Date: 10-18-2016

NCT: NCT03023930

Title: Opioid Use Disorder in the Emergency Department: CTN 0069

Document: Informed Consent Form

Approved Template
MUST BE APPROVED
FOR SITES BEFORE USE
Jan 30, 2017
WIRB®

FOCUS GROUP PATIENT PARTICIPANT INFORMATION SHEET
VERBAL CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

TITLE: Opioid Use Disorder in the Emergency Department

PROTOCOL NO.: CTN-0069
WIRB® Protocol #20162913

SPONSOR: Yale University

INVESTIGATORS: Name
Address
City, State, Zip
Country

STUDY-RELATED PHONE NUMBER(S): Name
Number

Introduction

You are being asked to join a research study. The following information will explain the purpose of the study, what you will be asked to do, and the potential risks and benefits. You should ask questions before deciding whether you wish to participate, or at any time during the course of the study.

Purpose

The purpose of this study is to understand knowledge, experiences and attitudes of providers, staff and patients regarding the evidence, clinical environment and needs for delivering treatment for opioid use disorder in Emergency Departments, office-based practices, and community-based programs. You are being asked to participate because you have been identified as someone who has an important perspective for helping us understand current practices and for informing how we can improve the delivery of treatment for opioid use disorder in these locations.

This study will be coordinated by Yale School of Medicine and the Western Institutional Review Board. Gail D'Onofrio, MD, MS is the overall Principal Investigator for this study and [NAME OF SITE PI] is the Site Principal Investigator at [INSERT NAME OF HOSPITAL/OR OUTPATIENT PROVIDER]. A description of this study will be available on http://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. Data from this study will be available to researchers on another website, https://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.

Procedures
If you choose to participate in the study, you will be asked to participate in up to three interviews or focus groups and a brief survey. Approximately 120 subjects will participate in this study.

These conversations will be digitally recorded and transcribed. It is expected that each of these conversations will take no more than 90 minutes and the survey will take you no more than 10 minutes. Any personally identifying information will be removed before these transcripts are shared. You have the right to review or remove any of your comments from the tapes, and they will be erased three years after the completion of the study.

Possible Benefits
By identifying barriers and facilitators to treatment for opioid use disorder in Emergency Departments, office-based practices, and community-based programs, the current research can directly inform future practices designed to improve the delivery of treatments for opioid use disorder in these locations.

Economic considerations
You will be reimbursed for your time with a $50 gift card for each time you participate. According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income. There are no anticipated costs to you associated with participating in this study.

Possible Risks
Your part in this research study consists of participating in either a focus group or interview and completing a brief survey. This study does not require you to have procedures or treatments. Therefore, being in this study does not involve any physical risks to you. However, there is a slight risk regarding the loss of confidentiality about your participation in this study if information about you becomes known to persons outside this study. The researchers are required to keep your study information confidential, however, so the risk of breach of confidentiality is very low. Any psychological, social, legal, or financial risks are essentially non-existent, and further minimized by our strict adherence to policies regarding subject confidentiality and privacy, as required by the Institutional Review Board (IRB), the Western IRB, associated with this study that reviews, approves, and monitors research on human subjects. More information on how confidentiality is protected can be found below.

Alternatives to Participation
You may choose not to participate.

Privacy / Confidentiality
To protect your confidentiality, your name and other identifying information will not be recorded on any study documents. We will only collect information that is needed for research. Only the researchers involved in this study and those responsible for research oversight will have access to the information you provide. Findings will only be shared in summary format and collected in a de-identified format. None of the information contained in the interviews or focus groups will be fed back to your providers in a manner in which you could be identified personally.

