INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Following Opioid Overdose Survivors to Improve Emergency Department-Based Services: A Pilot Study

You are invited to participate in a research study that seeks to understand what happens to opioid overdose survivors or people who are admitted to the ED for an opioid related issues after they leave the emergency department. The study is being conducted by Dr. Alan McGuire, at the IU Richard M. Fairbanks School of Public Health and is funded by the National Institute on Drug Abuse (NIDA).

STUDY PURPOSE

The purpose of this study is to test POINT (Planned Outreach, Intervention, Naloxone, and Treatment) as a model for an emergency-department outreach intervention that seeks to address barriers to medication assisted treatment (MAT) for opioid use disorders by providing intensive outreach, assistance navigating treatment access, and recovery coaching for patients following an overdose or patients who are admitted to the emergency department for an opioid related issue.

We aim to understand the impact this program has on participants.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of approximately 800 individuals enrolled in the study.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will

- Complete an interview that will take approximately 30-60 minutes. The interview will cover such topics as: basic demographic information, social support, living arrangement, drug use, context of your current overdose, substance use treatment history, physical and mental health, and contact information we may use to follow-up with you at a later date.
- We will also collect information about you from the following existing databases:
    - Indiana University Health: Methodist Hospital, Ball Memorial Hospital, or University Hospital
    - Indiana University Health Physicians
    - Eskenazi Health
    - Franciscan Health
    - IUMG – Primary Care Physicians
    - Eskenazi Health Physicians
    - Indiana Network for Patient Care (*contains hospital and overdose admission data*)
    - INSPECT (*contains prescription information for controlled substances*)
    - Division of Mental Health and Addiction (*contains methadone treatment information*)
    - Indiana Office of Medicaid Planning and Policy (*contains Medicaid enrollment information*)
    - Indiana Department of Child Services (*contains child welfare involvement information*)
    - Valle Vista Health Systems *(contains addiction and mental health treatment data)*
    - Midtown Community Health *(contains mental health treatment data)*
    - Clean Slate Centers *(contains addiction treatment data)*
    - Marion County Health Department/Coroner's Office (*state health/vital records*)
    - Delaware County Health Department/Coroner's Office (*state health/vital records*)
- We will continue to collect information from these systems from three years prior to today and two years after today.
- You <u>may</u> also be asked to participate in a series of 3 follow-up telephone interviews after you leave the emergency department (ED). If so,

- In the initial interview, a researcher will ask about what it was like to be approached by a recovery coach in the ED, types of treatment resources you accessed since leaving the ED, types of resources you find most helpful, your motivation , your experiences with medication assisted treatment, and your overall recovery experience.
    - In the two interviews following, the researcher will ask about changes that may have occurs in your motivation, treatment accessed, and overall recovery experience.
- Each interview will last between 30-60 minutes and will be audio recorded.
- Each interview will be conducted over the telephone.
- Each interview will be approximately 1-2 months apart.

RISKS OF TAKING PART IN THE STUDY

Potential risks of taking part in this study include:

Baseline Data Collection:

- It is possible that your identifiable data including your personal health information may be compromised during transfer to Indiana University.
- If your data are compromised, you may be identified as having received emergency department treatment for an opioid overdose.
- You may feel uncomfortable answering some of the more sensitive interview questions, particularly those regarding substance use.
- You may experience fatigue completing the interview.

Follow-Up Telephone Interview:

- If asked to complete the follow-up telephone interviews, there is the possibility of lost confidentiality related to the audio-recording.
- If asked to complete the follow-up telephone interviews, there is also the possibility that you may be uncomfortable answering questions about substance use or treatment.

In order to minimize these risks:

Baseline Data Collection:

- We will do everything we can to keep others from learning about your participation in this study:
    - The data manager for this research study will work with the sources listed above to merge and disguise your identity in all data files.
    - The data manager will follow all procedures to assure the confidentiality of personally identifiable and sensitive data.
    - Once the data is merged, any identifiable information will be destroyed.
    - We will not store any contact information collected from you with data collected from existing administrative, health, and public databases.
    - The data will be stored on a secure, password protected computer on a secure Indiana University network.
- You may refuse to answer any question you are uncomfortable with.
- You may request to take a break if you feel tired.
- You can request we stop the interview at any time.

Follow-Up Telephone Interview:

- For all audio recorded interviews, we will store the recordings on a secure, password protected folder that is only accessible by the research team.
- During the audio-recorded interviews, you may choose not to participate in any of the three interviews if asked, you may skip any question you don't want to answer, and you may end the interviews at any time.

BENEFITS OF TAKING PART IN THE STUDY

The benefits to participation that are reasonable to expect for the individual are:

- The opportunity to discuss any past substance use behavior and/or reflect on your recent overdose.
- A list of resources that may benefit you as someone who uses opioids (these resources will be provided even if you do not choose to participate in the study).

- The opportunity to inform research that may lead to the development of stronger interventions to assist people at risk of future opioid overdose.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Participation is completely voluntary. You are under no obligation to participate, and you can still take part in POINT services even if you choose not to take part in the study.

If asked to complete the series of follow-up telephone interviews, participation is voluntary and you may decline this portion of the study and remain a study participant. Further, you may choose to participate in the first interview and decline participation in the additional two interviews. Each interview is voluntary.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor (the National Institutes of Health (NIH)), the Indiana Clinical and Translational Sciences Institute, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your research records, and the Regenstrief Instititute.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

PAYMENT

You will receive a $30 gift card at the end of baseline data collection.

If asked to complete a follow-up telephone interviews, a $30 gift card will be mailed to you after each interview is completed. You will also have the option to pick these gift cards up at the hospital in a sealed envelope.

