how you are feeling.
- Ask if you need resources to help you stay healthy and avoid spreading COVID-19.
- Explain how long you need to stay inside and away from other people.
- Ask questions to figure out how you may have been infected, if you have tested positive.
- Ask for names and contact information of everyone you had close contact with while you could have spread the virus to others, if you have tested positive.
- A Contact Tracer may also visit you in person to check on you. They will show you their identification card to prove they are a Contact Tracer.

As a facility performing point-of-care (POC) SARS-CoV-2 testing, we are required to report all results (positive, negative or indeterminate) via the New York State (NYS) Electronic Clinical Laboratory System (ECLRS) within 24 hours. When reporting COVID-19 results, we must also report patients' race and ethnicity, school, employment, and local address information.

What is ECLRS?

- ECLRS stands for Electronic Clinical Laboratory Reporting System.

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- It is a secure and rapid point of entry for reportable disease information to the NYS Department of Health (DOH).
- Test results (including COVID-19) are automatically distributed to the state, regional and local health departments, such as the NYC Health Department.

Why do we have to report COVID-19 tests in ECLRS?

- NYS Executive Order No. 202.61 requires all facilities that perform POC testing, including urgent care centers, medical offices, hospitals, nursing homes, pharmacies and clinics, to report COVID-19 test results via ECLRS. ‘
- COVID-19 POC test result information helps NYS and NYC to conduct contact tracing in a timely manner and prevent the further spread of COVID-19.

We will also ask you to sign a separate consent form for Healthix.

What is Healthix?

Healthix is a non-profit, health information exchange funded by the NYS Department of Health. Healthix provides patient information to thousands of physicians and providers in the Greater New York area.

Why is health information exchange important?

You likely receive medical care from several physicians and providers – each with their own medical record for you. If your providers share this information with one another, they will gain a fuller picture of your health. This health information exchange will improve our understanding of the effectiveness of our recruitment strategies and how often participants are testing for COVID-19.

How do I give consent?

We will ask you sign a Healthix Patient Consent Form. Your consent allows only individuals involved in your care to access your medical information in Healthix.

WILL THE SURVEY BE AUDIOTAPED?

The survey interview read to you by the research assistant may be audio recorded with a digital recorder. Please note that audio taping is optional. You are not required to have your interview recorded in order to participate in the study. The audio digital files help the research team to remember exactly what was said during the survey interviews and to ensure that the survey was done correctly. If you consent to being recorded, your name will not be on the digital audio file. Instead, you will be assigned an identification number to ensure confidentiality. All audio recordings will be private and will be kept in an electronically secure database. The files will be listened to only by the people doing the study and will be destroyed after the information has been written down, no later than ten years from now.

WHAT WILL YOU DO WITH MY DATA?

The information from the surveys will be collected using REDCap, a software program that develops surveys that can be accessed through a URL designated by the researchers. During online survey data collection, all data are stored directly onto a secure Columbia Irvine University Medical Center (CUIMC) server. Participants’ responses are de-identified since we will give each participant a unique ID number, which means identifying information like your name will be

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removed. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and CUIMC firewall. The only textual information present is the participants' ID numbers, IP addresses, and whether participants chose to enter textual data. All records and the results of the research will remain confidential to the extent permitted by law. Once you have agreed to participate in this study, you will only be identified by a code number; your name will not be connected with your information in any way so you cannot be identified. All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview will be part of your records at Alliance for Positive Change and no part of your interview will be shared with any of the Alliance for Positive Change or court staff. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific to each participant.

Your data will also be shared with 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. The 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). These data will be kept at the DCRI. The DCRI will not share these data with the NIH.

- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- 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.

I agree to be contacted for future research as stated above.

<input type="checkbox"/> Yes	<input type="checkbox"/> No
Initials	Initials

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.

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- 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.

HOW WILL YOU PROTECT MY PRIVACY?

Your privacy is very important to us. 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:

We have received a Certificate of Confidentiality, issued by the National Institute of Health, for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child or threatened violence to self or others. Such information will be reported to the appropriate authorities. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. 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.

In addition, the researchers will keep your responses private and confidential **except** in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to the Administration for Children's Services (ACS) as necessary. If we learn of this information, we will do whatever is necessary to protect anyone involved, including you. Part of what we will do is let the staff at Alliance for Positive Change know if you tell us you want to hurt yourself or someone else. Research staff may not be able to discuss this with you first.

We will ask your permission for our Research Staff to communicate with you via phone, text, direct messages through social media, or email regarding appointments for interviews. Receiving messages from our Research Staff is entirely voluntary and will have no impact on your participation in the study. We note that text messages often appear as a banner on phones without needing to be unlocked to view. The content of the text messages will not infringe on your privacy, we will not reveal study participation in our text messages to you. We also advise participants to remove banner alerts for text messages that include part of the message in the banner and replace with banner alerts that just include the number of the sender.

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WHAT ARE THE RISKS IN PARTICIPATING IN THIS STUDY?

There are no physical risks involved with participation in this study for you. Some of the interview questions ask about your experiences with drugs and alcohol. Some interview questions will also ask about experiences with COVID-19 illness, including those of your friends and family. These questions may make you feel embarrassed, worried, or upset. If this happens, the interviewer will spend time talking with you until you feel better. You may also experience distress during the COVID-19 testing and/or if you receive a reactive HIV or positive STI test result. Again, if this happens, research staff will spend time talking with you until you feel better, will explain the findings of the test and work with you to ensure you are linked to care.

WHAT ARE THE BENEFITS IN PARTICIPATING IN THIS STUDY?

There are no direct benefits to you from participating in the study. The results of this study may improve COVID-19 outcomes for substance users.

WHAT IS THE COMPENSATION FOR PARTICIPATING IN THIS STUDY?

You will receive \$20 for completing the survey.

WHAT ARE MY RESEARCH STANDARDS AND RIGHTS?

Your participation in this study is voluntary. You do not have to participate and can stop participation in this study at any time for any reason or for no reason at all. You can terminate participation in the study even after the study has started and can also refuse to answer any of the questions you are asked without terminating your participation. If you decide not to participate, or if you later decide to stop participation, you will not lose any benefits to which you are otherwise entitled, including services and care that are normally available to you through Alliance for Positive Change. The study is projected to conclude in December 2023. Results from the study may be available in future publications and conferences. If you are interested in receiving the results from the current study, including individual research results, you may contact us at 646-774-6965.

WHAT HAPPENS IF I AM INJURED?

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you.

WHAT DO I DO IF I HAVE QUESTIONS?

The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.

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Documentation of Consent:

I voluntarily agree to participate in the research study above.

Participant's name
(print): _____

Participant's
signature: _____

I voluntarily agree to have my interview audiotaped.

Participant's name (print): _____

Participant's signature: _____

Person Designated to Obtain Consent:

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions, and in my opinion, is freely consenting to participate in this research.