Voluntary Participation and Withdrawing from the Study

Participation in this study is completely voluntary. You are free to decline to participate, to end participation at any time for any reason, or to refuse to answer any individual question at any time. To withdraw from the study, write to [INSERT NAME OF SITE PI] at [INSERT NAME OF HOSPITAL/OR OUTPATIENT PROVIDER]; [INSERT ADDRESS OF SITE PI]. If you withdraw from the study, no new information will be gathered from you after that time. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as medical care). By providing verbal consent, you have not given up any of your legal rights. Your participation in this study will not impact the medical care which you receive. The researchers may also withdraw you from participating in the research if necessary (e.g., participant non-compliance). If you provide permission, you may be contacted for future studies if the researchers think you may qualify, but you are under no obligation to participate in this or other studies. Participation in any additional study is entirely voluntary and refusing to volunteer for an additional study will not affect your participation in the primary study.

Questions

By agreeing to participate, you are also agreeing that you have heard the above description of the research study. You have been told of the risks and benefits involved and, at this point, all of your questions regarding the study have been answered.

If you have further questions, concerns, or complaints about this study or if you have a research-related problem, you may contact the Site Principal Investigator, [INSERT NAME AND CONTACT OF SITE PI]. If you would like to talk with someone other than the researchers to discuss problems, concerns, complaints, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Western Institutional Review Board® (WIRB®) 1019 39th Avenue SE Suite 120, Puyallup Washington 98374-2115, Telephone: 1-800-562-4789 or 360-252-2500, E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

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TITLE: Opioid Use Disorder in the Emergency Department

PROTOCOL NO.: CTN-0069
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Introduction

You are being asked to join a research study. The following information will explain the purpose of the study, what you will be asked to do, and the potential risks and benefits. You should ask questions before deciding whether you wish to participate, or at any time during the course of the study.

Purpose

The purpose of this study is to understand knowledge, experiences and attitudes of providers, staff and patients regarding the evidence, clinical environment and needs for delivering treatment for opioid use disorder in Emergency Departments, office-based practices, and community-based programs. You are being asked to participate because you have been identified as someone who has an important perspective for helping us understand current practices and for informing how we can improve the delivery of treatment for opioid use disorder in these locations.

This study will be coordinated by Yale School of Medicine and the Western Institutional Review Board. Gail D'Onofrio, MD, MS is the overall Principal Investigator for this study and [NAME OF SITE PI] is the Site Principal Investigator at [INSERT NAME OF HOSPITAL/OR OUTPATIENT PROVIDER]. A description of this study will be available on http://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. Data from this study will be available to researchers on another website, https://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.

Procedures

If you choose to participate in the study, you will be asked to participate in up to three interviews or focus groups and a brief survey. Approximately 240 subjects will participate in this study. These conversations will be digitally recorded and transcribed. It is expected that each of these

conversations will take no more than 90 minutes and the survey will take you no more than 10 minutes. Any personally identifying information will be removed before these transcripts are shared. You have the right to review or remove any of your comments from the tapes, and they will be erased three years after the completion of the study.

Possible Benefits
By identifying barriers and facilitators to treatment for opioid use disorder in Emergency Departments, office-based practices, and community-based programs, the current research can directly inform future practices designed to improve the delivery of treatments for opioid use disorder in these locations.

Economic considerations
You will not be compensated for your participation and there are no anticipated costs to you associated with participating in this study.

Possible Risks
Your part in this research study consists of participating in either a focus group or interview and completing a brief survey. This study does not require you to have procedures or treatments. Therefore, being in this study does not involve any physical risks to you. However, there is a slight risk regarding the loss of confidentiality about your participation in this study, if information about you becomes known to persons outside this study. The researchers are required to keep your study information confidential, however, so the risk of breach of confidentiality is very low. Any psychological, social, legal, or financial risks are essentially non-existent, and further minimized by our strict adherence to policies regarding subject confidentiality and privacy, as required by the Institutional Review Board (IRB), the Western IRB, associated with this study that reviews, approves, and monitors research on human subjects. More information on how your confidentiality will be protected can be found below.

Alternatives to Participation
You may choose not to participate.

Privacy / Confidentiality
To protect your confidentiality, your name and other identifying information will not be recorded on any study documents. We will only collect information that is needed for research. Only the researchers involved in this study and those responsible for research oversight will have access to the information you provide. Findings will only be shared in summary format and collected in a de-identified format. None of the information contained in the interviews or focus groups will be fed back to your providers in a manner in which you could be identified personally.