CONTACTS FOR QUESTIONS OR PROBLEMS

For questions about the study, contact Dr. Alan McGuire at (317) 988-2725. For questions about your rights as a research participant, to discuss concerns about a research study, to obtain information, or to offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

VOLUNTARY NATURE OF THIS STUDY

Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Deciding not to participate or leaving the study will not result in any penalty or loss of benefits and will not affect your current or future relations or the quality of care you receive from IU Health Methodist.

Depending on when you choose to leave the study, we may have already obtained information from the sources listed in "Procedures from the Study." If we have already obtained this information, the data will be kept for study purposes because this information is de-identified when given to us (i.e. we would not be able to determine which records belong to you). If we have not already obtained this information, we would not obtain these records on you at all.

SUBJECT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study.

I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____

Date:_____(must be dated by the subject)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____

Date:_____

Form date: September 17, 2019

INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Following Opioid Overdose Survivors to Improve Emergency Department-Based Services: A Pilot Study

You are invited to participate in a research study that seeks to understand what happens to opioid overdose survivors and people admitted to the hospital for opioid-related health issues after they leave the emergency department. The study is being conducted by Dr. Alan McGuire, at the IU Richard M. Fairbanks School of Public Health and is funded by the National Institute on Drug Abuse (NIDA).

STUDY PURPOSE

The purpose of this study is to understand what happens to people who survive an opioid overdose or who are admitted to the ED for an opioid related issue after they leave the emergency department. More specifically, we want to understand if and how people engage with substance use disorder treatment, their future engagement with various health and social services, and changes in their health.

NUMBER OF PEOPLE TAKING PART IN THE STUDY

If you agree to participate, you will be one of approximately 800 individuals enrolled in the study.

PROCEDURES FOR THE STUDY

If you agree to be in the study, you will

- Complete an interview that will take approximately 30-60 minutes. The interview will cover such topics as: basic demographic information, social support, living arrangement, drug use, context of your current overdose, substance use treatment history, physical and mental health, and contact information we may use to follow-up with you at a later date.
- We will also collect information about you from the following existing databases:
    - Indiana University Health: Methodist Hospital, Ball Memorial Hospital, or University Hospital
    - Indiana University Health Physicians
    - Eskenazi Health
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    - Marion County Health Department/Coroner's Office (*state health/vital records*)
    - Delaware County Health Department/Coroner's Office (*state health/vital records*)
- We will continue to collect information from these system from three years prior to today and two years after today.
- You <u>may</u> also be asked to participate in a follow-up telephone interview after you leave the emergency department (ED). If so,
    - A researcher will ask about the types of treatment resources you accessed since leaving the ED, types of resources you find most helpful, your motivation, your experiences with medication assisted treatment, and your overall recovery experience.
    - The interview will last between 30-60 minutes and will be audio recorded.
    - The interview will be conducted over the telephone.

RISKS OF TAKING PART IN THE STUDY

Potential risks of taking part in this study include:
Baseline Data Collection:

- It is possible that your identifiable data including your personal health information may be compromised during transfer to Indiana University.
- If your data are compromised, you may be identified as having received emergency department treatment for an opioid overdose.
- You may feel uncomfortable answering some of the more sensitive interview questions, particularly those regarding substance use.
- You may experience fatigue completing the interview.

Follow-Up Telephone Interview:

- If asked to complete a follow-up telephone interview, there is the possibility of lost confidentiality related to the audio-recording.
- If asked to complete a follow-up telephone interview, there is also the possibility that you may be uncomfortable answering questions about substance use or treatment.

In order to minimize these risks:
Baseline Data Collection:

- We will do everything we can to keep others from learning about your participation in this study:
    - The data manager for this research study will work with the sources listed above to merge and disguise your identity in all data files.
    - The data manager will follow all procedures to assure the confidentiality of personally identifiable and sensitive data.
    - Once the data is merged, any identifiable information will be destroyed.
    - We will not store any contact information collected from you with data collected from existing administrative, health, and public databases.
    - The data will be stored on a secure, password protected computer on a secure Indiana University network.
- You may refuse to answer any question you are uncomfortable with.
- You may request to take a break if you feel tired.
- You can request we stop the interview at any time.

Follow-Up Telephone Interview:

- For all audio recorded interviews, we will store the recordings on a secure, password protected folder that is only accessible by the research team.
- During the audio-recorded interview, you may choose not to participate if asked, you may skip any question you don't want to answer, and you may end the interview at any time.

BENEFITS OF TAKING PART IN THE STUDY

The benefits to participation that are reasonable to expect for the individual are:

- The opportunity to discuss and reflect on any past substance use behavior and/or your recent overdose.
- A list of resources that may benefit you as someone who uses opioids (these resources will be provided even if you do not choose to participate in the study).
- The opportunity to inform research that may lead to the development of stronger interventions to assist people at risk of future opioid overdose.

ALTERNATIVES TO TAKING PART IN THE STUDY:

Participation is completely voluntary. You are under no obligation to participate, and you will still receive the same standard of care from hospital staff even if you chose not to take part in the study.

If asked to complete a follow-up telephone interview, participation is voluntary and you may decline this portion of the study and remain a study participant.

CONFIDENTIALITY

Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, the study sponsor (the National Institutes of Health (NIH)), the Indiana Clinical and Translational Sciences Institute, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP) who may need to access your research records, and the Regenstrief Institute.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects;
(4) for the purpose of auditing or program evaluation by the government or funding agency;

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

PAYMENT

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I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Subject's Printed Name:_____

Subject's Signature:_____

Date:_____(must be dated by the subject)

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____

Date:_____

Form date: September 17, 2019