Print name: _____

Signature: _____

Date: _____

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removed. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and CUIMC firewall. The only textual information present is the participants' ID numbers, IP addresses, and whether participants chose to enter textual data. All records and the results of the research will remain confidential to the extent permitted by law. Once you have agreed to participate in this study, you will only be identified by a code number; your name will not be connected with your information in any way so you cannot be identified. All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview will be part of your records at Argus Community Inc. and no part of your interview will be shared with any of the Argus Community Inc. or court staff. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific to each participant.

Your data will also be shared with 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. The 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). These data will be kept at the DCRI. The DCRI will not share these data with the NIH.

- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- 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.

I agree to be contacted for future research as stated above.

<input type="checkbox"/> Yes	<input type="checkbox"/> No
Initials	Initials

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.

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- 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.

HOW WILL YOU PROTECT MY PRIVACY?

Your privacy is very important to us. 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:

We have received a Certificate of Confidentiality, issued by the National Institute of Health, for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child or threatened violence to self or others. Such information will be reported to the appropriate authorities. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. 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.

In addition, the researchers will keep your responses private and confidential **except** in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to the Administration for Children's Services (ACS) as necessary. If we learn of this information, we will do whatever is necessary to protect anyone involved, including you. Part of what we will do is let the staff at Argus Community Inc. know if you tell us you want to hurt yourself or someone else. Research staff may not be able to discuss this with you first.

We will ask your permission for our Research Staff to communicate with you via phone, text, direct messages through social media, or email regarding appointments for interviews. Receiving messages from our Research Staff is entirely voluntary and will have no impact on your participation in the study. We note that text messages often appear as a banner on phones without needing to be unlocked to view. The content of the text messages will not infringe on your privacy, we will not reveal study participation in our text messages to you. We also advise participants to remove banner alerts for text messages that include part of the message in the banner and replace with banner alerts that just include the number of the sender.

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WHAT ARE THE RISKS IN PARTICIPATING IN THIS STUDY?

There are no physical risks involved with participation in this study for you. Some of the interview questions ask about your experiences with drugs and alcohol. Some interview questions will also ask about experiences with COVID-19 illness, including those of your friends and family. These questions may make you feel embarrassed, worried, or upset. If this happens, the interviewer will spend time talking with you until you feel better. You may also experience distress during the COVID-19 testing and/or if you receive a reactive HIV or positive STI test result. Again, if this happens, research staff will spend time talking with you until you feel better, will explain the findings of the test and work with you to ensure you are linked to care.

WHAT ARE THE BENEFITS IN PARTICIPATING IN THIS STUDY?

There are no direct benefits to you from participating in the study. The results of this study may improve COVID-19 outcomes for substance users.

WHAT IS THE COMPENSATION FOR PARTICIPATING IN THIS STUDY?

You will receive \$20 for completing the survey.

WHAT ARE MY RESEARCH STANDARDS AND RIGHTS?

Your participation in this study is voluntary. You do not have to participate and can stop participation in this study at any time for any reason or for no reason at all. You can terminate participation in the study even after the study has started and can also refuse to answer any of the questions you are asked without terminating your participation. If you decide not to participate, or if you later decide to stop participation, you will not lose any benefits to which you are otherwise entitled, including services and care that are normally available to you through Argus Community Inc.. The study is projected to conclude in December 2023. Results from the study may be available in future publications and conferences. If you are interested in receiving the results from the current study, including individual research results, you may contact us at 646-774-6965.

WHAT HAPPENS IF I AM INJURED?

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you.

WHAT DO I DO IF I HAVE QUESTIONS?

The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.

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Documentation of Consent:

I voluntarily agree to participate in the research study above.

Participant's name

(print): _____

Participant's

signature: _____

I voluntarily agree to have my interview audiotaped.

Participant's name (print): _____

Participant's signature: _____

Person Designated to Obtain Consent:

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions, and in my opinion, is freely consenting to participate in this research.

Print name: _____

Signature: _____

Date: _____

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CONSENT SUMMARY PAGE

Overview

Below is a summary of the study that you are asked to participate in. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The consent form contains detailed information about the study and about the risks which you will need to consider before making your decision. Read the consent form carefully and discuss it with others before deciding to take part. And remember that, even if you agree to participate, you can change your mind at any time

Voluntary

As with all research, this is a voluntary study, and you do not have to participate if you do not want to. Also, you may stop participating at any time.

Procedures

- Participate in 1 survey
- You will be offered an opportunity for COVID-19 testing – it is voluntary
- Refer up to three peers to participate in the study

Risks and Inconveniences

This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). These include loss of confidentiality related to your responses and possible discomfort because of the types of questions we ask.

Benefits

This research study is not meant to benefit you directly.

Questions

You may contact the study principal investigator, Dr. Kate Elkington at 646-774-6965 with any questions.

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WHAT IS THE PURPOSE OF THE STUDY?

We are asking you to participate in *Leveraging Social Networks to Increase COVID-19 Testing Uptake: a Comparison of Credible Messenger and Chain Referral Recruitment Approaches*, which is a RADx-UP program to increase COVID-19 testing uptake among people who use opioids and other substances in New York City. The goal of *Leveraging Social Networks* is to encourage people who use opioids and other substances to get tested regularly for COVID-19. We will explore the potential for two peer recruitment strategies, chain referral and credible messenger, to identify which can achieve greater reach and uptake of COVID-19 tests among individuals who use opioids and other drugs. We are asking you to complete a survey and participate in COVID-19 tests. You are being asked to participate in this study because you reside in New York City and use opioids or other substances. There will be 500 participants in the program.

WHAT IS the NIH and RADx-UP?

This study is funded by the NIH as part of the RADx-UP research program. The NIH stands for the National Institutes of Health. 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 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 combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

WHAT WILL YOU ASK OF ME?

If you decide to join this study, we will gather data (information) about you directly through a survey. We will also ask you to get a series of COVID-19 tests with us. 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 also ask you information about COVID-19, including information about any symptoms (a change in your health) and test results. We will ask about your medical history and if you have or have not had vaccines and why, information about your health, education, family, home, relationships, and social life, among others. We will also ask you to participate in COVID-19 testing.

WHAT ARE THE ALTERNATIVES TO STUDY PARTICIPATION?

Your participation is voluntary. You do not have to participate in this study in order to get services that are otherwise available to you through Alliance for Positive Change. The alternative to participating is simply not to take part; if you do not take part in this study, you will still receive all services as usual through Alliance for Positive Change. Study participation will not affect anything related to your status at Argus Community Inc, either positively or negatively.

WHAT IS THE STUDY PROCEDURE?

We will conduct the survey as described above when you arrive at the research site. A research assistant will conduct the brief survey with you, which will take about 30-40 minutes, and will record your responses to the questions in a computer.

