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NYU Langone Health

Research Subject Informed Consent Form

Title of Study:	Measuring Improvement in the Quality of Emergency Department-Initiated Treatment of Opioid Use Disorders Using Observation S20-01951
Principal Investigator:	Ryan McCormack, MD Ronald O. Perelman Department of Emergency Medicine NYU Langone Health 227 East 30th Street (212) 263-2862
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1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The purpose of this research study is to see if treatment of OUD in the Emergency Department (ED) is better when the visit is allowed to be longer, up to 23 hours, compared to a usual ED visit (that lasts up to about 3-5 hours). We call these longer visits “observation.” Observation usually involves staying overnight, but not more than 24 hours. Depending on the hospital and other factors, patients placed in observation may either stay in the ED or might stay in a separate unit of the hospital.

3. How long will I be in the study? How many other people will be in the study?

Your participation in the study will last 3 months. **We will meet with you 3 times: today, in 1 month, and in 3 months.** This study will enroll 230 participants across study sites.

4. What will I be asked to do in the study?

If you choose to take part in the study, we will ask you to sign this consent form – saying you give your permission – before we start any of the following study activities.

If you want to participate in the study, you would need to be willing to be treated in either the ED (probably 3-5 hours) or observation (which could be up to 23 hours).

Once you agree to participate in the study, we will use a computer program to assign you to either a regular ED visit or an ED visit with observation. **You will have a 50/50 chance of being either in the ED or observation group.** This is called randomization, because it is done at random, like flipping of a coin.

You will receive all of your medical care by your ED doctor and team. For the research study, we will ask you questions, do a drug screen, and review your health records and medical claims today, in one month and in 3 months.

We will ask you questions about many things, including about yourself (like your age, education, housing), your use of opioids, healthcare visits, the quality of your health, life, and treatment, and other topics. This would occur today and at visits in 1 month and 3 months. You may skip over any questions that you find uncomfortable.

At each of these visits, we will collect urine or saliva or both for a drug screen. We will test your urine or saliva for substances such as cocaine, marijuana, and opioids, including heroin, fentanyl, methadone, buprenorphine and others. This is for research purposes (not for legal purposes).

With your permission, we will review your medical records, contact your doctor to confirm which treatments you have received, and review your insurance claims (if you have Medicaid) along with a database which includes all prescriptions you have filled (the Prescription Drug Monitoring Program) for the period of one year prior to study enrollment to two years following study enrollment. This will allow us to see if you are receiving medications or other treatment for OUD and learn more about the costs and cost-savings associated with starting treatment in the ED.

Study Visits/Calls

Visit 1: Screening and Enrollment Visit (Today)

- We will describe the study, review this informed consent form, and answer any questions you have about the study.
- We will confirm that you meet all of the requirements to take part in the study. To do this, we will review your medical chart, speak with your doctor, and ask you questions. We will also collect contact information for you and multiple friends or family members who could help us get in touch with you. If you do not meet the requirements or if we think it may be unsafe for you to participate, we will explain why you cannot take part in the study.
- You will be randomized to receive treatment though a regular ED visit or an ED visit with Observation.
- We will ask you questions about your demographics (age, race, education, etc.), substance use, health and life quality, healthcare use, and other topics.
- We will review medical records from this hospital and other medical facilities, along with your Medicaid insurance claims, and your prescriptions. We will collect information about what treatment and other care you received during this visit and other visits (before and after).

- We will collect urine or saliva or both for a drug screen.
- We will schedule a time for you to return to meet with us in 1 month.
- We will compensate you for your time and transportation.

Visit 2: Follow up 1 (in 1 month)

- You will return to meet with us in person on the hospital campus or our office. Other private, safe spaces to conduct the visit will be considered only if necessary. It may be possible to meet virtually if it is unsafe to meet in person.
- We will ask you many of the same questions we asked at the first visit and about your use of opioids, any substance use treatment or other healthcare use since we last met. We will also ask you questions about treatment satisfaction, quality of life, and general health.
- We will collect urine or saliva or both for another drug screen.
- We will compensate you for your time and transportation.

Visit 3: Follow up 2 (in 3 months)

- You will return to see us again to repeat everything done during Visit 2, including the drug screen. This will be the end of your participation in the study. However, the study team will continue to monitor your healthcare visit use and medication use for up to 2 years by reviewing health records, Medicaid claims, and the prescription drug monitoring program database.
- We will compensate you for your time and transportation.

No identifiable private information or specimens collected and/or used for the purposes of this research will be used or distributed for future research studies.

5. What are the possible risks or discomforts?

Participation in this study may involve some added risks or discomforts. These risks are minimal. You may contact the study doctor if you are concerned about anything during the course of your participation in this study.

This study affects your medical treatment by determining whether your visit today will be either (1) a regular ED visit or (2) a longer ED Observation visit. That is the only way the study affects your health care. All other decisions are between you and your doctor, including whether or not you start buprenorphine or any other treatments today. You should tell your doctor or nurse about your medical problems and treatment wishes and any side-effects or problems you may have related to your treatments.

