Clinicaltrials.gov Registration #: NCT04253782

Protocol Title: *A Multi-Tiered Safety Net Following Naloxone Resuscitation from Opioid Overdose*

Version Date: 05/26/2021

Informed Consent Form

COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH STUDY
YALE UNIVERSITY SCHOOL OF MEDICINE
YALE NEW HAVEN HOSPITAL (YNHH)

Study Title: *A Multi-Tiered Safety Net Following Naloxone Resuscitation from Opioid Overdose*

Principal Investigator (the person who is responsible for this research):
Daniel Joseph MD

Phone Number: Dr. Joseph is available between 9:00AM-5:00PM (Monday-Friday) and may be contacted at 1(203)785-4404.

Research Summary:
You are invited to participate in a study about treating people with opioid use disorder (OUD). Our intervention involves connecting you with a variety of important community resources that hopefully will help you to make progress toward long-term recovery.

- If you decide to participate in this study, we will connect with you electronically/remotely (including over the phone), and then will ask that you select one of three options that may help you with your opioid addiction:
  1) treatment with buprenorphine/naloxone (BUP),
  2) recovery-coach facilitated treatment (e.g., methadone maintenance, intensive outpatient treatment, and/or residential treatment)
  3) education only (materials provided by the Connecticut Community for Addiction Recovery (CCAR) https://ccar.us/).

Throughout the study, you may switch to any other option.

- To help you decide if you want to participate, we will ask that you meet online and/or over the phone with a paramedic and an addiction recovery coach from CCAR to discuss the options.
- Depending on the option you choose, you will be asked to attend, online and/or by phone, at least 2 visits or 7 visits at the most. (If you select 1) treatment with BUP, then you may have the option of 7 follow-up visits.) Each visit will take about an hour at most.
- We will also collect data during the visits and may use and analyze it for up to 6 years from the study's completion. We will collect information about the following:
  - Mental and physical health (focusing on aspects related to overdose, use of illicit substances and prescription medication, and treatment)
  - Personal information about where you live and details about your background
  - Contact information
  - Legal history
  - Employment and educational history
  - Insurance coverage
  - Recovery history

  There are some risks from participating in this study:
  - Ongoing illicit opioid use—including the potential for overdose—is possible.
  - There is a chance that confidential information about you mistakenly could be shared or given to someone who should not see it.
  - Detoxification from opioids can increase the risk for opioid overdose because you won't have the same tolerance to the drug as you stay clean for increased time periods.

- You may become upset or feel uncomfortable as you participate in interviews, answer questions and as you describe your medical history and drug use. We will provide support to you if you experience this discomfort or stress.
- If you are of childbearing age and/or are pregnant, you may still participate in this study. Compared with illicit opioid use, medication-assisted therapy may decrease the risk to the developing child.

Why is this study being offered to me?
You have tested positive for OUD. We are looking for 100-300 total participants to enroll in our study.

Who is paying for the study?
Our research is funded by the federal government through the Centers for Disease Control and Prevention (CDC). https://www.cdc.gov/

Who is providing other support for the study?
The Connecticut Community for Addiction Recovery (CCAR) is involved in training study personnel and implementing and overseeing the research intervention.

What is the study about?
We are inviting you to this study because you have a history of opioid use with at least 1 overdose event leading to resuscitation by naloxone. We wish to determine whether a new online and/or over-the-phone intervention connecting you with community resources and involving an addictions counselor from CCAR and a paramedic might help with preventing or decreasing the number of future overdoses.

What are you asking me to do, and how long will it take?
Within 30 days of consent signing we will meet with you electronically/remotely (including over the phone) at a convenient time of your choosing. During this meeting, we will ask you some basic questions about your physical and mental health history and treatment. After this time, we will meet with you online and/or by phone again for a maximum of 7 consecutive days (depending on which treatment option you are following). Next, we will establish a second online and/or phone meeting within 180 days of consent to participation. All meetings will be a maximum of 60 minutes or less.

What are the risks and discomforts of participating?
Confidentiality:
An important risk is the possibility that sensitive information obtained during the study will be disclosed. Your name will not be used when reporting results in our publications or when we analyze the results of the study. The CDC has granted us a Certificate of Confidentiality (CoC) to protect the information that we collect about you during the work. The CoC protects investigators from being forced, even under a court order or subpoena, to release information that could identify you.

Interviews and questionnaires:
You may feel uncomfortable or emotional while answering questions. We will provide support to help you as we discuss your history. You may also refuse to answer any questions.

Risks to women of childbearing potential and fetus:
Those who are of childbearing potential may participate in this research. Compared to opioid use, treatment with medication-assisted therapy (BUP or methadone) may increase the probability that a baby would not develop abnormally or come too early. However, recent findings suggest that fetal exposure to opioids may lead to neonatal opioid withdrawal syndrome (NOWS). This can be effectively managed, but may be life-threatening if not recognized and treated. Please ask your health care provider or Dr. Joseph, if you would like to discuss this further.

How will I know about new risks or important information about the study?
We will tell you if we learn any new information that could change your mind about taking part in this study.

How can the study possibly benefit me?
You might potentially benefit from participation in this research by gaining access to community resources, such as treatment options and educational materials, which could help with treating your condition.

How can the study possibly benefit other people?
We hope that we will learn more about what kind of treatment might best help others with OUD. We also want to help health care professionals know more about treating people with this condition.

Are there any costs to participation?
You will not have to pay for taking part in this study. The only costs include transportation and your time attending the online/phone study visits. We also will pay for ONE transport—to and from—a medical appointment of your choosing at any time during your participation in this research. However, there may be additional costs to you for routine medical care only. You or your health insurance must pay for services, supplies, procedures, and care that are part of your *routine* medical care. You will be responsible for any co-payments required by your insurance.