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After we conduct the survey, you will receive COVID-19 testing. We are using Abbott's rapid antigen test, BinaxNOW. You will be taken to the designated testing area by research staff while wearing a surgical or N95 mask(s), seated, and given a tissue and asked to blow your nose and discard the tissue in the trash. You will then be instructed to sanitize your hands. Research staff or peer workers will explain the testing procedure to you and demonstrate the appropriate technique to collect the specimen. You will self-collect the sample and give the sample to the research staff member or peer worker who will label the sample with your name and date of birth and then immediately process the sample. Test results will be communicated directly to you by the research staff member or peer worker who supervised the collection and processing of the sample. We will ask you to return to the research site to receive COVID-19 tests twice a week for four weeks.

If you test positive for COVID-19, you will be instructed to stop all attempts at peer recruitment. You will be referred to the NYC Test and Trace Corps for contact tracing. Contact tracing involves finding people who tested positive or were exposed to COVID-19 and asking them to safely separate from other people until they can no longer spread the virus. New York State law and the New York City Health Code requires us to send positive test results to the NYC Health Department. The NYC Health Department will securely share your information with the Test & Trace Corps in compliance with privacy laws that allow this type of information to be used to protect public health and stop the spread of disease.

The NYC Test & Trace Corps is committed to protecting the privacy and security of New Yorkers' personal health information as required by federal, state and local law and in keeping with the NYC Health + Hospitals' and the City Health Department's long-time experience in guarding such information. The information that the NYC Test & Trace Corps receives through contact tracing is confidential and protected under the New York City Health Code.

The NYC Test & Trace Corps will not ask about anyone's immigration status. The Corps database will not be linked to any law enforcement databases. Any information the NYC Test & Trace Corps obtains will be stored securely and used by authorized staff for the limited purpose of protecting public health.

A Contact Tracer will call you to:

- Ask how you are feeling.
- Ask if you need resources to help you stay healthy and avoid spreading COVID-19.
- Explain how long you need to stay inside and away from other people.
- Ask questions to figure out how you may have been infected, if you have tested positive.
- Ask for names and contact information of everyone you had close contact with while you could have spread the virus to others, if you have tested positive.
- A Contact Tracer may also visit you in person to check on you. They will show you their identification card to prove they are a Contact Tracer.

As a facility performing point-of-care (POC) SARS-CoV-2 testing, we are required to report all results (positive, negative or indeterminate) via the New York State (NYS) Electronic Clinical Laboratory System (ECLRS) within 24 hours. When reporting COVID-19 results, we must also report patients' race and ethnicity, school, employment, and local address information.

What is ECLRS?

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- ECLRS stands for Electronic Clinical Laboratory Reporting System.
- It is a secure and rapid point of entry for reportable disease information to the NYS Department of Health (DOH).
- Test results (including COVID-19) are automatically distributed to the state, regional and local health departments, such as the NYC Health Department.

Why do we have to report COVID-19 tests in ECLRS?

- NYS Executive Order No. 202.61 requires all facilities that perform POC testing, including urgent care centers, medical offices, hospitals, nursing homes, pharmacies and clinics, to report COVID-19 test results via ECLRS. ‘
- COVID-19 POC test result information helps NYS and NYC to conduct contact tracing in a timely manner and prevent the further spread of COVID-19.

We will also ask you to sign a separate consent form for Healthix.

What is Healthix?

Healthix is a non-profit, health information exchange funded by the NYS Department of Health. Healthix provides patient information to thousands of physicians and providers in the Greater New York area.

Why is health information exchange important?

You likely receive medical care from several physicians and providers – each with their own medical record for you. If your providers share this information with one another, they will gain a fuller picture of your health. This health information exchange will improve our understanding of the effectiveness of our recruitment strategies and how often participants are testing for COVID-19.

How do I give consent?

We will ask you sign a Healthix Patient Consent Form. Your consent allows only individuals involved in your care to access your medical information in Healthix.

WILL THE SURVEY BE AUDIOTAPED?

The survey interview read to you by the research assistant may be audio recorded with a digital recorder. Please note that audio taping is optional. You are not required to have your interview recorded in order to participate in the study. The audio digital files help the research team to remember exactly what was said during the survey interviews and to ensure that the survey was done correctly. If you consent to being recorded, your name will not be on the digital audio file. Instead, you will be assigned an identification number to ensure confidentiality. All audio recordings will be private and will be kept in an electronically secure database. The files will be listened to only by the people doing the study and will be destroyed after the information has been written down, no later than ten years from now.

WHAT WILL YOU DO WITH MY DATA?

The information from the surveys will be collected using REDCap, a software program that develops surveys that can be accessed through a URL designated by the researchers. During online survey data collection, all data are stored directly onto a secure Columbia Irvine University Medical Center (CUIMC) server. Participants’ responses are de-identified since we will give each

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participant a unique ID number, which means identifying information like your name will be removed. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and CUIMC firewall. The only textual information present is the participants' ID numbers, IP addresses, and whether participants chose to enter textual data. All records and the results of the research will remain confidential to the extent permitted by law. Once you have agreed to participate in this study, you will only be identified by a code number; your name will not be connected with your information in any way so you cannot be identified. All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview will be part of your records at Alliance for Positive Change and no part of your interview will be shared with any of the Alliance for Positive Change or court staff. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific to each participant.

Your data will also be shared with 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. The 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.

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- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- 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.

I agree to be contacted for future research as stated above.

_____ Yes	_____ No
Initials	Initials

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.
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WHAT ARE THE BENEFITS IN PARTICIPATING IN THIS STUDY?

There are no direct benefits to you from participating in the study. The results of this study may improve COVID-19 outcomes for substance users.

WHAT IS THE COMPENSATION FOR PARTICIPATING IN THIS STUDY?

You will receive \$20 for completing the survey. We will ask you to refer up to three peers to participate in the study. You will receive \$10 for each referral who is found to be eligible and completes the survey. We will use numbered recruitment coupons to track your referrals so we can compensate you. If any of your referrals are interviewed, we will contact you promptly so that you can return to the research office to receive your referral compensation.

WHAT ARE MY RESEARCH STANDARDS AND RIGHTS?

Your participation in this study is voluntary. You do not have to participate and can stop participation in this study at any time for any reason or for no reason at all. You can terminate participation in the study even after the study has started and can also refuse to answer any of the questions you are asked without terminating your participation. If you decide not to participate, or if you later decide to stop participation, you will not lose any benefits to which you are otherwise entitled, including services and care that are normally available to you through Alliance for Positive Change. The study is projected to conclude in December 2023. Results from the study may be available in future publications and conferences. If you are interested in receiving the results from the current study, including individual research results, you may contact us at 646-774-6965.

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Documentation of Consent:

I voluntarily agree to participate in the research study above.

