ALBERT EINSTEIN COLLEGE OF MEDICINE
MONTEFIORE MEDICAL CENTER

DOCUMENTATION OF INFORMED CONSENT AND HIPAA AUTHORIZATION

Introduction

You are being asked to participate in a research study called "Buprenorphine treatment at syringe exchanges to reduce opioid misuse and HIV risk". Your participation is voluntary -- it is up to you whether you would like to participate. It is fine to say "no" now or at any time after you have started the study. If you say "no," your decision will not affect any of your rights or benefits or your access to care.

The researcher in charge of this project is called the "Principal Investigator." His name is Aaron Fox, MD. You can reach Dr. Fox at:
Office Address: 3300 Kossuth Ave
Bronx, NY 10467
Telephone #: 718-920-7173
For questions about the research study, or if you believe you have an injury, contact the Principal Investigator or the IRB.

The Institutional Review Board (IRB) of the Albert Einstein College of Medicine and Montefiore Medical Center has approved this research study. The IRB # is in the stamp in the upper right hand corner. If you have questions regarding your rights as a research subject you may contact the IRB office at 718-430-2253, by e-mail at irb@einsteinmed.edu, or by mail:

Einstein IRB
Albert Einstein College of Medicine
1300 Morris Park Ave., Belfer Bldg #1002
Bronx, New York 10461

Support for this research study is provided by
National Institute on Drug Abuse

Why is this study being done?

The goal of this study is to test whether starting buprenorphine treatment at syringe exchange programs is safe and effective. Nearly all participants of syringe exchange programs meet clinical criteria for opioid use disorder, but very few engage in buprenorphine treatment for opioid use disorder. We seek to test a new strategy of onsite treatment at the syringe exchange program in order to increase engagement in buprenorphine treatment.

Buprenrophine-Naloxone is approved by the U.S. Food and Drug Administration (FDA) to treat opioid use disorder.

Why am I being asked to participate?

You are being asked to participate in this study because you are a participant of one of the partnering syringe exchange programs. You may have seen one of our study flyers or a syringe exchange program staff member may have suggested you as a participant. We will enroll 250 participants of two different syringe exchange programs in New York City. We are looking for subjects who are: 18 years or older, diagnosed opioid use disorder, interested in buprenorphine treatment, and are willing to accept referral to a community health center.

However, you cannot be in this study if you have received similar opioid agonist treatment in the past 30 days, or have severe alcohol or benzodiazepine use disorder, unstable mental illness, or are pregnant.

What will happen if I participate in the study?

We will be studying two strategies of buprenorphine treatment – onsite treatment or referral to a community health center. You will be assigned to one strategy based on random chance (like a flip of a coin). If you are assigned to the onsite treatment group, over 2 weeks, you will see a buprenorphine provider twice at the syringe exchange program. Each treatment visit will take 45-60 minutes. At the first treatment visit, the provider will assess whether you meet the criteria for buprenorphine treatment and write a prescription for a one week supply of buprenorphine if appropriate. You will receive the medication from a community pharmacy. You will see the provider again after one week and receive a second prescription for another one week supply of buprenorphine. After these two treatment visits, the study team will assist you in transferring your care to a community health center to continue buprenorphine treatment. If you are assigned to the referral group, the study team will assist you in making an appointment at the community health center to start buprenorphine treatment. Regardless of assignment, all participants will also complete 8 study visits over 6 months. Study visits will take 30-45 minutes. At these visits, a study coordinator will collect a urine sample for drug testing. At each study visit, you will also complete a questionnaire, which will include questions about your illicit drug use, mental health, and any criminal background you may have. We will also collect your medical records to determine whether or not you have continued buprenorphine treatment at the community health center.

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

How many people will take part in the research study?

You will be one of about 250 people who will be participating in this study. The study will be conducted at 3 locations outside of Montefiore Medical Center/Albert Einstein College of Medicine/North Bronx Health Network.

Specimen Banking (Future Use and Storage)

No Specimens or Data is Stored
We will destroy the specimens and information about you when the study is complete. Information about you will be kept for 25 years as per institutional policy, but will not be used for future studies.

INITIAL YOUR CHOICE BELOW

_____ I consent to be contacted in the future to learn about:

_____ New research protocols that I may wish to join.

_____ General information about research findings.

_____ I do not want to be contacted at all.

Will I be paid for being in this research study?

You will receive a maximum of $170 in Clincard payments (like a Visa gift card) for 8 study visits. You will also receive compensation for a two-way transit pass at each study visit. If you start buprenorphine treatment, you will also be provided with $20 Clincard payment for returning electronic monitors. If you choose to withdraw from the study before all visits are completed, you will be paid only for the visits you completed. Payment for study visits at baseline, and 2, 4, 8, 12, and 24 weeks after enrollment will be $25 in Clincard payments. Payment for study visits at 1 and 6 weeks after enrollment will be $10 Clincard payments. Payments may not be available for up to 48 hours.

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

Will it cost me anything to participate in this study?

