**CLINICAL RESEARCH INFORMED CONSENT FORM**
**AND**
**AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION**

**YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL**

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|---|---|
| **Sponsor / Study Title:** | **National Institute on Drug Abuse /Randomized Controlled Trial to Evaluate Feasibility and Preliminary Efficacy of an Opioid Stewardship Program in Hospitalized Patients with Chronic Pain** |
| **Protocol Number:** | **2000032638** |
| **Principal Investigator: (Study Doctor)** | **Melissa Weimer, DO, MCR** |
| **Telephone: 203-506-2423** | |
| **Address:** | **Yale New Haven Hospital**<br>**20 York Street**<br>**New Haven, CT, 06510**<br><br>**Yale New Haven Hospital St Raphael' s Campus**<br>**1450 Chapel St**<br>**New Haven, CT, 06511** |

**SUMMARY OF KEY INFORMATION ABOUT THIS STUDY**
We are asking you to join a research study. This consent form contains important information to help you decide if you want to join the study or not.

**PURPOSE:**
The purpose of this research study is to learn whether a hospital-based program (called the opioid stewardship intervention) designed to improve pain management for hospitalized people with chronic pain who take opioid medications is feasible to do and improves these outcomes.

This study will test the feasibility and effectiveness of a program in which a pharmacist/doctor team reviews the medical record of a hospitalized adult patient to determine whether the care the patient receives is in line with best practices for management of pain and opioid medications. The pharmacist/doctor team will provide advice to the clinical team of each patient on ways to improve pain management and reduce risk of opioid-related harms, such as overdose, addiction, or side effects.

**DURATION:**
Your participation will last during your hospitalization to about one month after you leave the hospital.

**PROCEDURES:**
Your study participation will take about 1 hour total, spread over two visits. You will be randomly assigned to the opioid stewardship intervention or to continue treatment as usual (TAU) for your pain. There will be 1 visit for a baseline interview and 1 follow-up visit shortly before you are

discharged from the hospital. During these visits, study staff will ask you questions about your pain, your mood, recent medication and drug use, and your behaviors. We will also review your medical record during the hospitalization and thirty days after your discharge from the hospital.

**POTENTIAL RISKS:**

There are some risks that are possible from participating in this study:

- Some of the questions we will ask you are personal and may make you uncomfortable.
- You may experience some temporary discomfort or side effects, including increased pain, if your clinical team decides to take action on pain management recommendations provided by this study.
- As with all research, there is a risk of a privacy breach of your confidential health data.

See section "What are the risks of the study?" for additional information.

**POTENTIAL BENEFITS:**

This study may have no benefits for you. However, you may experience better pain management, fewer side effects from opioid medications, and reduced risk of harms from your opioid medications. This study may help the study doctors learn more about ways to best treat patients with chronic pain on opioid medications.

**COSTS:**

There is no cost to you to participate in this study. Neither you, nor your insurance provider, will be charged for anything done only for this research study. Standard medical care for your condition is your responsibility or the responsibility of your insurance provider or governmental program.

**VOLUNTARY PARTICIPATION:**

This is a voluntary research study and 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. You do not have to join the study. If you do not participate in this study, you can still receive a usual treatment medication for the management of OUD or any symptoms of withdrawal.

**END OF CONSENT SUMMARY**

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.

**Instructions:**
Please read this consent form carefully and take your time deciding about whether to participate. As the researchers discuss this consent form with you, please ask them to explain anything that you do not fully understand. The purpose of the study, procedures, benefits, risks, inconveniences, discomforts, and other important information about the study are detailed below. If you decide you are interested in participating and wish to proceed to the next step, we will ask you to complete a short quiz at the end of this form to ensure you understand what is involved in your participation. After you complete the quiz, we will review your answers to make sure you understand what will be involved in your participation. Then, you will be asked to sign and date this consent form. You will be given a copy of this form to keep. Please feel free to discuss this with any family members, doctors, or important figures in your life before signing and dating the consent form. You do not have to make this decision today.

**Why is this study being done?**
The purpose of the study is to learn whether hospitalized people with chronic pain who take opioid medications are more likely to have improvements in their pain and decreases in their risk of harms related to opioid use if they participate in an "opioid stewardship program," a program in which doctors make recommendations that follow the best guidelines for pain management for people who take opioid medications.

**Who is funding this study and where is it being conducted?**
This study is funded by the National Institute on Drug Abuse (NIDA), one of the branches of the National Institutes of Health (NIH). The research is being conducted at Yale New Haven Hospital under the supervision of the study doctor listed on the first page of this form.

