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BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK
[INSERT INSTITUTION NAME]

PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: Emergency Department Outcomes for Patients with Opioid Use Disorder
Protocol #: CTN-0079-A1
Sponsor: National Institute on Drug Abuse (NIDA)
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KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a participant in a research study because you reported opioid use and are a patient in the Emergency Department.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	The purpose of this study is to learn how treatment for opioid use is provided in the emergency department.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	Your participation in this study may consist of two visits. The first visit will occur within 7 days after your visit to the emergency department; the second visit approximately 30 days later. Your participation in the second visit will be determined after your first visit with study staff.
Procedures	The main procedures in the study include: • Answer questions about education, employment, health care, insurance, behaviors (such as tobacco, alcohol and drug use), motivation for study participation, treatment choices, overdoses, health services, and about how you feel in general. • Sign a separate release of information form that allows the research team to contact treatment providers and access health information for up to 2 years from date of signing the Release of Information form. • Perform a drug screen as part of the research activities.
Risks	There are not expected to be any physical risks to you as part of this study. Loss of confidentiality is a possible risk from participation and will be discussed below.

Benefit	While there is no direct benefit to you from your participation in this study, we think that what we learn will be of real benefit to others in the future.
Alternative to Study Participation	Participation in this study is completely voluntary. The alternative to participating is to not participate.
Costs	You and/or your insurance will be responsible for the costs of the regular treatment received in the Emergency Department.
Confidentiality	There are protections put in place by the study protocol and study site to help guard the privacy and confidentiality of your personal health information and study information.

This overview does not include all of the information you need to know before deciding whether or not to take part in this research study. Additional detail is given in the full consent document, which can be found below. Be sure to review the rest of this consent form before deciding about participation.

INFORMED CONSENT FORM

INTRODUCTION

You are being asked to be a participant in a research study designed to look at Emergency Department patients who report opioid use (heroin or prescription painkillers).

This study will try to determine the outcomes among Emergency Department patients with opioid use. You have been asked to participate because you reported opioid use and are a patient in the Emergency Department.

This consent form explains this research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the research staff to explain anything in this form or about the study that is unclear. Please take time to read this information carefully. If you agree to take part in this research study, you must sign this consent form.

This is a multi-site study supported by the National Institute on Drug Abuse (NIDA).

DISCLOSURE OF FINANCIAL INTERESTS

The National Institute on Drug Abuse is providing funds to [INSERT NAME OF DOCTOR OR INSTITUTION] for the conduct of this multi-site study.

PURPOSE OF THE STUDY

The purpose of this study is to learn how treatment for opioid use is provided in the emergency department. The study will look at how patients engage in treatment and the decisions that patients and providers make regarding treatment for opioid use.

NUMBER OF PARTICIPANTS AND LENGTH OF STUDY
Your participation in this study will consist of either one or two research visits. Visits may occur remotely (by phone, virtual conference) or in-person. The first visit will occur today or within 7 days after your visit to the emergency department. During this first visit, study staff will determine if you are eligible to have a second research visit. The second research visit, if you are eligible will occur approximately 30 days after your visit to the emergency department. Examples of reasons why you may not be eligible for a second research visit include if you do not complete the first research visit, if you do not have a phone or other way for us to contact you, or for other reasons determined by research staff.

Approximately 120 participants will be enrolled at two research sites, with about 60 from this site.

STUDY PROCEDURES
If you agree to participate in this study:

<u>During your first research visit, you will:</u>
- Provide contact information so we can reach you, with your permission, by phone, e-mail, mail or other (e.g., Facebook private messenger) during the course of the study. You will need to provide two unique means of contact to enroll in the study.
- Answer questions about education, employment, health care, insurance, behaviors (such as tobacco, alcohol and drug use), motivation for study participation, treatment choices, overdoses, health services, and about how you feel in general. *Some of these questions are about personal and sensitive information, including activities that are illegal such as illegal drug use. You should take this into account when deciding whether you want to be in this study.*
- Sign a separate release of information form that allows the research team to:
    - Contact any treatment provider where you may receive care for your drug use to obtain information regarding your future enrollment in drug treatment
    - Access to medical claims, treatment, and health services information for 24 months from date of signing the release of information form.
- Perform a drug screen test.

Research activities during your first research visit will take approximately 1.5 hours.

<u>Follow up visit (Second research visit)</u>
After your first research visit, you may complete another research visit in about 30 days. As stated above, study staff will determine your eligibility and inform you about whether you will be invited back for the second follow-up visit.

This follow-up visit is very important to the study and the research team will make every effort to contact you. If research staff has difficulty getting in touch with you for your follow-up visit, they may search public databases in an effort to locate you.

