COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: CODE-PRO (Capturing Opioid Use Disorder Electronically & Patient Reported Outcomes)
Principal Investigator: Kathryn Hawk, MD, MHS
Funding Source: Patient-Centered Outcomes Research Trust Fund, U.S. Department of Health and Human Services

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to look at how we can improve the use of electronic records to provide better information to doctors and researchers.
- Study procedures will include setting up an account to access your electronic records and allow researchers to access them, filling out three electronic surveys, and possibly receiving one phone call.
- There are no visits required for this study outside of your ED visit today.
- Enrollment today should not take more than 20 minutes. Surveys will take less than 5 minutes.
- There are some risks from participating in this study. Somebody outside of the research team or your physician may learn confidential information about you.
- The study may have some benefits for you**.** You will be able to access your medical information more easily using your phone or a mobile device.
- There are other choices available to you outside of this research. You can access your health records without using an electronic account.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You can also 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.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Take as much time as you need before you make your decision. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, you will have to sign this form.

Why is this study being offered to me?

We are asking you to take part in a research study. The study will look at how electronic health records are used for patients with substance use disorder. We also want to find out what information about patients' opioid use would be most helpful to physicians in the emergency department. We want you to take part in this study because your answers on a health survey suggest you are using opioids. You could meet criteria for opioid use disorder. We are looking for about 200 patients from the Yale-New Haven Hospital to join the study.

What are you asking me to do and how long will it take?
This is what you will do if you agree to participate in this study:

1. You will register for a Hugo account using your own mobile device. You can use a device belonging to the research team for registration if you do not have your own. A researcher will help you. Hugo is a mobile health platform that connects patients with their electronic medical records. Hugo can also send electronic surveys to you by text or email. To register, you will have to enter basic information including

first name, last name, and email address. You will have to choose a secure password. To complete your registration, you will have to accept standard terms and conditions and a privacy notice from Hugo Health. Hugo Health is the developer of the Hugo platform.

2. You will need to check your email and click the confirmation link to activate your new Hugo account. If you do not have an email account, a member of the research team can help you set one up. You can choose from a variety of free and commercial email providers.
3. During the registration process, you will see a list of health systems and pharmacies that use Hugo. You will need to link your account with the systems and/or pharmacies where you have received care. You will enter your patient portal username and password as all of these are password-protected. If you forget your password, you can reset it by. You will get an email with a link to create a new password. A research assistant can help you with setting up any new accounts, finding usernames, and resetting your passwords.
4. Research assistants will help you link your Hugo account with this research study. Ask them any questions about how your data will be shared with others. They can explain any study information that you think is unclear.
5. We will ask you to agree to share your data. That will include demographics and your health information. These are the examples of health information: your diagnoses, medications, treatments, and other information about your substance use. It is possible that during this study, clinician notes may become available and be shared.
6. Researchers will only have access to your data for one year after you agree to take part in this study. You can use your Hugo account and access your electronic health records for as long as you want.
7. Once you have linked your accounts, we will send you a short survey by email or text to your mobile device today. The survey should take no more than 5 minutes to complete. Once you finish the survey, you will receive a $10 electronic gift card. We will send it right away to the email linked with your Hugo account.
8. We will send you a second short mobile survey via email or text two days after you join this study. Once you complete the survey, we will send you a $10 electronic gift card to your email.
9. After the second survey, we may call you to discuss your medications and treatment. This call should take less than five minutes.
10. We will send you a third short mobile survey via email or text one month after joining this study. Once you complete the survey, we will send you a $10 electronic gift card to your email. There will not be any more surveys or phone calls about this study.

What are the risks and discomforts of participating?

We do not expect any physical risks to you from taking part in this study. You may feel uncomfortable answering some questions about your substance use. You will spend some time setting up your Hugo account and completing your follow-up survey. Taking part in this study should not make your ED visit any longer. There is always a risk that your data may be shared with people who should not have access to it. We are doing everything we can to not let that happen.

