HOPE Consortium Consent Procedure

Updated 1-24-18

1. Review HOPE Consortium Client Fact Sheet to explain to patient what you are asking for and why. **Please consider that consenting all patients who meet the criteria of opioid and/or methamphetamine use disorder, age ≥ 18, and residing in the defined region will give us the richest database to determine what works in treating opioid and/or methamphetamine use disorders in this region. It is especially important to be able to look at the outcomes for people who do not use the grant-funded services (care coordination and/or MAT) to help determine funding going forward.

2. If patient indicates that he/she is interested/willing, review the 5-page consent form with the patient and answer all questions. It is **NOT** acceptable to simply hand the patient the form and tell them to let you know if there are any questions.

3. After review of the full document, fill out the last page (signature page) **completely**. The printed and written name of the client **AND** the agency person who presented the information **MUST** be entered in order for the consent to be considered complete. Provide a **copy** to the client after signatures are completed.

4. **NOTE:** If the patient has been receiving services under the grant prior to the date of consent (i.e., this is not a brand new patient to the grant), a line may be written in on the last page directly above that statement: "You will receive a signed copy of this consent form," with the following wording: **"I consent to entry of my information from _____ (date) forward."** The patient does need to initial that statement **prior** to signing and dating the document.

   This additional line allows entry of needed information into REDCap. Example: If the consent has only today's date on it, but the care coordination assessment was completed on November 15, 2016, information from the care coordination assessment could not be entered.

5. To complete the consent process, the patient must complete and sign the HOPE Consortium Release of Information (ROI), which is a release specific to sharing of data entered into the REDCap database. Provide a **copy** to the client after signatures are completed.

6. Following completion of the consent and ROI, information needs to be entered into REDCap.
   a. It is important that the date of consent entered into REDCap reflects the earliest date on the signature page. Using the example above, the add-in line should be date 11/15/2016 (or before if an agency was providing services that should be reflected in REDCap) and the consent date recorded in REDCap would be 11/15/2016. This date would allow the care coordination assessment data to be entered for the 11/15/2016 date.
   b. The completed signature page of the consent needs to be scanned and uploaded into REDcap.
   c. The completed ROI should also be scanned and uploaded into REDCap. Date of ROI should always be the actual date on which the ROI was signed.

d. The ROI is good for one year and a new ROI must be signed by the patient on an annual basis to continue use of REDCap. An annual date for ROI update will be selected for the entire HOPE Consortium and all patients will be asked to re-sign an ROI at this time, even if it has been less than a year since original signature.

7. The entire completed consent form and ROI should be kept on file at the agency that completed the consent process. The consent and ROI are not part of the medical record, but do need to be handled like all AODA-related information that includes patient identifiers.

HOPE Consortium – Client Fact Sheet

Updated 1-24-18

What is the purpose of the HOPE Consortium?

- To provide treatment services for opioid and/or methamphetamine use disorders in rural, underserved areas in Wisconsin
- Data collected will allow us to conduct research and improve our understanding of how best to treat individuals with an opioid and/or methamphetamine use disorder in our region.

How was I chosen to participate in 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.

How do I participate in the HOPE Consortium?

If you choose to participate in this program, you will be asked to:

- 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

What potential benefits are there to participating in the HOPE Consortium?

If you choose to participate in this program, you will be eligible for:

- Care coordination at no cost to you
- Medications and urine drug toxicology agreed upon as part of your treatment plan that is not covered by your insurance

What potential risks do I face by participating in the HOPE Consortium?

- All treatment methods used by this program are well-established and considered standard for treatment of opioid and/or methamphetamine use disorders. Each treatment method employed has the potential for some risks and discomfort.
- As with any other type of data collection, there is a potential for a breach of confidentiality. If such a breach were to occur there could be social and psychological discomforts.

How are you protecting my confidentiality?

- Information that you provide will not be shared with anyone except service providers directly involved in your care.
- Data shared with the Marshfield Clinic Research Foundation and HOPE Consortium partners for research purposes will be de-identified to ensure that your privacy remains intact.
- All paper files will be stored in a secure office location and electronic files will be stored in an encrypted database.