The risks and/or discomforts associated with the study include the following:

- **Emotional Discomfort**
  We will ask you sensitive and personal questions about your substance use, personal life, housing, etc. If ever you don't want to answer a question, you can refuse. You can also let us know if you need a break.

- **Loss of Confidentiality**
  Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

- **Other Risks**
  As with all research, this study may involve risks that we are not aware of yet.

6. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

7. What are the possible benefits of the study?

- You may not have any direct benefits by participating in the study.
- You will help us learn how to improve care for other patients with OUD in the future. As such, you will be helping society – and you should feel good about your service to the community.
- You will receive all of your care just as you would in the ED (whether or not you participate in the study), except that you may have an extended visit in ED observation.
- Prior studies have shown that patients who are asked a series of questions about their substance use tend to have better treatment outcomes than patients who do not complete detailed assessments. So, it is possible that you will benefit just by us asking you questions today and at the next two visits.

8. What other choices do I have if I do not participate?

Taking part in this study is voluntary. You may choose not to take part in the study. Also, if you participate, **you may choose to leave the study at any time**.

You will receive treatment in the ED today whether or not you participate in the study.

- If you do not participate, you will receive care in the ED – as usual.
- If you do participate, you will have a regular ED visit (as usual) or have a longer ED visit through observation. This is the only way being in the study affects your treatment.

Whether or not you participate, the study team doesn't make any decisions about whether or not you will receive medications or other treatment of OUD or any other condition. The medical treatment you receive in the ED, if any, is up to you and your doctor. Whether or not you are in the study, you should speak with your doctor about your OUD and ask about treatment options and other resources that may be available for you.

Deciding not to participate, or deciding to leave the study will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with your doctors or with the hospital.

9. Will I be paid for being in this study?

You will receive $75 value for your time and transportation after each visit. If you choose to leave or are withdrawn from the study for any reason before finishing the entire study, you will be paid for each completed visit. If you complete all the study visits, you will receive $225 value for being in this study.

Your choices for compensation include a ClinCard, a phone, and/or a pre-paid phone plan including unlimited talk and text, and 1GB of data for 30-days, 60-days, or 90-days. Possible compensation options include but are not limited to:

- $75 on ClinCard (like a debit/credit card)

OR

- A phone with a 60-day pre-paid plan and a ClinCard with approximately $5-$30

OR

- A phone with a 30-day pre-paid plan and a ClinCard with approximately $15-$50

If you decide to receive the phone, the cost of the phone and pre-paid plan will be deducted from the $75 value loaded on the ClinCard. We anticipate the cost of the phone will be approximately $5-$40, and the cost of each 30-days of pre-paid service is approximately $20.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (i.e. check, ClinCard or bank gift card), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

You are required to track all payments made to you by NYU Langone for your participation in any research for this calendar year. You must let us know immediately if/when the total research payments presently equal or is likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please advise Ryan McCormack at Ryan.McCormack@nyulangone.org or 212-263-2862.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00, and you may be taxed on these research payments above $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete a IRS W9. If you do not have either of these numbers or are not willing to complete the IRS, you may be in the study but will not receive any payment.

10. Will I have to pay for anything?

If you participate in the study, your medical care (including medications and tests ordered by your doctor) will be billed to you and/or your insurance provider in the same way it would be billed if you did not participate. The charges for an ED stay that includes observation may be more than for a standard ED visit. Otherwise, there should be no additional costs to you for participating in this research study.

You will not be billed for any research procedures, including the study drug screens or fees associated with accessing medical records or administrative databases.

11. What happens if I am injured from being in the study?

We do not anticipate any injuries directly related to study participation because this study involves no procedures or medications. If you think you have been injured as a result of taking part in this research

study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this consent form.

There are no plans for the NYU Grossman School of Medicine or Medical Center to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

12. When is the study over? Can I leave the Study before it ends?

Your participation in **the study ends after the 3-month research visit**. However, the study team will continue to monitor your healthcare visit use and medication use for up to two years by reviewing health records, Medicaid claims, and the prescription drug monitoring program database. These activities do not require active participation on your behalf.

YES, you can leave the study early. If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Ryan McCormack at (212) 263-2862.

The Principal Investigator may also withdraw you from the study without your consent for one or more of the following reasons

- Failure to follow the instructions of the Principal Investigator and/or study staff
- The Principal investigator decides that continuing your participation could be harmful to you
- If you exhibit disruptive or dangerous behavior
- The study is cancelled
- Other administrative reasons
- Unanticipated circumstances

If you are withdrawn from the study, the reason will be explained to you.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping. Another reason to tell your research doctor is to discuss what follow-up care and testing could be most helpful for you.

13. How will you protect my confidentiality?

Your medical information is protected health information, or "PHI", and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality
To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health. This means that your research information, including lab results, x-rays, MRIs, information about the investigational drug used in this study, may be included in your NYU Langone Health electronic medical record.

14. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institutes of Health
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research
- H+H personnel responsible for the support or oversight of the study at Bellevue Hospital

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

15. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU School of Medicine's IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

16. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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 website site at any time.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date