

NCT05934591 Unique Protocol ID: UIUC IRB 23828
Improving Attendance in Community Wise
Consent Document 6/2/2023

Informed Consent to Participate Community Wise Engagement

NAME OF LEAD RESEARCHERS: Dr. Liliane Windsor, MSW and Ms. Carla Ellis

RESEARCH STUDY: We invite you to participate in a research study that seeks to evaluate Community Wise, a new program seeking to reduce substance misuse. We want to find the intervention delivery format that results in people attending the largest number of intervention sessions. To decide if you want to take part in this study, you need to know about its risks and benefits. I will go over this informed consent form with you. Once all your questions have been answered, I will ask you if you want to participate in the study. If you want to participate, you and I will sign this document. You will get a copy of it.

This research is confidential. The research records will include some information about you but this information will be stored in such a manner that will keep your identity separate from your responses. Some of the information collected about you will include your name, address and phone number. You will also be asked some personal questions and to share some of the personal experiences you've had. For example, questions and discussions will be about mental health and substance misuse. Please note that we will limit access to the research data and keep it stored in a password secured online server.

PURPOSE: The purpose of this research study is to refine the Community Wise program so that it is as efficient as it can be. This study seeks to test if different ways of delivering the intervention will increase the number of sessions people attend.

DURATION: If you agree to participate in this study you will complete up to two research interviews (each lasting up to 15 minutes) and attending eight weekly group meetings (two hours each). It will take approximately nine weeks to complete the meetings and all of the interviews.

PROCEDURES: If you agree to participate, we will ask you to take part in eight weekly group sessions (approximately 2 hours each) led by a peer facilitator where you will meet with other people in St. Clair County who have had similar experiences as you. We will randomly assign you (picked by chance or luck) to one of two possible intervention delivery strategies: 1) receive \$20 for each session you attend or not to receive payment; and 2) attend open or closed groups. Closed groups start and finish with the same people. Open groups allow anyone to join on any given week. **Note you will not be able to choose which intervention delivery strategy you will be joining.** This means you could be randomized to join the no payment group. If that happens, you will not get paid to attend intervention sessions, even if you know other people are receiving \$20 for each session they attend. On the other hand, if you are randomized to the paid group, you will receive \$20 for each session you attend. You will need to agree to join the study before knowing your randomization result. That means that when you agree to join the study, you intend to attend the Community Wise group sessions whether you get paid or not. Thus, attending the sessions may help you reduce your substance misuse, regardless of payment.

All study groups will consist of weekly group meetings led by a group facilitator. In these groups, you and the other group members will talk about your feelings and experiences.

Examples of discussion topics include racism, sexism, classism, mental health issues, substance use, and your relationship with your community. You may also learn tools that you can use to improve your health.

PARTICIPANTS: 128 people will be recruited from St. Clair County, IL. All participants will be adults (over 18 years old) with a history of substance use disorder.

RISKS/DISCOMFORTS: Discussing issues related to mental health, substance use, and other personal experiences can be painful and uncomfortable. You always have the right to stop participating in the research study and program at any time without penalty. If you feel upset during any part of the study, for example, during the group sessions or during the survey, you may stop participating. At that time we can let you speak with our project manager or a trained counselor at the Comprehensive Behavioral Health Center (CBHC). If necessary, we will refer you to affordable services in the community that can help address emotional issues that may arise during your participation in this study.

While we will take several steps to protect your identity and the confidentiality of your responses (see details below), there is a small chance that confidentiality may be lost. For instance, data could be stolen online by an unauthorized person. We will take every precaution to prevent this from happening, including the use of a password protected secured server to safeguard your information. **The only instance where the researcher will reveal information you provide is if during your participation you tell us about child abuse or about yourself or someone else being in danger that is about to happen. In these circumstances, the researcher will notify the appropriate authorities.** If you begin to reveal this information during your participation, we will remind you that such information cannot be kept confidential or secret.

We will ask you to provide extensive contact information to ensure that we can reach you over the next two months. This includes social media accounts and contact information of friends or family who may help us reach you. We will also ask your permission to look for you at places where you hang out or at your home, if we cannot reach you via phone or e-mail. We will only look for you if you grant us permission to do so. If you miss intervention sessions, we will call you to ask why you were unable to attend.

BENEFITS: We hope that the group sessions in this study will help you with issues you may be having with substance misuse. However, we cannot guarantee that these sessions will have a positive effect or any effect at all. In participating, however, you are helping us gather information that could potentially improve the lives of individuals who have had similar experiences as you. You may also find that the group discussions may help you think about some issues in new and more useful ways. You may feel empowered by having the opportunity to share your stories, relate to others and gain a voice that can be used to help your community. If you are under Drug Court supervision and you chose to do so, you will be able to use completion of the Community Wise intervention to meet your mandated treatment requirement.

ALTERNATIVES: Participating in this study is completely voluntary. It is your choice to participate in this study and all of its components. Choosing not to be part of the study will not involve any penalty or loss of benefits to you. Your participation or nonparticipation in this study will not have any effect on your legal matters or your relationship with providers at CBHC, methadone maintenance, parole, or probation. You may use the Community Wise program to

satisfy the Drug Court mandated treatment requirement. If you chose to do that, you will need to sign a release authorizing us to provide your program attendance record to your Drug Court supervisor.