**The following definitions may help you understand this study:**

> **Randomization** means a computer program will place you by chance (like a flip of a coin) in one of the two study groups: opioid stewardship program or treatment as usual (TAU). About half of study participants will receive the opioid stewardship program and half will receive TAU before being discharged from the hospital.
>
> You should not agree to take part in this study if you are not willing to be in either of the two study groups.
>
> **Treatment as usual (TAU)** is the same care you would receive from your hospital doctors if you choose not to participate in this research.
>
> **Researchers** means the study doctor and research personnel at the study site.

**Why am I being asked to take part in this research study?**
You are being asked to take part in this study because you have chronic pain, take opioid medications, and are hospitalized.

**Do I have to take part in this research study?**
No. You have the right to choose whether you want to take part in this study. If you decide to participate and later change your mind, you are free to stop at any time. If you decide not to take part in this research study, it will not change your legal rights or the quality of health care that you receive in the Yale New Have Health System.

**How many people will take part in this study?**

About 100 people will take part in this study.

**Who will be asked to participate?**
This study will recruit hospitalized persons 18 years of age or older with chronic pain who are prescribed opioids.

**What will my responsibilities be during the study?**
While you are part of this study, it is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your contact information changes.
- Report to the researchers any injury or illnesses while you are in the study even if you do not think they are related to your participation in the study.

**What is involved in the study?**
If you volunteer to take part in this research study, you will be asked to sign and date this consent form and will complete two interviews. All questions asked in this study are for research purposes only.

**Screening Phase**
Screening for this study will involve reviewing your medical records and asking you questions. This phase takes place before you sign the consent form to make sure it is safe and appropriate for you to be in this study.

The following activities will help us determine if you qualify to participate in the study.

- We will review your medical chart for evidence that you are an adult, hospitalized on a medical floor at Yale-New Haven Hospital, and have chronic pain.
- You will be asked about your chronic pain and pain medication use.

**The Baseline Interview**
The baseline interview will begin only after you have provided consent. The baseline phase generally takes about 10-20 minutes and includes assessments regarding your pain, pain medications, mood, medical history, lifestyle, and behaviors.

**The Intervention Phase**

- **Opioid Stewardship program:** If you are randomized to receive the opioid stewardship program, you do not need to do anything. A pharmacist/physician team will review your medical record, focusing on your pain levels and pain medications, and submit recommendations to your care team about best practices for improving your pain and reducing risks of opioid use. These recommendations may include increasing or decreasing your opioid medications, adding or removing other medicines, and seeking additional care. Your doctors, not the study doctors, will decide whether to consider the recommendations by the study team.
- **TAU:** If you are randomized to the treatment as usual group, you will receive the same care you would receive if you do not enroll in the study.

**The Follow-up Phase**
One follow-up interview will be scheduled shortly before you are discharged from the hospital.

The follow-up visit may take around 10-20 minutes. You will be asked to answer questions similar to the ones you answered on the baseline interview, including questions about pain, mood, and your satisfaction with your pain care.

About thirty days after you leave the hospital, we will check your medical record to determine if you have been readmitted to the emergency department or the hospital.

**Staying in Touch During the Study**

We will ask you for different ways to contact you so we can remind you of the follow-up interview. We will also ask you to let us know about other people who can pass you a message to contact us. If we need to contact those people, we will not reveal any information about the study, unless you have signed a release of information for us to do so. We will only contact the people you give us permission to contact for the purpose of reminding you of appointments if we can't reach you directly.

**How long can I expect to be in this study?**

This study includes a baseline interview, close to the time of enrollment, and a follow-up interview shortly before your hospital discharge. We will also review your medical record at 30 days after you are discharged from the hospital. The total duration of the study includes the days you are hospitalized after enrollment and about 30 days after you are discharged.

**What are the risks of the study?**

Psychological Stress: Some of the questions we will ask you may make you feel uncomfortable, upset, embarrassed, or disappointed. Questions will cover your personal habits, lifestyles, and drug and/or alcohol use. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time. Refusal to answer any questions or deciding to not participate in the study will not affect the healthcare you receive at study site. Some of these questions may include whether you have feelings of harming yourself.

If you are having suicidal thoughts call the study doctor at the telephone number listed on the first page of this form. If you feel in crisis, you can call 911 and/or a Nationwide Suicide Hotline that is answered 24 hours a day with a skilled, trained counselor. One example is the National Suicide Prevention Lifeline at 1-800-273-TALK (8255).

Temporary Discomfort: It is possible that you may feel some pain or discomfort if your care team decides to change your pain management regimen in response to the study's recommendations. This discomfort might include increased pain, opioid withdrawal effects, or other effects of regimen changes. Every effort will be made to minimize any discomfort. If you experience discomfort and are concerned it may be due to the study, please discuss this with your clinical care team in the hospital.