Will I be paid for participation?
Three Stop & Shop gift cards may be mailed or given to you: One ($25) upon consent to participate, another ($25) after the first online/phone visit, and a final one ($25) after the second—for a total value of $75 upon study completion.

What are my choices if I decide not to take part in this study?
Instead of participating in this study, you may receive treatment (e.g., medication-assisted therapy such as methadone or BUP) and support services through institutions such as YNHH, the Veterans Affairs, and/or CCAR. You also are welcome to participate in another study.

Confidentiality and privacy
If you decide to take part in this research, 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 Centers for Disease Control and Prevention (CDC). 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 report it to the appropriate authorities. Because this research is sponsored by the Department of Health and Human Services (DHHS) through the CDC, staff from that and other DHHS 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 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 records. This information will be de-identified using Research Electronic Data Capture (REDCap®) software 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, Dr. Daniel Joseph, will keep a link that identifies you to your coded information, and this link will be kept secure and available only to Dr. Joseph and/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 and 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 6 years after the study's completion. 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, etc.).

How will you keep my data safe and private?

We will keep information that we collect about you confidential. Your consent form will be placed in a locked cabinet and will be stored for 6 years after the study's completion. After this time, such documents will be destroyed. All collected data will be stored in a secure, encrypted online website, REDCap®. We will share it with others if you agree to it or when we must because U.S. federal or state law requires it. When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we will ask you for permission. Your information could be used for future studies or distributed to another investigator for such studies without additional informed consent from you.

What information will you collect about me in this study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to a Yale Privacy Officer at 203-432-5919. The specific information that we may collect, share, and review includes the following:

- The entire health record; any medical, laboratory, or research records held in EPIC
- Admissions to the Emergency Department and to a YNHH hospital (York Street and/or St. Raphael campus)
- Length of stay during admission
- Diagnosis upon admission
- Diagnosis upon discharge
- Admissions to the hospital
- Laboratory results from urinalysis
- Records about all medications and drugs

How will you use and share my information?

We will use your information to conduct the study described in this consent form. We may share your information with the following parties:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program (HRPP) and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.

- Governmental agencies to whom certain diseases (reportable diseases) must be released
- Health care providers who perform services connected with this study
- Laboratories and other individuals and organizations that analyze your health information in connection with this study (including the Connecticut Community for Addiction Recovery), according to the study plan
- Co-investigators and other investigators
- Study coordinator and members of the research team
- Data and Safety Monitoring Boards (DSMB) and others who are authorized to oversee this study
- Elm City Communities, the Housing Authority of New Haven, with whom we are collaborating (de-identified data only, such as enrollment numbers and percentages of decreased opioid use, if applicable)

We will do our best to make sure your information stays private. However, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by it. Let us know if you have questions about this.

Why must I sign this document?
By signing this form, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?
The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw your permission at any time. You may withdraw your permission by telling the study staff, by calling Dr. Daniel Joseph (1(203)785-4404) or notifying him in writing: 464 Congress Avenue, New Haven, CT 06519. If you withdraw, you will not be able to stay in this study. However, any treatment that you get from your health care providers will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected, however, may still be used and given to others until the end of the research study to ensure the integrity of the study and/or oversight.

Who will pay for treatment if I am injured or become ill due to participation in the study?
If you are injured during participation in the study, seek treatment and contact the study doctor as soon as you are able. Yale School of Medicine and YNHH do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this research, 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 available. You do not give up any of your legal rights by signing this form.

What if I want to refuse or end participation before the study is over?
Taking part in this study is your choice. You can choose to participate or refrain from doing so. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits. We would still treat you with standard therapy or, at your request, refer you to a clinic or doctor who can offer this treatment. Not participating or withdrawing later will not harm your relationship with your own doctors or with this institution. To withdraw from the study, you can call a member of the research team and tell him or her that you no longer want to be involved. Also, Dr. Joseph may withdraw you from the research at any time at his discretion.

What will happen with my data if I stop participating?

If you withdraw from study participation, we cannot guarantee that your data will also be withdrawn. This is because such data might have been used anonymously in analyses, presentations, and conference proceedings at a time(s) before you asked for your data to be withdrawn. However, if you decide to withdraw while you are still participating in visits, we can remove your information from the study.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand. If you have questions later or if you have a research-related problem, please call Dr. Joseph at 1(203)785-4404. If you have questions about your rights as a research participant, or if you have complaints about this research, you may call the Yale Institutional Review Boards at 1(203)785-4688 or email hrpp@yale.edu. A description of this clinical trial is available on *ClinicalTrials.gov*. Its identifier is the following: NCT04253782. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this site at any time.

Emergency contact numbers

9-1-1

National Suicide Prevention Lifeline:
1(800)273-8255
https://suicidepreventionlifeline.org/

Connecticut Suicide & Crisis Hotlines
http://www.suicidehotlines.com/connecticut.html

Would you like to participate in this study? Are you 18 years of age or older?

Authorization and Permission

Your signature below indicates that you have read this consent document and that you agree to be in this study. We will give you a copy of this form.

Participant Printed Name	Participant Signature	Date

Person Obtaining Consent Printed Name	Person Obtaining Consent Signature	Date

Complete if the participant is not fluent in English and an interpreter was used to obtain consent. Participants who do not read or understand English must not sign this full consent form, but instead sign the short form translated into their native language. This form should be signed by the investigator and interpreter only. If the interpreter is affiliated with the study team, the signature of an impartial witness is also required.

Print name of interpreter: _____

Signature of interpreter: _____ Date: _____

An oral translation of this document was administered to the participant in (state the language) by an individual proficient in English and _____ (state language).

Print name of impartial witness: _____

Signature of impartial witness: _____Date: _____