

Agenda Item # 5b

Research Informed Consent Form
Marshfield Clinic Health System
1000 N. Oak Avenue, Marshfield, WI 54449
SP Code: BAR20117 PI: Kathrine Barnes, MS, MPH, CPH

Title: Substance Abuse and Recovery in the Northwoods

Introduction and Purpose of Study

You are invited to take part in a research study conducted by the Marshfield Clinic Research Institute in collaboration with the HOPE Consortium.

You are eligible to participate in this research because you currently or have in the past been diagnosed with a substance use disorder, you are 18 years of age or older, and you live in the northern Wisconsin region served by the HOPE Consortium (Forest, Iron, Oneida, Price, and Vilas counties and Forest County Potawatomi, Lac du Flambeau Chippewa, and Sokaogon Chippewa tribal communities). We want to ultimately understand how to improve substance use disorder treatment and recovery support in your area and allow the people who have been directly affected by substance abuse guide the decisions that are made. Your participation will involve semi-structured interviews and/or participant observation. Interviews last anywhere from 30 minutes to 2 hours or longer – however long you choose. Participant observation lasts for approximately one full day (8-10 hours). You may participate in one or both parts of the research. You can participate anywhere from July 2018 until approximately April 2020 as much or as little as you wish. During this time, we hope to talk to a total of 15-20 eligible individuals.

Being in this study is voluntary. Whether or not you decide to take part in this research 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. Ask the study staff as many questions as you wish about this consent form and what will happen to you as part of this research.

Study Plan

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

- Participate in a semi-structured, recorded interview on:
 - how substance use disorder treatment and recovery support can be improved in your area,
 - your personal story related to substance abuse,
 - risks involved with substance abuse as you see them,
 - and what makes recovery easy or difficult for you.
- Participate in a day of participant observation:
 - The study principal investigator (PI) shadows you for a normal day to experience first-hand what substance use disorder treatment and/or recovery looks like. Sometimes it can be difficult to describe what this experience is like exactly or we get so used to a certain way of doing things that we miss how it could be improved.

You can participate in one or both parts of the study for as long or as little as you would like.

Potential Risks and Discomforts

The main risk of your participation in this study is that someone not involved with the study sees or hears what you say. Because the study involves your history of substance use, this may mean someone may find out you have this history that you did not want to know. We do several things to protect you against this risk. Only the PI will have access to the audio recorder with

your voice on it. This recording will be transferred from the audio recorder to a password-protected computer as soon as possible. You will be given a pseudonym, or fake name, by which your quotes will be identified in any presentations or academic journals and you may enter the study with a fake name; I do not need to know your real name for you to participate in this study. All identifying information that could link you to the study will be changed. For example, if you tell me you live on Main Street in city X, I may instead say you live on Oak Street in city Y. The goal is to change the identifying details so that even someone who knows you well would not be able to attribute you to any particular quote(s).

Audio recordings of your interviews and participant observation will be transcribed by GMR Transcription, who is not affiliated with Marshfield Clinic Health System. This means your audio file will be uploaded to the company's secure server, transcribed by a professional transcriber into searchable text, and re-uploaded to the company's secure server where I will download it for analysis. The audio file and transcript will then be permanently deleted from the transcriber's computer. GMR Transcription performs random security checks to ensure their transcribers are compliant with this policy. To help make this process more comfortable for you, I will not say or ask for addresses, street names, or names in the audio recording. I will notify you when I turn the audio recorder on or off.

Because this consent form is the only study document that links your name to the study, you will not be asked to sign this document. You will be provided a copy of it at the conclusion of the consent process.

It is possible the subject of the interviews could make you uncomfortable. Please feel free to stop the interview or participant observation at any time for any reason. You can choose to pick up again at a later date or leave the study entirely. If you choose to leave the study, the data gathered about you up to that point will be used unless you e-mail or write the PI and ask to have all your information removed from the study. This will mean it will be like you never participated in the study in the first place.

Potential Benefits to Subjects

Some people who participate in interviews and participant observation, also known as ethnographic research, report greater insight into their own motivations and opinions. You will also have the opportunity to potentially improve substance use disorder treatment and recovery support in your area because your suggestions and insights from this study will be provided to the individuals who coordinate much of the substance use disorder treatment and recovery support in your area.

You can also elect to receive a plain language write up of the research findings (identifiable information removed) and will be offered the opportunity to provide feedback on study results.

Alternatives to this Study

There are no alternatives to participating in this study.

Cost for Participation

There will be no additional costs to you for participating in this study. You may choose the location of your interview to reduce the cost of transportation. Unfortunately, I am not able to conduct interviews at your place of residence. If you need assistance securing a safe, private location to participate in the interview, please contact the PI who will coordinate with local agencies to identify a location in your area. Your name and identifying details will not be included on communication about securing a location (i.e., I will not forward an e-mail from you

with your name or e-mail to anyone else, I will not provide a phone number for someone to reach you at, etc), unless you choose to directly correspond with someone.

Payment for Participation

There are no monetary incentives as part of this study for your time and effort.

Data or Sample Sharing

As stated above, audio recordings of your interviews and participant observation will be transcribed by GMR Transcription, which is not affiliated with Marshfield Clinic Health System. This means your audio file will be uploaded to the company's secure server, transcribed by a professional transcriber into searchable text, re-uploaded to the company's secure server, and downloaded by me for analysis. The audio file and transcript will then be permanently deleted from the transcriber's computer. GMR Transcription performs random security checks to ensure their transcribers are compliant with this policy. To help make this process more comfortable for you, I will not say or ask for addresses, street names, or names in the audio recording. I will notify you when I turn the audio recorder on or off.

Confidentiality

All efforts will be made to maintain confidentiality. Your quotes with identifying details removed and the results of this study will be shared in presentations and written reports to policymakers, those providing substance use disorder treatment and recovery support in your area or across the nation, other researchers, and academic journals. Again, the goal is to change the identifying details so that even someone who knows you well would not be able to identify you based on any particular quote(s).

New Findings

We do not anticipate any findings that will be directly affect you as a result of this research. However, you may wish to receive a plain language write up of the research findings around the conclusion of the project in April 2020.

Please check one of the following options:

- Yes, I want to be provided with this information.
 I do NOT want to be provided with this information.

Because the goal of this research is to include your opinion and insight into research and the care you and your community may eventually have access to, it is sometimes helpful to have research participants review the proposed results before being shown to anyone outside the study. I will receive your feedback and do my best to incorporate it.

Please check one of the following options:

- Yes, I want to be contacted to review results.
 I do NOT want to be contacted to review results.

Withdrawal from the Study

You may change your mind about taking part in this research at any time. You may withdraw your consent for all or part of the research. As stated above, if you choose to leave the study, the data gathered about you up to that point will be used unless you e-mail or write the PI and ask to have all your information removed from the study. This will mean it will be like you never participated in the study in the first place.

Study Contacts

For more information about this research, you may contact Kathrine Barnes, Marshfield Clinic at **1-800-782-8581** ext. 1-7150 or at **barnes.kate@marshfieldresearch.org**.

Rights of Research Subjects

Being in this study 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 give verbal consent to this form, your relationship with your treatment providers and this institution will not change.

You are not giving up any legal rights by agreeing to this consent document or taking part in this research study.

If you have any questions about your rights as a research subject, you may contact Marshfield Clinic Health System's Institutional Review Board (IRB) at 1-800-782-8581 ext. 9-3022. The IRB is responsible for helping protect the rights and welfare of human research subjects. You may also call this number to discuss problems and concerns, to request information or ask questions, and to offer input.

IRB Approval Date
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Revised: 01/26/2018