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: There may possibly be other side effects that are unknown at this time. If you are concerned about other unknown side effects, please discuss this with the researchers and your study doctor. There may be risks that are unforeseeable.

**How will risks be minimized or prevented?**

You will be closely monitored by study staff. Trained study staff will do everything possible to

prevent or minimize possible risks. You will be referred for appropriate medical treatment if you are injured in the study. Your data will be protected in accordance with Yale and NIH standards.

**If I agree to take part in this research study, will I be told of any new risks/findings that may be found during the study?**
Yes. You will be told if any significant new information becomes available during the study that could cause you to change your mind about participating or that is important to your health or safety.

**What are the possible benefits of this study?**
If you agree to take part in this study, there may or may not be direct benefits to you. The researchers cannot guarantee that you will benefit from participation in this research. You may experience improvements in your pain or reduced risk of harms from your opioid medications.

Information learned from this study may benefit others with chronic pain who use opioid medications in the future.

**What options are available if I decide not to take part in this research study?**
You do not have to participate in this research to receive care for your medical concerns. Instead of being in this study, you have the following options:

- You can receive standard care for your condition at this facility.
- You can discuss further options with your hospital doctors.

Please talk to the researchers or your hospital doctors about your options.

**Will I be paid if I take part in this research study?**
Yes. You will be paid, via a gift card, $25 for enrolling and $25 for completing the follow-up interview shortly before discharge.

If you leave the study early for any reason, you will be paid only for the parts of the study you have already completed.

**How will I be paid?**
You will receive study payments in the form of two gift cards. You will receive one $25 gift card upon completion of the baseline interview and another $25 gift card upon completion of the final interview.

**Will my insurance provider or I be charged for the costs of any part of this research study?**
No. Neither you, nor your insurance provider, will be charged for anything done only for this research study. However, the standard medical care for your condition (care you would have received whether or not you were in this study) is your responsibility or the responsibility of your insurance provider or governmental program.

**What will happen if I believe I am harmed as a result of taking part in this study?**
It is important that you report any illness or injury to the research team listed at the top of this form immediately. If you think that you have been hurt by taking part in this research, call the study doctor at the number listed on the first page of this form, as soon as possible. The study will not provide treatments for these illness or injury but will help you seek appropriate medical care.

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine and Yale-New Haven Hospital do not provide funds 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 available.

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

**Can I stop taking part in this research study?**
Yes. If you decide to participate and later change your mind, you are free to stop taking part in the research study at any time.

If you decide to stop taking part in this research study, it will not affect your relationship with study staff or study doctors. Whether you participate or not will have no effect on your legal rights or the quality of your healthcare.

**Are there procedures I should follow after stopping participation in the research?**
You may decide to stop your participation at any time. There are no consequences for early withdrawal. If you decide to stop taking part in the research study:

- Let your study staff know immediately that you wish to withdraw from the research, so that stopping can be done safely.
- Discuss your future medical care options your regular doctor and/or the study doctor.
- If you are willing, you may be asked to complete some final study questionnaires.

**If I agree to take part in this research study, can I be removed from the study without my consent?**
Yes. You should know that the study doctor may take you out of this study if it is deemed necessary, even if you would like to continue. The decision to take you out of this study may be made to protect your health and safety or the safety of others. You may also be removed because it is part of the research plan that people who develop certain conditions may not continue to participate. If you are asked to end participation early, you will be compensated for any research activities that you have completed.

**Will my information be kept confidential?**
Every effort will be made to maintain the confidentiality of your study records, but it cannot be guaranteed. Confidentiality and the protection of study participants' privacy is of the utmost importance at all times. Records of your participation in this study will be held confidential except when sharing the information is required by law or as described in this informed consent. The Investigator, the sponsor or persons working on behalf of the sponsor, and under certain circumstances, the Yale Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. This means that absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

To help us further protect your information, this research is covered by a Certificate of Confidentiality from the U.S. Department of Health and Human Services (HHS). With this

Certificate of Confidentiality, the researchers cannot be forced to disclose information that may identify you in any judicial, administrative, legislative, or other proceeding, whether at the federal, state, or local level, even in response to a court order or subpoena. There are situations, however, where we are required to disclose information consistent with state or other laws, such as:

- to HHS for audit or program evaluation purposes
- if you pose imminent physical harm to yourself or others
- if you pose immediate mental or emotional injury to yourself
- if the researchers learn that a child has been, or may be, abused or neglected
- If the researchers learn that an elderly or disabled person has been, or is being, abused, neglected or exploited.