The follow-up visit will take approximately 30 to 45 minutes.
At this visit you will:
- Confirm contact information so we can reach you, with your permission, by phone, e-mail, mail or other (e.g., Facebook private messenger) during the course of the study should we need to contact you after the second visit.
- Answer questions about recent substance use, health services use, overdoses, treatment satisfaction, and quality of life events.
- Perform a drug screen test.

If you are in jail or prison, on probation or parole, or under house arrest or electronic monitoring, we would still like to find out how you are doing. Therefore, if necessary, we will make an effort to collect follow-up data from you over the phone or in person, if feasible. Your continued participation in this study will have no effect on your criminal case, or release or parole from jail or prison, or probation case.

To facilitate this follow-up visit, the study team will contact the proper authorities to obtain permission for your continued research participation while incarcerated. We may need to disclose that you are participating in the study, if the facility requires this information. Details of the nature of the research will not be shared with staff at the jail/prison, and visits, whether in person or by phone, will only be conducted if your confidentiality can be maintained and no audio-taping occurs. Any assessment or procedure scheduled for your visit will be completed unless not allowed by the facility.

RISKS AND DISCOMFORTS
Treatment for all your medical conditions, including your opioid use, will be decided upon by you and your Emergency Department doctor. Participation in the follow-up visit may cause inconvenience, but we will do everything that we can to schedule the follow-up visit at a time and location that is agreeable. Loss of confidentiality is another risk from participation in this study and will be discussed below.

NEW INFORMATION
You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

BENEFITS
It cannot be promised that you will receive any benefit from being in this study. The study may be beneficial to people in the future if it helps us identify effective methods of treating similar patients with opioid use.

ALTERNATIVES TO STUDY PARTICIPATION
Participation in this study is completely voluntary. The alternative to participating is to not participate. You may also decline to answer questions that you do not want to answer.

COSTS OF PARTICIPATION
You and/or your insurance will be responsible for the costs of the regular treatment received in the Emergency Department. The costs for these standard procedures will be billed to your insurance in the usual way. You will be responsible for any costs your insurance does not cover. If you are uninsured, you will be billed for them.

COMPENSATION FOR PARTICIPATION

You will receive compensation for completion of research activities to compensate you for your time and inconvenience. Compensation is as follows:

Research Visit	Description of Research Visit/Activities	Compensation
Screening/Enrollment **and** Baseline	- Screening assessments are surveys that you have already completed. - Enrollment occurs after signing this consent form and research staff confirm your eligibility. - Baseline assessments are completed after enrollment.	Your choices for compensation include - Up to $75 in gift cards only **OR** - A cell phone with a pre-paid plan for up to 2 months and a gift card for approximately $5- $15. If you decide to receive the phone, the cost of the phone and pre-paid plan will be deducted from your gift cards. We anticipate the cost of the phone to be approximately $60 and no more than $70, which would provide you with a gift card for approximately $5-$15. In order to receive the $75 valued compensation, you must complete the Screening/Enrollment visit and the Baseline visit within 7 days of your ED visit. These visits may all take place today or on separate days. If you complete the Screening/Enrollment visit only, you will be reimbursed $25 in the form of a gift card. You will receive compensation immediately after completing both the Screening/Enrollment and Baseline visit.
Research Visit	**Description of Research Visit/Activities**	**Compensation**
Follow-up (Day 30)	The Follow-up (Day 30) research visit is completed about 30 days after your ED visit. The assessments at this visit are similar to those completed at the Baseline visit.	$100 gift card only You will receive compensation immediately after completing the 30-day follow-up visit.

Tax law may require the payer (e.g. research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive $600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you received from the study.

Your biospecimens, with or without identifiers, may be used for commercial profit and you will not share in this profit.

If you are in jail or prison, on probation or parole, or under house arrest or electronic monitoring during this study, you may still be eligible to receive compensation for your continued participation if your institution approves the amount and method of compensation.

COMPENSATION FOR INJURY

If you are injured as a result of your participation in this study, immediate, short term medical care will be made available to you. The costs of such medical care will be yours either directly or through your insurance company or government program. No other compensation will be offered by [INSERT NAME OF INSTITUTION], the sponsor, or the Biomedical Research Alliance of New York Institutional Review Board.

You are not giving up any legal right to seek additional compensation through the courts by signing this form.

CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study drug may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the Sponsor or the Sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

Confidentiality of Your Medical Records

Your medical records will be kept in accordance with state and federal laws concerning the privacy and confidentiality of medical information. The confidentiality of your medical record is also protected by federal privacy regulations, as described below.

Confidentiality of Your Study Information

Your study records include information that identifies you and that is kept in research files. We will try to keep this information confidential, but we cannot guarantee it. If data from this study are to be published or presented, you will not be identified in any way.

