HOPE Consortium Consent Form

Updated 1-24-18

Title: Rural Opioid and Methamphetamine Use Disorder Treatment Program (HOPE Consortium)

You are invited to take part in a program offered by the State of Wisconsin Department of Health Services (DHS) and the HOPE Consortium.

You have been asked to participate in this program because you reside in a county or tribal land that is participating in the program and have been diagnosed with an opioid and/or methamphetamine use disorder.

Participating Counties/Tribes:

- Forest County
- Forest County Potawatomi
- Iron County
- Lac du Flambeau Band of Lake Superior Chippewa
- Oneida County
- Price County
- Sokaogon Band of Lake Superior Chippewa
- Vilas County

You are eligible to participate in this program if you meet the following requirements:

- Reside in a participating county or tribal region
- Greater than 18 years of age
- Diagnosis of opioid and/or methamphetamine use disorder

The purpose of this program is to provide treatment services for opioid and/or methamphetamine use disorders in rural, underserved areas in Wisconsin.

Being in this program is voluntary. Whether or not you decide to take part in this program is completely up to you. You should read the following information carefully before you make a decision. In writing this consent form, some technical words were necessary. Please ask for an explanation of any you do not understand. Please ask as many questions as you wish about this consent form and what will happen to you as part of this program.

Program Plan

If you volunteer for this program, you will be asked to do the following things:

- Complete a series of short surveys to evaluate your quality of life
- Follow the treatment plan developed with you by your treatment team
- Attend scheduled appointments with program staff
- Agree to have your health information included in an electronic database

While in this program, you will work with your treatment team to develop a treatment service plan. Your plan may be abstinence-based or it may involve medication assisted treatment (MAT). That decision will be between you and your treatment team. One of the purposes of this program is to follow

the outcomes of different approaches to the treatment of opioid and/or methamphetamine dependence.

If you do enroll in this program, you will be eligible for:

- Care Coordination at no cost to you
- Buprenorphine combination products or naltrexone, if it is an agreed upon part of your opioid use disorder treatment plan. The program will pay for these medications if your insurance will not.
- Urine Drug Toxicology (UDT) testing to monitor treatment compliance. The program will pay for the UDT if your insurance will not.

You can continue in the program until the program ends OR you meet criteria for discharge from treatment services per DHS 75.03(17).

Potential Risks and Discomforts

This program uses treatment methods that are well-established and considered standard of care. Each treatment method employed in this program has the potential for risks and discomfort.

Abstinence

Common Side Effects:

- Opioid withdrawal symptoms (low energy, hot and cold sweats, muscle aches and pains, abdominal cramps, craving for opioids)
- Methamphetamine withdrawal symptoms (tiredness, low energy, headache, increased appetite, sleep disturbances, shaking and tremors, hot and cold sweats, depression, anxiety)

Rare Side Effects:

- In rare cases, methamphetamine withdrawal symptoms may include extreme anxiety, panic, and suicidal thoughts or paranoia and hallucinations

Medication Assisted Treatment (MAT) For Opioid Use Disorder Risks/Side Effects:

Common Side Effects:

- Headache
- Numbness or tingling
- Drowsiness or sleep problems
- Stomach discomfort

Rare Side Effects:

- Allergic reaction
- Life-threatening respiratory depression
- Life-threatening changes in heart rhythm (QT prolongation)
- Neonatal opioid withdrawal syndrome

If you are taking a buprenorphine combination product, you should not take benzodiazepines (tranquilizers) or alcohol. Doing so can lead to life-threatening complications. Always notify your treatment team if you are starting a new medication, or if you use anything from the street.

This program may also involve risks or discomforts that are presently not known.

Pregnancy, Birth Control and Breast Feeding
You may become involved in this program because you are pregnant and treatment for opioid and/or methamphetamine dependence is the recommended standard of care for you and your baby. It is important that you keep all appointments with your treatment team, as well as all of your obstetrics and other medical appointments.

If you become pregnant while in this program, notify your treatment providers as soon as possible so that your treatment plan can be reviewed and modified to best meet your needs.

Discuss breastfeeding with your program team and obstetrics team to plan how to best meet the needs of your baby.

Data Collection
This program will collect and store information about you, your medical history, and your program participation, including protected health information. The information will be collected using paper forms and an electronic data collection tool. All paper files will be stored in a secure office location and electronic files will be stored in an encrypted database. There is a potential for a breach of confidentiality. If such a breach were to occur there could be social and psychological discomforts.