Participant's name
(print): _____

Participant's
signature: _____

I voluntarily agree to have my interview audiotaped.

Participant's name (print): _____

Participant's signature: _____

Person Designated to Obtain Consent:

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions, and in my opinion, is freely consenting to participate in this research.

Print name: _____

Signature: _____

Date: _____

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We are asking you to participate in *Leveraging Social Networks to Increase COVID-19 Testing Uptake: a Comparison of Credible Messenger and Chain Referral Recruitment Approaches*, which is a RADx-UP program to increase COVID-19 testing uptake among people who use opioids and other substances in New York City. The goal of *Leveraging Social Networks* is to encourage people who use opioids and other substances to get tested regularly for COVID-19. We will explore the potential for two peer recruitment strategies, chain referral and credible messenger, to identify which can achieve greater reach and uptake of COVID-19 tests among individuals who use opioids and other drugs. We are asking you to complete a survey and participate in COVID-19 tests. You are being asked to participate in this study because you reside in New York City and use opioids or other substances. There will be 500 participants in the program.

WHAT IS the NIH and RADx-UP?

This study is funded by the NIH as part of the RADx-UP research program. The NIH stands for the National Institutes of Health. 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 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 combine these with data from other people who join RADx-UP. We will study the data from all who join to understand how to help more people at risk for or with COVID-19.

WHAT WILL YOU ASK OF ME?

If you decide to join this study, we will gather data (information) about you directly through a survey. We will also ask you to get a series of COVID-19 tests with us. 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 also ask you information about COVID-19, including information about any symptoms (a change in your health) and test results. We will ask about your medical history and if you have or have not had vaccines and why, information about your health, education, family, home, relationships, and social life, among others. We will also ask you to participate in COVID-19 testing.

WHAT ARE THE ALTERNATIVES TO STUDY PARTICIPATION?

Your participation is voluntary. You do not have to participate in this study in order to get services that are otherwise available to you through Argus Community Inc.. The alternative to participating is simply not to take part; if you do not take part in this study, you will still receive all services as usual through Argus Community Inc. Study participation will not affect anything related to your status at Argus Community Inc, either positively or negatively.

WHAT IS THE STUDY PROCEDURE?

We will conduct the survey as described above when you arrive at the research site. A research assistant will conduct the brief survey with you, which will take about 30-40 minutes, and will record your responses to the questions in a computer.

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After we conduct the survey, you will receive COVID-19 testing. We are using Abbott's rapid antigen test, BinaxNOW. You will be taken to the designated testing area by research staff while wearing a surgical or N95 mask(s), seated, and given a tissue and asked to blow your nose and discard the tissue in the trash. You will then be instructed to sanitize your hands. Research staff or peer workers will explain the testing procedure to you and demonstrate the appropriate technique to collect the specimen. You will self-collect the sample and give the sample to the research staff member or peer worker who will label the sample with your name and date of birth and then immediately process the sample. Test results will be communicated directly to you by the research staff member or peer worker who supervised the collection and processing of the sample. We will ask you to return to the research site to receive COVID-19 tests twice a week for four weeks.

If you test positive for COVID-19, you will be instructed to stop all attempts at peer recruitment. You will be referred to the NYC Test and Trace Corps for contact tracing. Contact tracing involves finding people who tested positive or were exposed to COVID-19 and asking them to safely separate from other people until they can no longer spread the virus. New York State law and the New York City Health Code requires us to send positive test results to the NYC Health Department. The NYC Health Department will securely share your information with the Test & Trace Corps in compliance with privacy laws that allow this type of information to be used to protect public health and stop the spread of disease.

The NYC Test & Trace Corps is committed to protecting the privacy and security of New Yorkers' personal health information as required by federal, state and local law and in keeping with the NYC Health + Hospitals' and the City Health Department's long-time experience in guarding such information. The information that the NYC Test & Trace Corps receives through contact tracing is confidential and protected under the New York City Health Code.

The NYC Test & Trace Corps will not ask about anyone's immigration status. The Corps database will not be linked to any law enforcement databases. Any information the NYC Test & Trace Corps obtains will be stored securely and used by authorized staff for the limited purpose of protecting public health.

A Contact Tracer will call you to:

- Ask how you are feeling.
- Ask if you need resources to help you stay healthy and avoid spreading COVID-19.
- Explain how long you need to stay inside and away from other people.
- Ask questions to figure out how you may have been infected, if you have tested positive.
- Ask for names and contact information of everyone you had close contact with while you could have spread the virus to others, if you have tested positive.
- A Contact Tracer may also visit you in person to check on you. They will show you their identification card to prove they are a Contact Tracer.

As a facility performing point-of-care (POC) SARS-CoV-2 testing, we are required to report all results (positive, negative or indeterminate) via the New York State (NYS) Electronic Clinical Laboratory System (ECLRS) within 24 hours. When reporting COVID-19 results, we must also report patients' race and ethnicity, school, employment, and local address information.

What is ECLRS?

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- ECLRS stands for Electronic Clinical Laboratory Reporting System.
- It is a secure and rapid point of entry for reportable disease information to the NYS Department of Health (DOH).
- Test results (including COVID-19) are automatically distributed to the state, regional and local health departments, such as the NYC Health Department.

Why do we have to report COVID-19 tests in ECLRS?

- NYS Executive Order No. 202.61 requires all facilities that perform POC testing, including urgent care centers, medical offices, hospitals, nursing homes, pharmacies and clinics, to report COVID-19 test results via ECLRS. ‘
- COVID-19 POC test result information helps NYS and NYC to conduct contact tracing in a timely manner and prevent the further spread of COVID-19.

We will also ask you to sign a separate consent form for Healthix.

What is Healthix?

Healthix is a non-profit, health information exchange funded by the NYS Department of Health. Healthix provides patient information to thousands of physicians and providers in the Greater New York area.

Why is health information exchange important?

You likely receive medical care from several physicians and providers – each with their own medical record for you. If your providers share this information with one another, they will gain a fuller picture of your health. This health information exchange will improve our understanding of the effectiveness of our recruitment strategies and how often participants are testing for COVID-19.

How do I give consent?

We will ask you sign a Healthix Patient Consent Form. Your consent allows only individuals involved in your care to access your medical information in Healthix.

WILL THE SURVEY BE AUDIOTAPED?

The survey interview read to you by the research assistant may be audio recorded with a digital recorder. Please note that audio taping is optional. You are not required to have your interview recorded in order to participate in the study. The audio digital files help the research team to remember exactly what was said during the survey interviews and to ensure that the survey was done correctly. If you consent to being recorded, your name will not be on the digital audio file. Instead, you will be assigned an identification number to ensure confidentiality. All audio recordings will be private and will be kept in an electronically secure database. The files will be listened to only by the people doing the study and will be destroyed after the information has been written down, no later than ten years from now.