Voluntary Participation and Withdrawing from the Study
Participation in this study is completely voluntary. You are free to decline to participate, to end participation at any time for any reason, or to refuse to answer any individual question at any time. To withdraw from the study, write to [INSERT NAME OF SITE PI] at [INSERT NAME OF HOSPITAL/OR OUTPATIENT PROVIDER]; [INSERT ADDRESS OF SITE PI]. If you withdraw from the study, no new information will be gathered from you after that time. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to ensure the integrity of the study and/or study oversight. Refusing to participate will involve no

penalty or loss of benefits to which you are otherwise entitled (such as your employment). By providing verbal consent, you have not given up any of your legal rights. The researchers may also withdraw you from participating in the research if necessary (e.g., participant non-compliance). If you provide permission, you may be contacted for future studies if the researchers think you may qualify, but you are under no obligation to participate in this or other studies. Participation in any additional study is entirely voluntary and refusing to volunteer for an additional study will not affect your participation in the primary study.

Questions

By agreeing to participate, you are also agreeing that you have heard the above description of the research study. You have been told of the risks and benefits involved and, at this point, all of your questions regarding the study have been answered.

If you have further questions, concerns, or complaints about this study or if you have a research-related problem, you may contact the Site Principal Investigator, [INSERT NAME AND CONTACT OF SITE PI]. If you would like to talk with someone other than the researchers to discuss problems, concerns, complaints, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Western Institutional Review Board® (WIRB®) 1019 39th Avenue SE Suite 120, Puyallup Washington 98374-2115, Telephone: 1-800-562-4789 or 360-252-2500, E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

COMPOUND AUTHORIZATION AND CONSENT

TITLE: Opioid Use Disorder in the Emergency Department

PROTOCOL NO.: CTN-0069
WIRB® Protocol #20162913

SPONSOR: Yale University

INVESTIGATORS: Name
Address
City, State, Zip
Country

STUDY-RELATED PHONE NUMBER(S): Name
Number

Invitation to Participate and Description of Project

You are invited to participate in a research study designed to look at patients with opioid use disorder. Specifically, this study will try to determine the outcomes among people who are addicted to opioids (heroin or prescription pain killers). You have been asked to participate because you have provided a urine sample and answered questions on a health survey that suggest you meet criteria for opioid use disorder. Approximately 960 patients from four different emergency departments (EDs) will be involved in this study. This study will be coordinated by Yale School of Medicine and the Western Institutional Review Board. Gail D'Onofrio, MD, MS is the overall Pricincipal Investigator for this study and [NAME OF SITE PI] is the site Principal Investigator for the study at [INSERT NAME OF HOSPITAL].

In order to decide whether or not you wish to be a part of this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you agree to participate in this study:

During your ED visit today you will be asked to:

- 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.

- answer some questions about: age, gender, race, education, employment, health care, insurance, legal issues, behaviors (such as: tobacco, alcohol and drug use), and about how you feel, in general.

- Sign a release of information form allowing us to contact any treatment provider where you may receive care for your drug use to obtain specific information regarding your future enrollment in drug treatment.

After today's visit, you will also:

- complete 1 more in-person survey scheduled for 30 days from now.

- provide 1 more urine sample scheduled for 30 days from now.

Possible Risks and Inconveniences

Treatment for all your medical conditions, including your opioid use will be decided upon by you and your ED provider. Participation in this study should not make your ED visit any longer. Participation in the follow-up visit and 30 day survey may cause a slight inconvenience for you, but we will do everything that we can to schedule these at a time that is agreeable to you. Any psychological, social, legal, or financial risks are minimized by our strict adherence to policies regarding subject confidentiality and privacy, as required by the Institutional Review Board (IRB), the Western IRB, associated with this study that reviews, approves, and monitors research on human subjects. Loss of confidentiality is another possible risk from participation in this study and will be discussed below.