Potential Benefits to Subjects
This program makes available treatment options that may not be available or have limited availability in North Central Wisconsin. By participating in this program you may be able to utilize some of these treatment options. Not all treatment options will be available to all participants. Priority for medication assisted treatment for opioid use disorders will be given to pregnant participants.

It is not possible to know if you will benefit by taking part in this program. Based upon experience with these services, we believe it may be of benefit to people with your condition.

Alternatives to this Program
You do not have to be in this program to get treatment or medical care at any of the participating sites. If you choose not to take part, your treatment provider will talk with you about other care options. Not all treatment options will be available at every site.

Cost for Participation
Some of the visits, tests, and procedures required as part of this program would be required for the treatment of your condition whether or not you participate in this program. These are considered "standard of care" and you/your insurance company will be billed for these costs. You will also be responsible for any associated co-payments and deductibles. The program's sponsor is providing funds to cover care coordination visits, which are not considered 'standard of care.' If your insurance will not cover the medication utilized in MAT or the UDT required for MAT compliance monitoring, the program will pay for it and you will not be billed.

You may want to meet with a representative from the Marshfield Clinic Patient Assistance Center to discuss potential costs or check with your insurance company to find out what they will pay for if you participate in the program.

Payment for Participation
There is no compensation for this program.

Data or Sample Sharing
Your de-identified data will be shared with the Marshfield Clinic Research Institute and consortium partners. The information gathered in this program may be used for research purposes and in ways that will not reveal who you are. Federal or state laws may require us to show information to government officials (or sponsors) who are responsible for monitoring the safety of this program. You will not be identified in any publication resulting from this program or in any data files shared with other consortium partners or researchers.

Emergency Care and Compensation for Injury
If you become ill or injured (physically, psychologically or otherwise) as a result of participation in this program, medical care is available at Marshfield Clinic or the health care facility of your choice. You or your health insurer would be responsible for this cost. Family Health Center of Marshfield, Inc. has no plans to compensate you for such illness or injury, financially or otherwise.

Confidentiality
Your AODA, medical, hospital, or other billing records and program material that would identify you will be held confidential and protected in accordance with each consortium partner's confidentiality policies. Medical records that identify you, the consent form you signed, and any other program information, may be inspected by the following agencies:

- *Wisconsin Department of Health Services*
- *Other governmental regulatory (or health) agencies*
- *Marshfield Clinic Research Institute's Institutional Review Board*
- *Medical professionals who need to access your medical record for your continuing care*

Because of the need to release pertinent sections of information to these parties, all efforts will be made to maintain confidentiality. These people must also keep the information confidential. Your name will not be given to anyone not associated with the program unless required by law.

It is possible that in the course of this program, information not directly related to this program, but relevant to your health may be discovered. If this happens, you will be given the information so that you may consider follow-up with your health care provider.

Withdrawal from the program
You may change your mind about taking part in this program at any time. You may withdraw your consent for the entire program. If you decide to leave the program, please let your doctor and treatment provider know so you may do so safely.

Termination from Program
Participation in the program will stop if the following occurs:

- *The sponsor, for administrative reasons, decides to take you off or terminate the program*
- *You or your legal representative choose to change or stop your participation*
- *You do not follow the program instructions*
- *Your program doctor or treatment provider feels this program is no longer helping you*

If you withdraw or are terminated from the program your program files and data will continue to be protected. The sponsor of this program requires us to retain all records and data for this program for a

minimum of seven years after the conclusion of the program. At that time, the files and data may be destroyed.

Program Contacts
For more information about this program or to report injuries or side effects, you may contact Sheila Weix, Marshfield Clinic at **1-800-782-8581** ext. 3-1208. For 24-hour emergency contact call the nearest Emergency Room or 911.

Rights of Program Participants
Being in this program is voluntary. Refusing to participate or discontinuing participation at any time will involve no penalty or loss of benefits to which you are otherwise entitled. If you choose not to sign this consent form, your relationship with your doctor or treatment provider and this institution will not change.

You are not giving up any legal rights by signing this consent document and taking part in this program.

Signing the Consent
A signature indicates that:

- You have read the above.
- You have freely decided to take part in the program described above.
- The program's general purposes, details of involvement, and possible risks and discomforts have been explained to you.

You will receive a signed copy of this consent form.

_____	_____
Signature of Subject	Date of Signature
_____	_____
Printed Name of Subject	Date of Birth
_____	_____
Signature of Presenter	Date Presented
_____	
Printed Name of Presenter	