The researchers will not, in any case, disclose information about you or your participation in this study unless it is included in the Authorization for Use and Disclosure of Protected Health Information for Research Purposes or as stated above.

The Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about your involvement in this research study. In addition, the researchers may not use the Certificate to withhold information about your participation in this research study if you have provided written consent to anyone allowing the researchers to release such information. This means that you or your family must also actively protect your privacy.

We will not share any of your information with other researchers for future research studies, even if we remove all identifiers such as your name.

**Whom to contact about this study**

During the study, if you have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on the first page of this consent document

The Yale Human Research Protection Program is an independent entity established to help protect the rights of research participants. If you have any questions regarding your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail: Human Research Protection Program, P.O. Box 208327, New Haven CT 06520
- or call: (203)785-4688
- or by email: hrpp@yale.edu

Please reference study number 2000032638 when contacting the Human Research Protection Program.

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at (203) 432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, *Melissa Weimer, DO, MCR*, at *203-506-2423.*

## COMPREHENSION QUESTIONS

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|---|---|---|---|
| 1. | My participation in this study is entirely voluntary. | ☐ True | ☐ False |
| 2. | I will be asked to participate in one follow up visit shortly (within 48 hours) before I am discharged from the hospital. | ☐ True | ☐ False |
| 3. | There are no possible risks or discomforts associated with my participation in this research study. | ☐ True | ☐ False |
| 4. | The study doctor may end my participation in this research study to protect my health and safety, even if I would like to continue. | ☐ True | ☐ False |
| 5. | The study is guaranteed to improve my pain. | ☐ True | ☐ False |

## AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Some information about you may be shared with medical staff to conduct the study. This information might include the fact that you are in the study, your study visit dates, and any information necessary to treat you in the event of a medical or psychological emergency. None of the other information that you give us during the study will be part of your medical record; it will only be part of your research record.

You should know that certain organizations that may look at and/or copy your medical records/clinic treatment records, as they relate to your participation in this study, for research, quality assurance, and data analysis include:

- The National Institute on Drug Abuse (NIDA) (the study sponsor and its agents), study monitor(s), and auditor(s)
- NIDA's independent Clinical Trials Network's Data and Safety Monitoring Board
- Representatives from Yale University and the Yale Human Research Protection Program
- Your providers who are participants in the Electronic Medical Record (EMR) system
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator, Dr. Melissa Weimer, and other members of the Yale study team.

By signing and dating this authorization, you are acknowledging that any information that could be used to identify you will be treated in strict confidence to the extent allowed by the law. Nevertheless, some uses and disclosures of your information are necessary to conduct the study. If you agree to be part of this study, you will also be allowing the uses and disclosures of your private health information as needed for the purposes of this study as described in this consent and authorization.

We may put information from this study into your Electronic Medical Record (EMR), including recommendations for improving pain management and managing opioid risk. Your health care providers will be able to see these recommendations. Other people or groups such as a health insurance company who have access to your EMR may see this information.

Once your health data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here.

"Private health information" means information that identifies you and is collected:

- During this study
- From your past and current medical records maintained by your regular health care providers (including, if applicable, the study site), to the extent the information is relevant to this study or to your eligibility for this study

By signing and dating this authorization, you are agreeing that your private health information may be disclosed to and used by:

- The study doctors and other health care providers involved in this study
- Their staff
- The sponsor of this study (National Institute on Drug Abuse) and its agents

The findings of this study may be used for scientific meetings, written reports, and publications, but no information that could be used to identify you will be disclosed for these purposes.

Anyone obtaining access to your private health information under this authorization must agree to protect your information as required by this authorization.

This consent to use your private health information as described above does not expire.

If you later change your mind, you can revoke (take back) this consent by writing to the study doctor, saying that you no longer wish to allow your private health information to be used for this study. If you revoke your consent, you may no longer be able to participate in the study. Moreover, we cannot undo uses or disclosures of your private health information that have already taken place before you revoke consent and may continue to use or disclose previously obtained health information to maintain the integrity or reliability of the current research.

If you decide not to sign and date this form, you will not be able to take part in the study.

**STATEMENT OF AUTHORIZATION**

I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing and dating this form.

_____

Participant's Name (Printed)

_____ _____

Participant's Signature Date

**CONSENT TO PARTICIPATE**
**YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.**

Your signature and date below certify the following:

- I have read (or been read) the information provided above.
- I have received answers to all of my questions and have been told who to call if I have any more questions.
- I have freely decided to participate in this research.
- I understand that I am not giving up any of my legal rights.

_____
Participant's Name (Printed)

_____ _____
Participant's Signature Date

_____
Name of Person Obtaining Consent (Printed)

_____ _____
Signature of Person Obtaining Consent Date