NCT05934591 Unique Protocol ID: UIUC IRB 23828
Improving Attendance in Community Wise
Protocol
1/29/2023

ILLINOIS
Office for the Protection of Research Subjects

Protocol Form

Section 1: PRINCIPAL INVESTIGATOR (PI)

The Illinois Campus Administrative Manual allows assistant, associate, and full professors to act as PI. Other individuals may serve as PI after obtaining approval from the necessary party.			
Last Name: Windsor	First Name: Liliane	Degree(s): PhD	
Dept. or Unit: School of Social Work	Office Address: 1010 W. Nevada St		
Street Address:	City: Urbana	State: IL	Zip Code: 61801
Phone: 201-310-2766	E-mail: lwindsor@illinois.edu		
Urbana-Champaign Campus Status: Non-visiting member of (Mark One) ☒ Faculty ☐ Academic Professional/Staff (*Student Investigators cannot serve as PI*)			
Training ☒ Required CITI Training, Date of Completion (valid within the last 3 years), 2/10/2021 ☐ Additional training, Date of Completion,			

Section 2. RESEARCH TEAM

2A. Are there other investigators engaged in the research?
☒ Yes (include a Research Team Form)
☐ No

2B. If yes, are any of the researchers not affiliated with Illinois?
☒ Yes
☐ No

Section 3. PROTOCOL TITLE

Improving Attendance in Community Wise

Section 4. FUNDING SOURCE

4A. Is the research funded?
☐ Research is **not funded** and is **not pending** a funding decision (Proceed to Section 5).
☒ Research is **funded** (funding decision has been made).
☐ Funding decision is **pending**. Funding proposal submission date: 2/10/2023

4B. Indicate the source of the funding.
☒ University of Illinois Department, College or Campus, *please specify*: CSBS
☐ Federal, *please specify*:
☐ Commercial Sponsorship & Industry[1,2], *please specify*:

[1] Clarify whether or not sponsor requires specific language in the contractual agreement that impacts human subjects research
[2] Clarify whether or not the sponsor requires the protocol adhere to ICH GCP (E6) standards

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☐ State of Illinois Department or Agency, *please specify*: ☐ Other, *please specify*:
4C. Sponsor-assigned grant number, if known: N/A
4D. A complete copy of the funding proposal or contract is attached. ☒ Attached, *please specify title*: Improving Attendance in Community Wise
4E. Funding Agency Official To Be Notified of IRB Approval (if Applicable) **Name:** N/A **Agency:** **E-mail:** **Phone:**

Section 5. CONFLICTS OF INTEREST

Please indicate below whether any investigators or members of their immediate families have any of the following. If the answer to any of the following items is yes, please submit the University of Illinois approved conflict management plan. If you have any questions about conflicts of interest, contact coi@illinois.edu.
5A. Financial interest or fiduciary relationship with the research sponsor (e.g. investigator is a consultant for the research sponsor). ☐ Yes ☒ No
5B. Financial interest or fiduciary relationship that is related to the research (e.g. investigator owns a startup company, and the intellectual property developed in this protocol may be useful to the company). ☐ Yes ☒ No
5C. Two or more members of the same family are acting as research team members on this protocol. ☐ Yes ☒ No

Section 6. SUMMARY & PURPOSE OF RESEARCH

Rates of alcohol and substance misuse (ASM) in low-income, predominantly African American communities (from here on marginalized communities) are similar to the general population.[1] However, ASM has greater consequences (e.g., higher incarceration and HIV/HCV infection rates) for residents in these communities. While the etiology underpinning this inequity is complex, the root cause of these issues has been traced to social determinants of health (SDH; e.g., stigma; poverty; access to education, housing, and employment).[2,3]

Funded by the National Institute for Minority Health Disparities (NIMHD 5R01MD010629),[4] in partnership with the Critical Consciousness Collaborative Board (3CB),[5] we developed Community Wise (CW), a multi-level manualized behavioral intervention to decrease ASM frequency in a population of self-identified men with histories of substance use disorder (SUD) and incarceration in Essex County, NJ, U.S. The 3CB was founded in 2010 and developed and pilot-tested the original CW. To attain this goal, our team used the multiphase optimization strategy (MOST),[6] and were guided by community based participatory research (CBPR) principles to develop and optimize CW. MOST is an innovative methodological framework that employs experimental designs to engineer efficient and effective behavioral interventions. MOST guided

the optimization of CW with delivery cost of less than $2,000 per intervention cycle serving up to ten individuals simultaneously (this was the Medicaid allowable reimbursement cost for SUD group treatment services in 2015).[7] Clinical trial results showed larger ASM reduction (Cohen's d=–2·22, P=0·067) in the optimized CW group. Unfortunately, attendance across the 15 intervention sessions was low (only 15% of participants attended 50% of the sessions) and a limitation to the study. Low attendance was due to the intervention's closed group format, the study's randomization strategy, and instability of the study's population (homelessness, poverty).