How can the study possibly benefit me or other people?

You may have easier access to your health records in the Yale New Haven Health system or other health systems that use Hugo. The study may help people in the future as well. We hope to improve the way we collect and track information about opioid use. This way, physicians in the emergency department would have the most useful information they need to help their patients.

Will I be paid for participation?

You will get a $10 electronic gift card for each of the three surveys you complete. Electronic gift cards will be sent right after each survey to your email address listed in your Hugo account.

Are there any costs to participation?

You will not have to pay for taking part in this study. The only costs include your time joining the study today and completing the surveys.

What are my choices if I decide not to take part in this study?

You do not need to participate in this study to have access to your medical records.

How will you keep my data safe and private?

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 received 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 participants. 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.

The risk to patient privacy is no different with this study than it is with any other study that securely collects and appropriately stores personally identifiable information or protected health information. The risk may be less since researchers are only getting access to available past and present patient data for a period of one year following enrollment. After this study period, researchers will no longer have open access to your health data.

We understand that information about 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. 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. Any identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained. We will also share information about you with other researchers for future research but we will not use your name or other identifiers. We will not ask you for any additional permission.

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

- Demographics like age, gender and race
- Research study records
- Medical diagnoses
- Medication, treatment and prescriptions
- Other information relevant to your health and substance use

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

1. The U.S. Department of Health and Human Services (DHHS) agencies
2. Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
3. Companies who manage or provide Electronic Medical Record (EMR) for Yale New Haven Health System.
4. The Principal Investigator, Kathryn Hawk, MD, MHS and other research staff who are helping her with the study.
5. Me2Health dba Hugo Health, the company that owns the mobile application, in compliance with its Privacy Policy.
6. Health care providers who provide services to you in connection with this study.
7. Those individuals at Yale who are responsible for the financial oversight of research including billings and payments.

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 the Yale School of Medicine are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential. In addition, note that the Hugo is not required to comply with HIPAA but is required to maintain the confidentiality of your information as described in the privacy notice to be provided when you sign up for Hugo.

If, after you have signed this form, you have any questions about your privacy rights, you can speak to Yale Privacy Officer at 203-432-5919.

If I agree to take part in this research study, will I be told of any new risks or findings that may be found during the study?

Yes. You will be told if any new information becomes available during the study that could cause you to change your mind about continuing to participate or that is important to your health or safety.

What if I change my mind about this authorization?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Kathryn Hawk, Yale Department of Emergency Medicine, 464 Congress Ave, Suite 260, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.

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 take part, or you can choose not to take part in this study. You also can change your mind at any time. Refusing to participate or ending participation before the study is over 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). It will not harm your relationship with your own doctors or with Yale-New Haven Health or the care that you receive. However, you will not be able to enroll in this research study as a study participant if you do not allow use of your information as part of this study. You do not give up any of your legal rights by signing this form.

How can I end participation?

If you do participate, 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. The telephone number to do this is 203-737-4703. Within the Hugo application, you can discontinue sharing your study data at any time.

The researchers may withdraw you from participating in the research if necessary, likely only if there are unexpected concerns about the reliability of the data. Withdrawing from the study will involve no penalty or loss of benefits to which you are otherwise entitled.

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, you can call the Principal Investigator, Kathryn Hawk, at 203-737-4703.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

Where can I find information about this study?

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*. 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 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.

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 details 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 of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

Permission for Future Contact:

Permission to allow study staff to contact me about future research is completely voluntary. If I agree, the study team may contact me in the future about research on substance use. These studies would be approved by the IRB. At that time, I can decide whether or not I am interested in participating in a particular study. I will then be able to schedule an appointment to learn about the research project.

Please **initial** the appropriate line below:

_____ I request that study staff contact me about future studies for which I may be eligible.

_____ I do NOT want study staff to contact me about future studies for which I may be eligible.