WHAT WILL YOU DO WITH MY DATA?

The information from the surveys will be collected using REDCap, a software program that develops surveys that can be accessed through a URL designated by the researchers. During online survey data collection, all data are stored directly onto a secure Columbia Irvine University Medical Center (CUIMC) server. Participants’ responses are de-identified since we will give each

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participant a unique ID number, which means identifying information like your name will be removed. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and CUIMC firewall. The only textual information present is the participants' ID numbers, IP addresses, and whether participants chose to enter textual data. All records and the results of the research will remain confidential to the extent permitted by law. Once you have agreed to participate in this study, you will only be identified by a code number; your name will not be connected with your information in any way so you cannot be identified. All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview will be part of your records at Argus Community Inc. and no part of your interview will be shared with any of the Argus Community Inc. or court staff. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific to each participant.

Your data will also be shared with 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. The 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). These data will be kept at the DCRI. The DCRI will not share these data with the NIH.

- Your information will be linked with information from other sources, such as the Centers for Medicare and Medicaid Services and your electronic health record, among others.
- 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.

I agree to be contacted for future research as stated above.

_____ Yes	_____ No
Initials	Initials

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.

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- 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.

HOW WILL YOU PROTECT MY PRIVACY?

Your privacy is very important to us. 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:

We have received a Certificate of Confidentiality, issued by the National Institute of Health, for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child or threatened violence to self or others. Such information will be reported to the appropriate authorities. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. 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.

In addition, the researchers will keep your responses private and confidential **except** in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to the Administration for Children's Services (ACS) as necessary. If we learn of this information, we will do whatever is necessary to protect anyone involved, including you. Part of what we will do is let the staff at Argus Community Inc. know if you tell us you want to hurt yourself or someone else. Research staff may not be able to discuss this with you first.

We will ask your permission for our Research Staff to communicate with you via phone, text, direct messages through social media, or email regarding appointments for interviews. Receiving messages from our Research Staff is entirely voluntary and will have no impact on your participation in the study. We note that text messages often appear as a banner on phones without needing to be unlocked to view. The content of the text messages will not infringe on your privacy, we will not reveal study participation in our text messages to you. We also advise participants to remove banner alerts for text messages that include part of the message in the banner and replace with banner alerts that just include the number of the sender.

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WHAT ARE THE RISKS IN PARTICIPATING IN THIS STUDY?

There are no physical risks involved with participation in this study for you. Some of the interview questions ask about your experiences with drugs and alcohol. Some interview questions will also ask about experiences with COVID-19 illness, including those of your friends and family. These questions may make you feel embarrassed, worried, or upset. If this happens, the interviewer will spend time talking with you until you feel better. You may also experience distress during the COVID-19 testing and/or if you receive a reactive HIV or positive STI test result. Again, if this happens, research staff will spend time talking with you until you feel better, will explain the findings of the test and work with you to ensure you are linked to care.

WHAT ARE THE BENEFITS IN PARTICIPATING IN THIS STUDY?

There are no direct benefits to you from participating in the study. The results of this study may improve COVID-19 outcomes for substance users.

WHAT IS THE COMPENSATION FOR PARTICIPATING IN THIS STUDY?

You will receive \$20 for completing the survey. We will ask you to refer up to three peers to participate in the study. You will receive \$10 for each referral who is found to be eligible and completes the survey. We will use numbered recruitment coupons to track your referrals so we can compensate you. If any of your referrals are interviewed, we will contact you promptly so that you can return to the research office to receive your referral compensation.

WHAT ARE MY RESEARCH STANDARDS AND RIGHTS?

Your participation in this study is voluntary. You do not have to participate and can stop participation in this study at any time for any reason or for no reason at all. You can terminate participation in the study even after the study has started and can also refuse to answer any of the questions you are asked without terminating your participation. If you decide not to participate, or if you later decide to stop participation, you will not lose any benefits to which you are otherwise entitled, including services and care that are normally available to you through Argus Community Inc.. The study is projected to conclude in December 2023. Results from the study may be available in future publications and conferences. If you are interested in receiving the results from the current study, including individual research results, you may contact us at 646-774-6965.

WHAT HAPPENS IF I AM INJURED?

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you.

WHAT DO I DO IF I HAVE QUESTIONS?

The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants

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in research studies). You may call the IRB Main office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.

Documentation of Consent:

I voluntarily agree to participate in the research study above.

Participant's name
(print): _____

Participant's
signature: _____

I voluntarily agree to have my interview audiotaped.

Participant's name (print): _____

Participant's signature: _____

Person Designated to Obtain Consent:

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions, and in my opinion, is freely consenting to participate in this research.

Print name: _____

Signature: _____

Date: _____

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Comparison of Credible Messenger and Chain Referral Recruitment
Approaches (Phase 2)**

(Katherine Elkington, PhD; 646-774-6965)

KEY ELEMENTS:

- This project is research and participation is voluntary.
- Summary of the research:
 - The purpose of this project is to increase COVID-19 testing uptake among people who use opioids and other substances in New York City.
 - The duration of this study is two years.
 - The list of procedures
 - We are asking Alliance for Positive Change staff to complete a survey and participate in two focus groups
- Reasonable, foreseeable risks or discomforts:
 - There are no physical risks to participation in this study. You may reveal sensitive information in this study and may possibly experience feelings of discomfort when answering questions about the success or failures of working with people who use opioids and other substances. You may feel discussion of such personal information might have implications for your job duties and/or feel your job might be in jeopardy due to the information revealed or shared. You are free to not answer any of our questions or discontinue the survey at any point.
- Reasonable, expected benefits: There are no direct benefits to you in participating in the study. The primary benefits from this work are for the progress of science. The results of this study may improve the COVID-19 testing outcomes for people who use substances, including opioid users.
- Alternative procedures: Your participation in this study is voluntary. You do not have to take part in this study.

PURPOSE OF THE STUDY: We are asking you to participate in *Leveraging Social Networks to Increase COVID-19 Testing Uptake: a Comparison of Credible Messenger and Chain Referral Recruitment Approaches*, which is a RADx-UP program to increase COVID-19 testing uptake among people who use opioids and other substances in New York City. The goal of *Leveraging Social Networks* is to encourage people who use opioids and other substances to get tested regularly for COVID-19. We are asking you to complete a survey and participate in two focus groups. You are being asked to participate in this study because you are staff member at Alliance for Positive Change. There will be 500 study participants and approximately 20 staff participants in this study.

PARTICIPATION IS VOLUNTARY: Your participation in this study is voluntary. You do not have to take part in this study. Your employment status at Alliance for Positive Change will not be influenced in any way by your decision to participate or not.

ALTERNATIVE TO STUDY PARTICIPATION: The alternative to participating is simply not to participate. If you do not take part in this study, your employment status at Alliance for Positive Change will not be influenced in any way.