CONFIDENTIALITY: To make sure that your privacy and confidentiality are protected, your name will **not** appear on any records or results. We will ask you for contact information (e.g., phone number, address) so that we can reach you to schedule follow-up interviews, but that information will be kept in a password protected online server. There will be a code number placed on all of the documents related to your interviews and you will use a code name during the interviews and group sessions. Only the research assistant, Ms. Ellis, and Dr. Windsor will have access to the document that links your name to your code number. Your data will be kept confidential. Only researchers working on this study will have access to the information you provide, and they will know only your code name and number. Faculty, students, and staff at the University of Illinois who may see your information will maintain confidentiality to the extent of laws and university policies. Things that you say throughout the study will be reported in ways that will protect your identity. If we use specific things you say, we will not refer to you by name or number. For example, we might report that during one group session, "four people mentioned needing help finding housing."

Once the study is completed, other researchers may ask to use the data. Sharing data is an important way to create opportunities for new discoveries. Thus we will make every effort to make the data available to others, but only if we believe your identity and privacy are protected. In order to share the data, we will require an agreement that provides for the following conditions at minimum: (1) a commitment to use the data only for research purposes and not to identify any individual participant; (2) a commitment to secure the data using appropriate tools and computer technology; and (3) a commitment to destroy or return the data after analyses are completed. We will remove all personal identifiers from the data before we will allow it to be used by other researchers.

To help us protect your privacy, we obtained a **Certificate of Confidentiality** from the National Institutes of Health. With this Certificate, researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. We will use the Certificate of Confidentiality to resist any demands for information that would identify you, with the following exceptions:

- 1) The certificate cannot be used to resist a demand for information from personnel of the agency sponsoring the project and that will be used for auditing or program evaluation of agency-funded projects.
- 2) You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.
- 3) If you give another person or organization your written permission to receive research information, then we may not use the Certificate to withhold that information.
- 4) Mandated reporting of ongoing child maltreatment or imminent danger.

All project staff will be trained in how to protect confidentiality and will sign a pledge of confidentiality. Utmost care will be taken when contacting participants about enrollment and participation. Only study staff will talk with you directly unless you ask another authorized staff

person to leave a message. In general, we will not tell anyone any information about you. When this research is discussed or published, no one will know that you were in the study.

You must also be warned that peers who participate in your Community Wise group will learn information about you that you choose to share in the group. Group participants will make a pledge in the first group meeting to maintain confidentiality. While we hope that people will abide by this pledge, it is possible that group members will share information about you with other individuals.

FINANCIAL COSTS/PAYMENTS TO THE PARTICIPANT: You will receive \$20 for the weekly group discussions you attend IF you are randomized to the paid group (64 out of 128 people will be paid for attendance in Community Wise sessions and 64 people will NOT be paid). However, you will receive compensation for each interview activity you participate in, ranging from \$20 for the baseline questionnaire and \$30 for the follow-up questionnaire. All participants will receive \$5 per intervention session attended to offset transportation costs. You have the opportunity to receive a minimum of \$90 to a maximum of \$250 if you are eligible and choose to participate in all possible research activities over the period of nine weeks.

RIGHT TO REFUSE OR WITHDRAW: Your participation is voluntary. You may refuse to participate, or stop participating at any time, without any penalty or loss of benefits, and without any impact on past or future incarceration. You have the right to refuse to answer any question or participate in any aspect of the study. Additionally, we have the right to dismiss you from the study, including the group sessions, at any time. Finally, if you decide to stop participating, you may request that we destroy your data at any time during the study. At the end of the study we will destroy all identifying data and we will no longer be able to tell what data belongs to whom.

CONTACTS: If you have questions or suggestions about the study or the procedures, you may contact Dr. Liliane Windsor at (217) 300-1782 (lwindsor@illinois.edu). If you feel you have not been treated according to the descriptions in this form, or if you have any questions about your rights as a research participant, including questions, concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at 217-333-2670, e-mail OPRS at irb@illinois.edu.

I have read this entire form and I understand it completely. All of my questions regarding this form or this study have been answered to my complete satisfaction. I agree to participate in this study, Community Wise.

CONSENT TO ADD YOUR CONTACT INFORMATION TO A FUTURE STUDIES RECRUITMENT LIST

Please check your corresponding choice:

- ☐ I consent to study staff to add my contact information a recruitment list for future studies.
- ☐ I am not interested in being contacted about future studies.

Community Wise

Release form to contact Drug Court Officer

I _____, give Community Wise staff permission to contact my Drug Court supervisor and send them a program completion report. I understand that the only information the research staff will provide to my Drug Court supervisor is whether I am enrolled in the program, the dates and times of group meetings, general information about the study and the intervention, and my session attendance record.

Under no circumstances, the Community Wise staff will reveal to my Drug Court supervisor or anyone else any private information about me and the activities I am doing in the study. That includes all of the information collected for the research purposes and the content of the individual assessment and group sessions. I understand that my real name will not be attached to any of the research data and that even if a judge subpoenas the recorders, the research team will not disclose my information. The only instance where that will happen is if I or someone else is in imminent danger.

Signature: _____ Date: _____

Name of Drug Court supervisor: _____

Phone number for the Drug Court supervisor: _____