Possible Benefits

It is possible that you will benefit from participation in the study in that you may receive additional health information. In addition, the study may be beneficial to people in the future if it helps us identify effective methods of treating similar patients with opioid use disorder. It cannot be promised that you will receive any benefit from being in this study

Economic Considerations

You will be paid $50 after your enrollment today. You will be paid $50 for completing the one (1) additional survey at the 30-day follow up visit. Payments are made in the form of gift cards. According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income. You will still be responsible for any costs or co-pays required by your insurance company for standard ED treatment.

Alternatives

Participation in this study is completely voluntary. The alternative to participating is to not participate. Other options are available and your doctor can give you more information.

Confidentiality and Privacy

If you decide to take part in this research study, you will be asked to give us information about your substance use and associated problems. We have obtained a Certificate of Confidentiality (CoC) issued by the Department of Health and Human Services /National Institutes of Health. The CoC protects investigators from being forced, even under a court order or subpoena, to release information that could identify you. The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a participant's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. Because this research is sponsored by the Department of Health and Human Services through the National Institutes of Health, staff from that and other Department of Health and Human Services agencies may review records that identify you only for audit or program evaluation. They cannot report anything that would harm you or other research subjects. Even with a CoC in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for anyone to receive information about your participation in the research, then we may not use the CoC to withhold this information.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, address and telephone number and information about your health collected in research study records. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The site principal investigator, [INSERT SITE PI], will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the Site Principal Investigator or selected members of the research team. Any information that can identify you will remain confidential. Additional methods to safeguard the confidentiality of your data (e.g., storing research materials in locked cabinets, password-protecting data stored on a computer) will also be utilized. The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for approximately 12 months after completion of data analyses, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form indefinitely. Information about your study participation may be entered into your Electronic Medical Record (EMR). Once placed in your EMR, these results are accessible to all of your providers who participate in the EMR system. Information within your EMR may also be shared with others who are appropriate to have access to your EMR (e.g. health insurance company, disability provider.)

COMPOUND AUTHORIZATION AND CONSENT

The information about your health that will be collected in this study may include:

- Research study records
- Medical and laboratory records of those services provided in connection with this study.
- Medical records in your health systems EMR over the next 30 days
- The following information: records about phone calls made as part of this research, records about your study visits, survey data about substance use, employment, education, HIV risk taking behaviors, mental health, any additional health information provided, any referral for further treatment, and any medication received.

Information about you and your health which might identify you may be used or given to:

- The Site Principal Investigator [INSERT SITE PI]
- Study Principal Investigator, (Gail D'Onofrio, MD, MS), Co-Investigators, other investigators and Executive committee
- Study coordinator and members of the research team
- A Data and Safety Monitoring Board and others authorized to monitor the conduct of the study (e.g. Clinical Coordinating Center: The Emmes Corporation, Data and Statistics Coordinating Center: The Emmes Corporation)
- National Institutes of Health/Department of Health and Human Services
- Representatives from the IRB associated with the ED you are in today, Yale University and its Human Investigation Committee, and the WIRB-Copernicus Group, who are responsible for insuring research compliance
- Those providers who participate in the Electronic Medical Record system
- Those individuals at [INSERT NAME OF STUDY SITE] who are responsible for the financial oversight of research including billings and payments

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes. All health care

providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at this ED are required to comply with HIPAA and to ensure the confidentiality of your information.

The sponsor will see the research information we collect about you if they come to monitor the conduct of this research study. The "Sponsor" includes any persons that work for or are hired by the sponsor to conduct research activities related to this study. For this study the sponsor includes Department of Health and Human Services/National Institutes of Health. Researchers will also send the sponsor your health information during the study or at the end of the study. When researchers send information about you to the sponsor, they will not send information that directly identifies you. The sponsor may also use the information about you for other purposes related to this research or to similar research studies. There is a risk that once your information is shared, it may be given to others without permission.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

A description of this study will be available on http://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.

Data-share Website

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

In Case of Injury

If you are injured while on study, seek treatment and contact [INSERT SITE CONTACT] as soon as you are able.