(over)

What are my rights as a program participant?

- You may choose to not participate in this program at all. Your participation is completely voluntary and you may discontinue participation at any time.
- If you have any questions about your rights as a research subject, you may contact the Marshfield Clinic Research Institute's Institutional Review Board (IRB) at 1-800-782-8581 ext. 9-3022. The IRB is responsible for helping protect human research subjects.

Will there be any financial cost to me if I participate in the HOPE Consortium?

- You/your insurance company will be billed for costs associated with treatments that are recommended by your treatment team. You will also be responsible for any co-payments and deductibles.
- There will be no cost to you for care coordination visits.
- If your insurance will not cover medication used for treatment or urine testing required for compliance monitoring, the program will pay for it and you will not be billed.

What if I have more questions about the study?

- For more information about this program, you may contact Sheila Weix, Family Health Center Director of Substance Abuse Services at 1-800-782-8581 ext. 3-1208.

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	

2019 HOPE Consortium Release of Information for HOPE Grant Participants

Authorization for the Release of Confidential Information about Alcohol or Drug Treatment and Other Protected Health Information through the REDcap Database

I, (name of patient and DOB)_____

authorize all HOPE Consortium member alcohol and drug programs where I have been enrolled or treated and other HOPE Consortium member health care providers and entities participating in the REDcap database component of the HOPE Consortium to disclose/make information available through the REDcap database to HOPE Consortium member provider participants for electronic exchange. I also authorize the disclosure of this information to the following HOPE Consortium member agencies so they can gain access to and use the information for the purpose of providing me with treatment and care coordination:

DLM Consulting, LLC 12340 Warpath Lane Minocqua, WI 54548 715-356-5811	Family Health Center of Marshfield, Inc. – Alcohol & Drug Recovery Center 9792 Highway 70 West Minocqua, WI 54548 715-358-7377
Forest County Potawatomi Community 5416 Everybody's Rd. Crandon, WI 54520 715-478-4370	Iron County Human Services 300 Taconite St., Ste. 201 Hurley, WI 54534 715-561-3636
Price County Health and Human Services 104 South Eyder Avenue P.O. Box 88 Phillips, WI 54555 715-339-2158	The Human Service Center 705 E. Timber Dr. P.O. Box 897 Rhinelander, WI 54501 715-369-2215
Northland Counseling Services 300 Taconite St., Ste. 201 Hurley, WI 54534 715-561-3636	Marshfield Clinic, Inc. 1000 N. Oak Marshfield, WI 54449 715-387-5511
Options Counseling/Koinonia Residential Treatment Center 1991 Winnebago St. Rhinelander, WI 54501	Lac du Flambeau Band of Lake Superior Chippewa Indians 418 Old Abe Rd. Lac du Flambeau, WI 54538
Ascension Koller Behavioral Health 1020 Kabel Ave. Rhinelander, WI 54501 715-361-2805	This box left intentionally blank.

Information to be disclosed (please initial)**:**

___All data entered into the HOPE Consortium REDcap database including drug and/or alcohol treatment information. This information includes, but is not limited to: test results, Substance Use Disorder (SUD) diagnoses, appointment information, quality of life indicators, and demographic information. Treatment notes are NOT entered into this database.

Withdrawing Consent: I understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it, and that in any event this consent expires automatically as follows:

- One year from the date of signature_____(enter expiration date)

OR

- If the HOPE Consortium REDcap database ceases operations.

Re-disclosure of Information: I understand that any electronic health information about me may not be re-disclosed by HOPE Consortium entities covered by this consent to others except as allowed by state and federal regulations.

I understand that my alcohol and/or drug treatment records are protected under the federal regulations governing Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 45 C.F.R. Pts 160 & 164, and cannot be disclosed without my written consent unless otherwise provided for in the regulations.

I understand that I will not be denied services if I refuse to sign this form, but I will not be able to be a HOPE Grant participant.

I have been provided a copy of this form.

Dated_____

Signature of Patient_____

Witness_____