Identifiers might be removed from your identifiable private information or biospecimens. After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Certificate of Confidentiality

This study has a Certificate of Confidentiality from the National Institutes of Health. This means that we may not share or use study information in any legal or police activity at federal, state, or local levels. There are some exceptions to this:

- If the law requires reporting. (For example, information might be shared to report child abuse or contagious diseases).
- If you allow your data to be shared, including for your medical treatment.
- If it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The National Institute on Drug Abuse (NIDA) is supporting this project. People from NIDA and their partners may check on the study. When they check on the study, they may look at your information.

This Certificate of Confidentiality does not stop you from voluntarily sharing information about yourself or your being in the study. If you want us to share your research information with an insurer, medical provider, or any other person, you must tell the study team that it is ok to share it.

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. Additionally, data from this study will be available to researchers on another website, http://datashare.nida.nih.gov/ after the study is complete and the data analyzed. This website will not include information that can identify you. You can view this website at any time.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get your information and why they may be able to get it. Research staff must get your authorization (permission) to use or give out any health information that might identify you.

If you choose to be in this study, research staff will get personal information about you. This may include information that might identify you. Research staff may also get information about your health, including:

- Past and present medical records, including information on drug use and treatment
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by study staff. They might see the research information during and after the study.

Your information may be given to the National Institute on Drug Abuse and any persons or companies that are working for or with them. Information about you and your health which might identify you may also be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Biomedical Research Alliance of New York
- New York School of Medicine's Institutional Review Board
- The members and staff of [INSERT NAME OF SITE'S] Institutional Review Board
- The members and staff of [INSERT NAME OF SITE] research and medical staff
- Every health care provider who provides services to you in connection with this study
- Any individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol
- The following research sponsors and the people and companies they use to oversee, administer, or conduct the research: The National Institute on Drug Abuse, New York University School of Medicine researchers who are the lead site for this study

- The United States research regulatory agencies and other foreign regulatory agencies
- The Patient Advocate or Research Ombudsman
- Members of the [NAME OF UNIVERSITY AND/OR SITE] Clinical Trials Office/Office of Research and Sponsored Programs (if applicable)
- Accrediting agencies
- Data Safety Monitoring Board/Clinical Events Committee
- Health Insurers/Payors
- Clinical Coordinating Center/Contract Research Organization: The Emmes Company
- Data and Statistics Coordinating Center/Contract Research Organization: The Emmes Company

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by federal privacy laws. However, these groups are committed to keeping your personal health confidential.

If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This Authorization does not have an expiration date. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled.

You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies responsible for protecting your rights.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may discontinue your participation at any time during the study, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please send a written notice to the site principal investigator for the study listed at the top of this form. If you withdraw your permission, you will not be able to stay in this study.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the research office for a final study visit.

Permission to Contact You about Future Research

I authorize the principal investigator and his or her co-investigators to contact me about future research provided that the principal investigator and co-investigator are affiliated with the research protocol.

If I agree, research staff might contact me in the future and he or she will tell me about a research study. At that time, I can decide whether or not I am interested in participating in a particular study. I will then have the opportunity to contact the researcher to schedule an appointment to be fully informed about the research project. Please initial next to your choice below.

_____ I agree to be contacted by the Principal Investigator or Co-Investigators of this research study about future research studies

_____ I **do not** agree to be contacted by the Principal Investigator or Co-Investigators of this research study:

Your permission to allow us to contact you about future research would be greatly appreciated, but it is completely voluntary. If you choose not to allow us to contact you, it will not affect your care at any of the facilities. Please understand that giving your permission to do this is only for the purpose of helping us identify whether you may be willing to participate in and qualify for one of our future research studies. It does not mean that you must join in any study.

QUESTIONS/COMPLAINTS/CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, if you want to voice a complaint or concern about this research, or if you have a study related injury, or if you experience a research-related injury, you may contact [INSERT NAME OF SITE PI] at {INSERT SITE PI PHONE NUMBER}.

If you have any questions about your rights as a research participant or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board

(BRANY) at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.The Institutional Review Board is a committee that reviews studies that help protect the rights and welfare of subjects.

STATEMENT OF CONSENT

I have read this consent form. I have been informed of the risks and benefits involved. All of my questions have been answered to my satisfaction. The study staff will answer any future questions I may have. I will be given a copy of this signed consent form.

By signing this consent form, I voluntarily agree to participate in this study and agree to provide my Authorization for the uses and disclosures of my protected health information as described above.

_____
Participant's Name
(Printed)

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Consent and Authorization
(Printed)

_____ _____
Signature of Person Obtaining Consent and Authorization Date

[INSERT ADDITIONAL SIGNATURE LINES IF LOCAL PARTICIPATING SITE REQUIRES]