STUDY PROCEDURES: If you agree to participate, you will be asked to complete **one anonymous** survey. You will be emailed with a link to the online survey. The survey will

Version Date: 05/18/2021

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take approximately 15 minutes to complete. The survey covers topics about your impressions of the RADx-UP program, COVID-19, and your work at Alliance for Positive Change.

RISKS: There are no physical risks to participation in this study. You may reveal sensitive information in this study and may possibly experience feelings of discomfort when answering questions about the success or failures of working with people who use opioids and other substances. You may feel discussion of such personal information might have implications for your job duties and/or feel your job might be in jeopardy due to the information revealed or shared. Of course, you are free to not answer any of our questions or discontinue the survey at any point.

BENEFITS: There are no direct benefits to you in participating in the study. The primary benefits from this work are for the progress of science. The results of this study may improve the COVID-19 testing outcomes for people who use substances, including opioid users.

COMPENSATION: You will not receive any compensation for completing the surveys.

CONFIDENTIALITY - when we can and cannot keep this private: All records and the results of the research will remain private and confidential. None of the information you provide will be shared with your supervisors or any other staff at Alliance for Positive Change. We will do everything we can to protect your privacy. The researchers will keep your responses private and confidential **except** in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to Child Protective Services as necessary. If we learn of this information, we will do whatever is necessary to protect anyone involved, including you. Part of what we will do is let the staff at Alliance for Positive Change know if you tell us you want to hurt yourself or someone else. Research staff may not be able to discuss this with you first.

The information from the surveys will be collected using REDCap, a software program that develops surveys that can be accessed through a URL designated by the researchers. During online survey data collection, all data are stored directly onto a secure Columbia Irvine University Medical Center (CUIMC) server. Participants' responses are de-identified since we will give each participant a unique ID number, which means identifying information like your name will be removed. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and CUIMC firewall. The only textual information present is the participants' ID numbers, IP addresses, and whether participants chose to enter textual data. All records and the results of the research will remain confidential to the extent permitted by law. Once you have agreed to participate in this study, you will only be identified by a code

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number; your name will not be connected with your information in any way so you cannot be identified. All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview will be part of your records at Alliance for Positive Change and no part of your interview will be shared with any of the Alliance for Positive Change or court staff. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific to each participant.

Information from this research may be published but publications will not include the names of any study participants or any information that could identify you. Data stored in computers will only be available with a password.

We have received a Certificate of Confidentiality, issued by the National Institute of Health, for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. 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.

RESEARCH STANDARDS AND RIGHTS OF PARTICIPANTS: Your decision to take part in this is voluntary. Your supervisors will not be informed about your choice to participate or not in this study. Your choice will have no impact on your employment at Alliance for Positive Change. If you chose to participate, you can stop participation at any time **for any reason or for no reason at all**. You can also refuse to answer any of the questions you are asked **without terminating your participation in this study**. Doing either will in no way affect your employment at Alliance for Positive Change. Every effort will be made to keep all your research records confidential.

QUESTIONS AND COMPLAINTS: The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.

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- Reasonable, foreseeable risks or discomforts:
 - There are no physical risks to participation in this study. You may reveal sensitive information in this study and may possibly experience feelings of discomfort when answering questions about the success or failures of working with people who use opioids and other substances. You may feel discussion of such personal information might have implications for your job duties and/or feel your job might be in jeopardy due to the information revealed or shared. You are free to not answer any of our questions or discontinue the survey at any point.
- Reasonable, expected benefits: There are no direct benefits to you in participating in the study. The primary benefits from this work are for the progress of science. The results of this study may improve the COVID-19 testing outcomes for people who use substances, including opioid users.
- Alternative procedures: Your participation in this study is voluntary. You do not have to take part in this study.

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ALTERNATIVE TO STUDY PARTICIPATION: The alternative to participating is simply not to participate. If you do not take part in this study, your employment status at Argus Community Inc. will not be influenced in any way.

STUDY PROCEDURES: If you agree to participate, you will be asked to complete **one anonymous** survey. You will be emailed with a link to the online survey. The survey will Version date 4.4.2022

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(Katherine Elkington, PhD; 646-774-6965)

take approximately 15 minutes to complete. The survey covers topics about your impressions of the RADx-UP program, COVID-19, and your work at Argus Community Inc.

RISKS: There are no physical risks to participation in this study. You may reveal sensitive information in this study and may possibly experience feelings of discomfort when answering questions about the success or failures of working with people who use opioids and other substances. You may feel discussion of such personal information might have implications for your job duties and/or feel your job might be in jeopardy due to the information revealed or shared. Of course, you are free to not answer any of our questions or discontinue the survey at any point.

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COMPENSATION: You will not receive any compensation for completing the surveys.

CONFIDENTIALITY - when we can and cannot keep this private: All records and the results of the research will remain private and confidential. None of the information you provide will be shared with your supervisors or any other staff at Argus Community Inc. We will do everything we can to protect your privacy. The researchers will keep your responses private and confidential **except** in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to Child Protective Services as necessary. If we learn of this information, we will do whatever is necessary to protect anyone involved, including you. Part of what we will do is let the staff at Argus Community Inc. know if you tell us you want to hurt yourself or someone else. Research staff may not be able to discuss this with you first.

The information from the surveys will be collected using REDCap, a software program that develops surveys that can be accessed through a URL designated by the researchers. During online survey data collection, all data are stored directly onto a secure Columbia Irvine University Medical Center (CUIMC) server. Participants' responses are de-identified since we will give each participant a unique ID number, which means identifying information like your name will be removed. Responses are encrypted under a 128-bit SSL encryption (same security used when you enter credit card numbers in online purchases) and CUIMC firewall. The only textual information present is the participants' ID numbers, IP addresses, and whether participants chose to enter textual data. All records and the results of the research will remain confidential to the extent permitted by law. Once you have agreed to participate in this study, you will only be identified by a code number; your name will not be connected with your information in any way so you cannot

Argus Community, Inc. Staff Consent Form.
Leveraging Social Networks to Increase COVID-19 Testing Uptake: A
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Approaches (Phase 2)

(Katherine Elkington, PhD; 646-774-6965)

be identified. All study information including your name and other personal identifying information will be stored in an electronically secure database; all other study information will be coded and kept in locked files at the New York State Psychiatric Institute. Only research staff and institutional personnel, as part of routine audits, will have access to the files. No part of your interview will be part of your records at Argus Community Inc. and no part of your interview will be shared with any of the Argus Community Inc. or court staff. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific to each participant.

Information from this research may be published but publications will not include the names of any study participants or any information that could identify you. Data stored in computers will only be available with a password.

We have received a Certificate of Confidentiality, issued by the National Institute of Health, for this study. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. 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.