In order to improve upon our positive results and to test the intervention with participants who identify as female and do not have a history of incarceration, we propose a pilot study to: 1) identify strategies to improve attendance and reduce ASM, and 2) to test feasibility and acceptability of CW among people with a history of SUD living in marginalized communities. We will achieve these aims by conducting a 2^3 full factorial experiment. This pilot study will strengthen our application for an R01 grant to test CW's effectiveness against standard of care. This pilot will help us identify efficient strategies for improving attendance and, hence, maximize the interventions' effect in reducing ASM. As a highly efficient experimental design, a full factorial experiment will maximize study power and allow us to examine the individual and interactive contributions of each intervention delivery strategy on intervention attendance. MOST will inform which strategies will be retained, thus minimizing waste of resources. The current proposed research will also be conducted in partnership with the 3CB. As our primary individual level outcome, we will use number of sessions attended to pursue the following aim:

Study AIM: To test intervention delivery strategies that effect adequate attendance in CW interventions and marked reduction in ASM. We will test if different intervention delivery strategies will result in a clinically important intervention attendance with a minimum of 50% of participants attending at least 50% of the intervention. We will also compare the effect of different strategies on reducing ASM. Intervention delivery strategies include: 1) Recruiting individuals under supervision (those on parole, drug court, probation, or methadone maintenance); 2) Incentivizing intervention attendance; and 3) Delivering the intervention in an open group format. We will also compare intervention satisfaction measures between intervention strategies.

We will expand eligibility criteria to include women and people with SUD living in marginalized communities who have not been previously incarcerated. While women comprise a smaller percentage of people with SUD, they experience significant barriers to SUD treatment.[9] Our pilot study showed that women started the CW intervention with worse outcomes when compared to men but had significantly higher reductions of ASM.[10] While the original CW intervention was developed with and for formerly incarcerated people, it addresses concepts that are relevant to all people with SUD living in marginalized communities. Hence, the 3CB has recommended that we expand our eligibility criteria to reach a more diverse group of people. Our 2^3 full factorial design will examine change in attendance (N=128). Data will be collected at baseline and three months post-baseline. This study will impact public health as it will improve the potency of an optimized multi-level intervention adaptable to address different health inequities.

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6B. Indicate if your research includes any of the following:
- ☐ Secondary data (use of data collected for purposes other than the current research project)
- ☐ Data collected internationally (include International Research Form)
- ☐ Translated documents (include Certificate of Translation Form and translated documents)
- ☐ Research activities will take place at Carle (include documentation (email or letter) from Carle stating that the review of your Research Services Request Form is complete)

6C. Letters of support from outside institutions or entities that are allowing recruitment, research, or record access at their site(s) are attached. ☒ Yes ☐ Not Applicable

Section 7. PROCEDURES

7A. Select all research methods and/or data sources that apply.
- ☒ Surveys or questionnaires, *select all that apply*: ☐ Paper ☐ Telephone ☒ Online
- ☐ Interviews
- ☐ Focus groups
- ☐ Field work or ethnography
- ☐ Standardized written, oral, or visual tests
- ☐ Taste or smell testing
- ☒ Intervention or experimental manipulation
- ☐ Exercise and muscular strength testing
- ☐ Noninvasive procedures to collect biological specimens (e.g., hair and nail clippings, saliva, etc.)
- ☐ Noninvasive procedures to collect physiological data (e.g., physical sensors, electrocardiography, etc.)
- ☐ Procedures involving radiation
- ☐ Recording audio and/or video and/or taking photographs
- ☐ Recording other imaging
- ☐ Materials that have already been collected or already exist, *specify source of data*:
- ☐ HIPAA-protected data
- ☐ FERPA-protected data
- ☐ GDPR-protected data
- ☐ Other, *please specify*:

7B. List all testing instruments, surveys, interview guides, etc. that will be used in this research. Drafts or final copies of all research materials are attached. ☒ Yes

7C. List approximate study dates. Upon IRB Approval – April 31, 2024

7D. What is the duration of participants' involvement? Participants will complete a 15 minutes study orientation session and two 30 minutes online surveys. They will also be asked to attend 8, two-hour long weekly intervention sessions

7E. How many times will participants engage in research activities? Two times for study activities and 8 times for the intervention.

7F. Narratively describe the research procedures in the order in which they will be conducted.

