	CONSENT TO PARTICIPATE IN A RESEARCH STUDY (HFH IRB form rev: 02/2012)	DATE: MRN: NAME:

APPROVAL PERIOD Nov 13, 2014 – Oct 27, 2015 Institutional Review Board	**PROJECT TITLE:** Adjunct Methadone to Decrease the Duration of Mechanical Ventilation in the Medical Intensive Care Unit

Adjunct Methadone to Decrease the Duration of Mechanical Ventilation in the Medical Intensive Care Unit

Type: Informed Consent Form

NCT#02025855

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1. WHY IS THIS RESEARCH BEING DONE?

To make reading this consent form easier, the word 'you' throughout the consent form, refers to the person for whom you are the power of attorney or legal guardian.

This research is being conducted to evaluate if adding methadone, a pain medication, to the current Henry Ford Hospital pain and sedation protocol, will reduce the time a patient spends on mechanical ventilation (breathing machine). Methadone is an approved agent by the Food and Drug Administration (FDA) for pain management, and it has been studied extensively in humans, both adults and children. It has been proven safe and effective in preventing opioid withdrawal and managing moderate to severe pain. As part of this research, 23 patients will receive methadone, and 23 patients will receive a placebo in addition to the standard Henry Ford Hospital pain and sedation protocol. You have been asked to take part in a research study because you have required mechanical ventilation and treatment with a Henry Ford Hospital pain and sedation protocol above a certain dose. The purpose of this research study is to determine if adding methadone to the standard Henry Ford Hospital pain and sedation protocol will decrease the need for short acting pain medication and the time on mechanical ventilation.

There will be 46 people in this research study at Henry Ford Health System (HFHS).

As part of this study, you will be given the drug methadone. This drug is approved by The Food and Drug Administration for this purpose and has been used for this purpose.

2. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

There will be two groups in the study. The group you are assigned to will be chosen by chance (like flipping a coin).

You may be taking a placebo (a liquid that looks like the study drug but has no drug in it). Neither you nor your doctor will know which treatment you are receiving.

This study will be completed while the patient is in the intensive care unit. The patient will receive a dose that is calculated based on their current pain medication requirements, which will vary for each patient. The medication will be administered by mouth or by feeding the tubes three times daily for 7 days or until the patient no longer requires mechanical ventilation, whichever occurs first. There will be no required activities after the patient leaves the intensive care unit and all study medication will have discontinued prior to transfer or discharge from the intensive care unit.

Participation in this study will last a total of 7 days. As part of this study, you will have the following procedures.

Extra and experimental: You will receive methadone or placebo capsules by mouth or by feeding tube three times daily for a maximum of 7 days.

Extra and not experimental: A baseline electrocardiogram (ECG), which is frequently performed in the intensive care unit and determines if any abnormal heart rhythms are present.

3. WHAT ARE THE RISKS OF THE STUDY?

You should tell the person obtaining your consent about any other medical research studies you are involved in right now. While you are in the study, you are at risk for the following side effects:

- Likely: Sweating, drowsiness, rash, itching, urinary retention
- Less Likely: Respiratory depression, rash, itching, urinary retention
- Rare but Serious: Cardiac arrhythmias, cardiac or respiratory arrest, death

There may be additional risks or discomforts that are not known at this time.

If you are assigned to the placebo group, you will continue to receive the current standard of care. The protocol adjusts the doses of medications to achieve patient comfort. If the patient is assigned to receive methadone, they may become more drowsy and sedated initially. If you are over-sedated, the current Henry Ford Hospital pain and sedation protocol will reduce the doses of the other pain and sedation medications. If the patient remains over-sedated, the investigators and your physicians may decide to withdrawal the patient from the study.

Women who may be pregnant: There may be risks to you or to your unborn child if you are pregnant now. These risks include physical dependence/withdrawal, intrauterine growth retardation, and respiratory depression. There could be risks to you or your unborn child that the investigators cannot predict. Because of this, you cannot be in the study if you are pregnant, breastfeeding a child, or trying to become pregnant.

4. WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?

The benefits of participating in this study may include: a decreased time on mechanical ventilation, in the intensive care unit and hospital. You may not be helped by participating in this study. However, others may be helped by what is learned from this research.

5. WHAT OTHER OPTIONS ARE THERE?

You do not have to participate in this study. Your other choices may include:

- Pain and sedation can be managed without being in a study, such as with a standard Henry Ford Hospital pain and sedation protocol. These consist of receiving a pain medication and a sedative medication without the addition of methadone.
- Taking part in another study
- Getting no treatment

Talk to your doctor(s) about your choices before you decide if you will take part in this study.

6. WHAT ABOUT CONFIDENTIALITY?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

We may collect and use:

- Your existing medical records.

- New health information created during this study.
- Health insurance and other billing information.

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on, or oversee the research activities.
- Government officials who oversee research (Food and Drug Administration) and other foreign regulatory agencies.
- The Henry Ford Health System Institutional Review Board
- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.

Once your information has been released according to this consent form, it could be released again and may no longer be protected by federal privacy regulations.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at your research study information that is not in your medical record.

HFHS or others may publish the results of this study. No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This consent to use and release your personal and health information will not expire at the end of this research study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the principal investigator at the address listed on the first page of this form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

7. WHAT IF I AM INJURED?

There is no federal, state, or other program that will compensate you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this this study. You are not giving up any of your legal rights by signing this consent form.

8. WHO DO I CALL WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?

Thomas L. Smoot, Pharm D.or his staff member has explained this research study and has offered to answer any questions. If you have questions about the study procedures, or to report an injury you may contact Thomas L. Smoot at 313-916 ****. Medical treatment is available to you in case of an injury.

If you have questions about your rights as a research subject you may contact the Henry Ford Health System IRB Coordinator at (313) 916-****. The IRB is a group of people who review the research to protect your rights.

9. DO I HAVE TO PARTICIPATE IN THIS STUDY?

No, your participation in this research study is voluntary. If you decide to participate, you can stop at any time. If this happens, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFHS whether or not you participate in this study. There will be no penalties or loss of benefits to which you would otherwise be entitled if you choose not to participate or if you choose to stop your participation once you have started. You will be told about any significant information that is discovered that could reasonably affect your willingness to continue being in the study.

10. WHO ELSE CAN STOP MY PARTICIPATION?

The Principal Investigator, sponsor or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

11. WILL IT COST ANYTHING TO PARTICIPATE?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

12. WILL I BE PAID TO PARTICIPATE?

There will be no additional compensation to you for your participation in this sub-study.

13. CONSENT

You have read this consent form or it has been read to you. You understand what you are being asked to do. Your questions have been answered. Any technical terms you did not understand have been explained to you. You agree to be in this study. You will be given a copy of this consent form.

_____ _____ _____
Signature of Person Signing for Subject Date Time

_____
Print Name of Person Signing for Subject and Relationship to Subject

_____
Print Name of Subject

_____ _____ _____
Witness to Signature Date Time

_____ _____ _____
Signature of Person Obtaining Consent Date Time