If you take part in this study, you or your insurance will pay for the buprenorphine medication that is prescribed by the provider. If you continue buprenorphine treatment at the community health center, you or your insurance will also pay for the medical visits provided there.

What will happen if I am injured because I took part in this study?

If you are injured as a result of this research, only immediate, essential, short-term medical treatment as determined by the participating hospital,will be available for the injury without charge to you personally.

- No monetary compensation will be offered.
- You are not waiving any of your legal rights by signing this informed consent document.
- If additional treatment is required as a result of a physical injury related to the research, necessary medical treatment will be provided to you and billed to your insurance company or to you as part of your medical expenses.

Immediately report any discomforts, problems or injuries you experience during the course of your participation in the study to **Dr. Aaron Fox 718-920-7173**.

What else do I have to do?

- You must tell the research study doctor about any past and present diseases or allergies you are aware of and about all medications you are taking including “over-the-counter” remedies and nutritional supplements or herbs.
- If you do not feel well at any time, call your doctor or the research study doctor immediately.
- If you think you have become pregnant, contact your research study doctor immediately.
- If any other doctor recommends that you take any medicine, please inform him/her that you are taking part in a research study. You should give the other doctor the research study doctor’s name and phone number.
- You may carry out all your normal daily activities.

Confidentiality

We will keep your information confidential. Your research records will be kept confidential and your name will not be used in any written or verbal reports. Your information will be given a code number and separated from your name or any other information that could identify you. The form that links your name to the code number will be kept in a secure manner and only the investigator and study staff will have access to the file. All information will be kept in a secure manner and computer records will be password protected. Your study information will be kept as long as they are useful for this research.

Information collected during study visits (for example, questionnaires and urine drug tests) will not be entered into your Montefiore electronic medical record. However, if you start buprenorphine treatment, the medical information that you tell the provider will be entered into your Montefiore electronic medical record and will be available to clinicians and other staff at Montefiore who provide care to you.

The only people who can see your research records are:

- the research team and staff who work with them
- the organization that funded the research
- organizations and institutions involved in this research: **OnPoint NYC, BOOM!Health**
- groups that review research (the Einstein IRB, and the Office for Human Research Protections

These people who receive your health information, may not be required by privacy laws to protect it and may share your information with others without your permission, if permitted by laws governing them. All of these groups have been asked to keep your information confidential.

Are there any times we will not keep my data confidential?
If you give us information that suggests that your child or any other child is being abused, we are required by law to report that information to the Administration for Children's Services (ACS). Reporting this information may put you, your family, or others who are involved at risk of questioning and legal action by the authorities.

If you give us information that you may hurt yourself, we will break confidentiality to make a referral to an appropriate clinical provider (e.g., calling 911).

If you give us information that you may hurt someone else, we will report this information to the authorities.

Certificate of Confidentiality
As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study was requested or subpoenaed by government agencies or the courts, we will use the Certificate to attempt to legally refuse to provide it. This is rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations that the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for a review or evaluation of our research. The Certificate does not prevent you or a member of your

family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Are there any risks to me?

The risks related to participating in this research study are the same as what would be expected from routine clinical care when someone starts buprenorphine treatment.

The main side effects of buprenorphine are constipation, insomnia, irritability, and sedation. There is also the risk of "induced withdrawal." Opioids remain in your system for 24-48 hours, and if you take the buprenorphine when you have other opioids in your system, it can cause opioid withdrawal. This could include diarrhea, nausea, vomiting, musculoskeletal pain, sweating, and anxiety. The study provider will provide careful instructions on how to take the medication properly, but you will start taking your medication at home.

Buprenorphine is an opioid and overdoses are possible if you take buprenorphine with other sedating substances like alcohol or benzodiazepines.

Taking opioid pain medication (as used in this study) along with benzodiazepines (Xanax, Valium, Ativan) and/or alcohol can cause serious side effects including respiratory depression (slow and ineffective breathing which could be life threatening and cause death). These drugs should only be taken together under a physician's supervision. You should avoid drinking alcohol while taking buprenorphine. You agree to let the study team know all medications that you currently take or that are prescribed for you during the study.

The medications that you may receive during this study may cause drowsiness or sedation. You should not drive after receiving these medications.

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

Questionnaire
You may feel uncomfortable answering questions about drug use and sexual behaviors. You can choose not to answer questions that make you feel uncomfortable.

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

Are there possible benefits to me?

If you initiate buprenorphine treatment, participating in treatment can reduce opioid use, HIV risk, and opioid overdose. If you do not initiate buprenorphine treatment, the study will still generate important information about how to design programs for syringe exchange participants.

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

You can refuse to participate in the study. If you decide not to participate, the staff at the syringe exchange program will still give you all of the standard care and services that are appropriate for you.

Your other choices are to start buprenorphine treatment or methadone maintenance treatment at a program of your choice.

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

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

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

Can the study end my participation early?

Your participation will end if the investigator or study sponsor stops the study earlier than expected.

CONSENT TO PARTICIPATE

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

Printed name of participant	Signature of participant	Date	Time

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