This study does not offerfunds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is offered.

You do not give up any of your legal rights by signing this form.

COMPOUND AUTHORIZATION AND CONSENT

Voluntary Participation and Withdrawal

Participating in this study is voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study. If you provide permission, you may be contacted for future studies if the researchers think you may qualify, but you are under no obligation to participate in a new study. Participation in any additional study is entirely voluntary and refusing to volunteer for an additional study will not affect your participation in the primary study.

Withdrawing from the Study

If you do become a participant, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can call a member of the research team at any time and tell them that you no longer want to take part. This will cancel any future appointments. The researchers may also withdraw you from participating in the research if necessary (e.g., participant non-compliance).

Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled. It will not harm your relationship with your own doctors or with this ED. We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to [INSERT NAME OF SITE PI] at [INSERT NAME OF HOSPITAL]; [INSERT ADDRESS OF SITE PI].

If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

COMPOUND AUTHORIZATION AND CONSENT

If you have further questions, concerns, or complaints about this project or if you have a research-related problem, you may contact the Site Principal Investigator, [Name of Site PI] at [Phone Number]. If you would like to talk with someone other than the researchers to discuss problems, concerns, complaints and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Western Institutional Review Board® (WIRB®) 1019 39th Avenue SE Suite 120, Puyallup Washington 98374-2115, Telephone: 1-800-562-4789 or 360-252-2500, E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research. WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

COMPOUND AUTHORIZATION AND CONSENT

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 this future research is approved by the original IRB of record and that the principal investigator and co-investigator are affiliated with the research protocol.

If I agree, then someone from Dr. [Site PI name here]'s 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.

_____ I agree to be contacted by the Principal Investigator or Co-Investigators of the research study titled: Project ED Health

_____ I do not agree to be contacted by the Principal Investigator or Co-Investigators of the research study titled: Project ED Health

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 subjects who may qualify for one of our future research studies. It does not mean that you must join in any study.

COMPOUND AUTHORIZATION AND CONSENT

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Participant: _____

Signature: _____ Date: _____

Signature: _____ Date: _____
Site Principal Investigator

Or

Signature: _____ Date: _____
Person Obtaining Consent

CONSENT FOR RELEASE OF INFORMATION FOR RESEARCH PURPOSES

As part of this research study, I _____ (Name of Participant), hereby authorize any treatment facility where I receive care after my visit today to release/receive information from my health record to study researchers and/or the Principal Investigator. I understand that the purpose of the information is to follow up on referrals made while I was in the emergency department.

The type of information requested is:

- ☑ Presence at appointment(s) to primary care and/or specialty clinic(s)
- ☑ Utilization of community services such as Alcohol/Narcotic Anonymous
- ☑ Assessment and/or enrollment in alcohol/drug treatment facilities
- ☑ Hospitalizations and other emergency department visits.

I understand that this form serves as both a general authorization for the release of health information and a specific authorization for the release of information protected by specialized state and federal confidentiality laws and regulations. The information to be released may contain information pertaining to psychiatric, psychological, drug and/or alcohol, diagnoses or treatment. I understand that the information released by this consent will not be further relayed to any other person or entity besides those listed above without additional consent from me or as provided by law. This information will be used only to assess the effectiveness of this study with identifying the outcome of patients opioid use disorder seen in an emergency department setting.

The following statements will accompany alcohol, drug, and psychiatric treatment information that is released:

Alcohol and Drug Abuse Information Disclosure Statement

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to investigate or prosecute any alcohol or drug abuse patient.

COMPOUND AUTHORIZATION AND CONSENT

Psychiatric Record Disclosure Statement

This material shall not be transmitted to anyone without written consent or other authorization as provided in the aforementioned statutes.

This information will be used ONLY for the purposes of follow-up concerning this study. The information is kept under an identifying code and remains in a locked cabinet. It is NOT part of your medical record. This authorization expires automatically 18 months after date of signature.

Name of Participant: _____

Signature: _____ Date: _____

Signature: _____ Date: _____
Witness (Study Researcher)