RESEARCH STANDARDS AND RIGHTS OF PARTICIPANTS: Your decision to take part in this is voluntary. Your supervisors will not be informed about your choice to participate or not in this study. Your choice will have no impact on your employment at Argus Community Inc. If you chose to participate, you can stop participation at any time **for any reason or for no reason at all**. You can also refuse to answer any of the questions you are asked **without terminating your participation in this study**. Doing either will in no way affect your employment at Argus Community Inc. Every effort will be made to keep all your research records confidential.

QUESTIONS AND COMPLAINTS: The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.

LEVEL 2 RESEARCH CONSENT

In this Consent Form, you can choose whether to allow researchers working with NYSPI to obtain access to your medical records for research purposes through the health information exchange organization called **Healthix**. This can help researchers to collect medical records you have in different places where you get health care and make them available electronically to health care providers and researchers.

If you give consent, your medical records from different places where you get health care can be accessed using a statewide computer network. This Consent Form should be read together with the NYSPI consent to participate you signed when you agreed to enroll in the research study.

You may use this Consent Form to decide whether or not to allow researchers to see and obtain access to your electronic health records in this way. **Your choice will not affect your ability to get health services or health insurance coverage.**

If you check the “**I GIVE CONSENT**” box below, you are saying “Yes NYSPI’s researchers may see and get access to all of my medical records through **Healthix** for the activities described in section 1 of this Consent Form.”

Healthix is a not-for-profit organization. It shares information about people’s health electronically and securely to improve the quality of health care services. This kind of sharing is called ehealth or health information technology (health IT). To learn more about ehealth in New York State, read the brochure, “Better Information Means Better Care.” You can ask NYSPI’s researchers for it, or go to the website www.healthix.org.

Please carefully read the information on the back of this form before making your decision.

☐ **I GIVE CONSENT** for NYSPI’s researchers to access my electronic health information through **Healthix** for the activities described on this Consent Form.

Print Name of Patient

Patient’s Date of Birth

Signature of Patient or Patient’s Legal Representative

Date

Print Name of Legal Representative (if applicable)

Relationship of Legal Representative to Patient (if applicable)

IRB Protocol Number: _____

IRB Protocol Name: _____

Details about patient information in Healthix and the consent process:

How Your Information Will Be Used. Your electronic health information will be used by NYSPI researchers to conduct the following research study: **Leveraging Social Networks**. Additional information about this research is provided in the **NYSPI Consent Form**.

What Types of Information about You Are Included. If you give consent, NYSPI researchers may access types of electronic health information, listed below, through Healthix for research purposes. NYSPI researchers will only be permitted to use health information that is necessary for the research studies you have agreed to participate in. This information may relate to sensitive health conditions, including but not limited to:

Alcohol or drug use problems	Diagnostic Information	Living Situation
Substance use history summaries	Allergies	Social Supports
HIV/AIDS	Genetic (inherited) diseases or tests	Claims Encounter Data
Mental health conditions	Clinical notes	Laboratory Tests
Sexually transmitted diseases	Discharge summary	Radiology diagnostic tests
Medication and Dosages	Employment information	
Trauma history summary	Birth control and abortion (family planning)	

NYSPI researchers will take reasonable steps to minimize any incidental access to your health information that is not required for the research studies.

Where Health Information About You Comes From. Information about you comes from places that have provided you with medical care or health insurance ("Information Sources"). These may include hospitals, physicians, pharmacies, clinical laboratories, health insurers, the Medicaid program, and other ehealth organizations that exchange health information electronically. You can obtain an updated list of Information Sources at any time by checking Healthix's website at www.healthix.org or by calling 1(877) 695-4749.

Who May Access Information About You, If You Give Consent. Only research staff employed by NYSPI or outside researchers who are involved in the activities for which you have agreed to provide your information may access your information.

Penalties for Improper Access to or Use of Your Information. There are penalties for inappropriate access to or use of your electronic health information. If at any time you suspect someone who should not have seen or gotten access to information about you has done so, call Katherine Elkington at 646-774-6965; or contact Healthix at compliance@healthix.org or by calling 1-877-695-4749; or call the NYS Department of Health 877-690-2211.

Re-disclosure of Information. Any electronic health information about you may be re-disclosed by NYSPI researchers to others only to the extent permitted by state and federal laws and regulations. This is also true for health information about you that exists in a paper form. Some state and federal laws provide special protections for some kinds of sensitive health information, including HIV/AIDS and drug and alcohol treatment. Their special requirements must be followed whenever people receive these kinds of sensitive health information. Healthix and persons who access this information through Healthix must comply with these requirements. You will not be identified in the published results of any research studies conducted with your information.

Effective Period. This Consent Form will remain in effect until or the day you withdraw your consent.

Withdrawing Your Consent. You can withdraw your consent at any time by signing a Withdrawal of Consent Form and giving it to any of the researchers overseeing this study or Healthix, as applicable. You can get this form from any of NYSPI researchers or my contacting compliance@healthix.org or by calling Healthix at 1(877) 695-4749. Note: If NYSPI's researchers access your health information through Healthix while your consent is in effect, they may copy or include your information in their own research databases. Even if you later decide to withdraw your consent, NYSPI's researchers are not required to return your health information or remove it from these databases to the extent maintaining the information is necessary to complete the research study.

Healthix may be reimbursed for the services it provides in relation to granting NYSPI access to your information based on the consent.

Copy of Form. You are entitled to get a copy of this Consent Form after you sign it.

**Informed Consent for Participation in a Study
Leveraging Social Networks to Increase COVID-19 Testing Uptake: A Comparison of
Credible Messenger and Chain Referral Recruitment Approaches (Phase 2)**
(Katherine Elkington PhD, 646-774-6965)

CONSENT SUMMARY PAGE

Overview

Below is a summary of the study that you are asked to participate in. This outline is meant to be a guide for you to use while considering the study and reading the consent form. It is not meant to replace the consent form, which you will have to sign if you decide to participate in the study. The consent form contains detailed information about the study and about the risks which you will need to consider before making your decision. Read the consent form carefully and discuss it with others before deciding to take part. And remember that, even if you agree to participate, you can change your mind at any time

Voluntary

As with all research, this is a voluntary study, and you do not have to participate if you do not want to. Also, you may stop participating at any time.

Procedures

- Participate in 1 in-depth interview for about 1 hour about your experience participating in the RADx-UP program

Risks and Inconveniences

This study includes some risks and discomforts (please refer to the consent form for further details and explanations of these risks). These include loss of confidentiality related to your responses and possible discomfort because of the types of questions we ask.

Benefits

This research study is not meant to benefit you directly.

Questions

You may contact the study principal investigator, Dr. Kate Elkington at 646-774-6965 with any questions.

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Purpose of the study: We are asking you to participate in *Leveraging Social Networks to Increase COVID-19 Testing Uptake: A Comparison of Credible Messenger and Chain Referral Recruitment Approaches*, which is a RADx-UP program to increase COVID-19 testing uptake among people who use opioids and other substances in New York City. The goal of *Leveraging Social Networks* is to encourage people who use opioids and other substances to get tested regularly for COVID-19. We will explore the potential for two peer recruitment strategies, chain referral and credible messenger, to identify which can achieve greater reach and uptake of COVID-19 tests among individuals who use opioids and other drugs. We are asking you to complete an in-depth interview about your experience participating in the RADx-UP program. You are being asked to participate in this study because you reside in New York City and use opioids or other substances. There will be 500 participants in the program.

Alternatives to Study Participation: Your participation is voluntary. You do not have to participate in this study in order to get services that are otherwise available to you through Alliance for Positive Change or Argus Community Inc. The alternative to participating is simply not to take part; if you do not take part in this study, you will still receive all services as usual through Alliance for Positive Change or Argus Community Inc. and your terms at these organizations will not change. Study participation will not affect anything related to your status at Alliance for Positive Change or Argus Community Inc., either positively or negatively.

Study Procedures:

If you agree to participate in the study, we will be asking to complete an in-depth interview that will also take approximately 1 hour. If you are asked, but are not available for the interview today, we will contact you by phone, text, direct message through social media, or email to remind you about the interview appointment. If we are unable to reach you through any of these methods and if you have given us permission in the consent to contact form that you completed, we may also visit you at the address you provided to us so that we can arrange a time to do the interview with you. The in-depth interview will ask you more specific questions about your experiences, thoughts, and feelings participating in the RADx-UP study. We will ask you about 1) the effectiveness of credible messenger and chain referral strategies 2) challenges to referring peers during chain referral 3) experience participating in COVID-19 testing and 4) impact of COVID-19 repeat testing messaging.

You do not have to answer any questions that you do not want to answer. You will receive \$20 for the completion of the in-depth interview.

Audio taping: In-depth interviews will be audio recorded with a digital recorder. You must agree to be audio-recorded if you complete an in-depth interview.

The audio digital files help the research team to remember exactly what was said during the survey interviews and to ensure that the survey was done correctly. If you consent to being recorded, your name will not be on the digital audio file. Instead, you will be assigned an identification number to ensure confidentiality. All audio recordings will be private and will be kept in an electronically secure database. The interview recordings will be transcribed, the files will be listened to only by the people doing the study and will be destroyed after the information has been written down, no later than ten years from now.

Risks: The main risk to participation in this study is that you may experience a loss of confidentiality related to your interview responses or use of texts; we have several procedures in place to reduce this risk (see Confidentiality section below). The interview questions ask about your experiences

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with the RADx-UP program. They may make you feel embarrassed, worried, or upset. If this happens, the interviewer will spend time talking with you until you feel better.

Benefits: There are no direct benefits to you from participating in the study. The results of this study may improve substance use outcomes for justice-involved young adults and adults.

Compensation:

You will receive \$20 cash for completing the in-depth interview.

Confidentiality – when we can and cannot keep this private: All records and the results of the research will remain private and confidential. We will do everything we can to protect your privacy. The researchers will keep your responses private and confidential *except* in the following circumstances: 1) if we learn of threatened violence to self (e.g. thoughts of suicide) or others (e.g. thoughts of homicide) that you discuss, or 2) suspected or known physical abuse, sexual abuse or neglect of minors. If we learn of this information, we will take whatever measures are needed to protect individuals involved, and will voluntarily comply with State reporting laws on child abuse, harm to self or others, including reporting to the Administration for Children's Services (ACS) as necessary. If we learn of this information, we will do whatever is necessary to protect anyone involved, including you. Part of what we will do is let the staff at BJI know if you tell us you want to hurt yourself or someone else. Research staff may not be able to discuss this with you first.

Participants' interviews will not be tied to any names since we will give each participant a unique ID number to replace the participant's name. This survey will not be part of your record at Alliance for Positive Change or Argus Community Inc. and will not be shared with any of the agency staff. All records and the results of the research will remain confidential to the extent permitted by law. All study information will be kept in an electronically secure password protected database or in locked files at the New York State Psychiatric Institute. Your name and other personal identifying information will be stored in a different electronic password-protected database, separate from your study data; Only research staff and institutional personnel, as part of routine audits, will have access to the files. Your name will not go on any forms that will be completed as part of the study. You will be recognized by a number (code) that is specific to each participant. Information from this research may be published but publications will not include the names of any study participants or any information that could identify you.

We have a Certificate of Confidentiality, issued by the National Institute of Health. This Certificate prevents the researchers from being forced to release any identifiable research data (including under court order or subpoena) without your written consent. This Certificate does not prevent the researchers from reporting suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. 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.

We will ask your permission for our Research Staff to communicate with you via phone, text, direct messages through social media, or email regarding appointments for interviews. Receiving messages from our Research Staff is entirely voluntary and will have no impact on your participation in the study.

Research Standards and Rights: Your participation in this study is voluntary. You do not have to participate and can stop participation in this study at any time for any reason or for no reason at all.

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You can terminate participation in the study even after the study has started and can also refuse to answer any of the questions you are asked without terminating your participation. If you decide not to participate, or if you later decide to stop participation, you will not lose any benefits to which you are otherwise entitled, including services and care that are normally available to you through Alliance for Positive Change or Argus Community Inc. It will have absolutely no effect on your terms at either agency.

We would like to contact you in the future to follow up on this study and to see if you would be interested in participating in another research study. Please indicate below if you are willing to be contacted by the study team to follow up and /or discuss enrollment in new research.

____ (Initials) Yes, I agree to be contacted by the study team to follow up and /or discuss enrollment in new research.

____ (Initials) No, I do not want to be contacted by the study team to follow up and /or discuss enrollment in new research.

Your private information will not be used for future research studies or distributed to another investigator not associated with this project for future research studies, with or without identifiers.

In Case of Injury: Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research related injuries. If you believe that you have sustained an injury as a result of participating in a research study, you may contact the Principal Investigator at 646-774-6965 so that you can review the matter and identify the medical resources that may be available to you.

Questions: The research staff will answer, to the best of their knowledge, any questions concerning the procedures described above. If you have any questions about this study, you may contact Dr. Katherine Elkington at 646-774-6965. If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main office at (646) 774-7155 during regular office hours. You will be given a copy of this consent form to keep.

Documentation of Consent:

I voluntarily agree to participate in the research study above.

Participant's name (print): _____

Participant's signature: _____

I voluntarily agree to have my interview audiotaped.

Participant's name (print): _____

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Participant's signature: _____

Person Designated to Obtain Consent:

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions, and in my opinion, is freely consenting to participate in this research.

Print name: _____

Signature: _____

Date: _____