People interested in the study will call the study's number. A trained master's level clinician will conduct a brief phone screening to obtain self-reported eligibility on SUD, age, contact information, and whether they are currently under supervision. We will have recruitment quotas of 64 people based on self-reported gender (self-identified as men or woman) and supervision status. Intervention groups will be gender specific following recommendations from the literature and our previous CW pilot study. Phone screened participants will be invited to attend an in-person group orientation session to learn about the study, including randomization procedures and the different forms of CW delivery they may receive. Those interested will be invited to complete the baseline survey online in RedCAP. The survey will include a screening informed consent and an eligibility screen with a computerized Global Appraisal of Individual Needs-Substance Problem Scale (GAIN-SPS).[35] Those who are eligible and agree to the procedures will be consented and invited to complete the baseline assessment. Follow-ups will be completed online using RedCAP three months post baseline. Baseline and follow-up will include questions about SUD treatment services received over the past 3 months, the Timeline Follow Back questionnaire to measure alcohol, cannabis, cocaine, opioid, and heroin use in the past 30 days, and demographics. Follow ups will also include intervention satisfaction measures and questions about intervention attendance. Surveys will take 30 minutes to complete. Participants will receive $20 for baseline and $30 for follow up assessment. Intervention attendance will be recorded weekly in RedCAP by the peer facilitator. After the baseline assessment, participants will be asked to provide extensive locator information, including formal and informal contacts who can reach the participant in a variety of contingencies. Computer generated randomly permuted blocks will be used to assign participants into one of eight experimental conditions. Randomization will occur in Redcap immediately after completing the baseline and be stratified by gender. The research assistant will call participants after randomization to schedule the group's start date. The attached study flowchart summarizes all study procedures.

Intervention: Community Wise (CW) includes two, two-hour long group-building sessions and six two-hour long active components sessions. Sessions are delivered weekly by a trained peer facilitator. Group-building sessions create a safe space where participants can discuss racism, sexism, classism, and histories of marginalization in the context of ASM and drug traffic. Based on the optimization study, we identified two active components that increase critical consciousness and, thus, health inequities related to ASM. These include the Critical Dialogue (CD), prompted by thematic images (see table below) and aims to help participants develop a deeper understanding of how marginalizing processes (e.g., systematic stigma; feelings of rage as victims of discrimination) impact their lives and behavior; and 2) Capacity Building Projects (CBP) designed to create collaborative efforts to overcome and dismantle marginalizing processes by building positive social and organizational relationships and community capacity through the development and implementation of community projects aiming to address social determinants of health. Our study detected no difference when the intervention was delivered by peer facilitators versus licensed facilitators. Trained peer facilitators can deliver the intervention at a lower cost and benefit from a new employment opportunity.

Participant tracking: Most of our participants earn less than 10,000 yearly and many will likely be homeless. While they share phone numbers and email addresses with the study team, they may be

unable to answer their pre-paid phone when they run out of minutes or they may not be able to access a computer easily. Thus, collecting extensive tracking information is critical to make sure we can reach them. We ask for alternative contact numbers, places where they hang out (especially important for those who are homeless), and social media accounts to maximize our chances to find them in case we lose touch. We have used this approach in all our previous studies without any problems. When collecting this information, the RA explains to participants why we ask this information and asks them if it is ok with them. We also ask participants what they would like us to say if we are looking for them. We follow the participants' instructions and they can refuse to offer alternative contacts or grant permission for us to look for them at any time during the study.

Section 8. PERFORMANCE SITES TO INCLUDE INTERNATIONAL, SCHOOL, AND COLLABORATIVE STUDIES

8A. List all research sites for the protocol. For non-University of Illinois at Urbana-Champaign sites, describe their status of approval and provide contact information for the site. If the site has an IRB, note whether the IRB has approved the research or plans to defer review to the University of Illinois at Urbana-Champaign.	
Performances Sites	
#1	Comprehensive Behavioral Health Center 505 South 8th Street- East St. Louis, Illinois 62201, They do not have an IRB and will defer to UIUC
#2	
#3	
If there are additional performance sites, include them on an attachment and check here: ☐	
8B. Is this a multi-center study in which the Illinois investigator is the lead investigator, or the University of Illinois at Urbana-Champaign is the lead site? ☐ Yes ☒ No **If yes, answer 8C and 8D. If no, proceed to Section 8E.**	
8C. Who is the prime recipient of funding, if funded? N/A	
8D. What is the management and communication plan for information that might be relevant to the protection of research subjects (e.g. unanticipated problems involving risks to subjects, interim results, and protocol modifications)? N/A	
8E. If subjects will be recruited from Illinois public or private elementary or secondary schools, additional deadlines and procedures may apply. Criminal background clearances might be required. Special consideration must be given to the exclusion of protected populations. Please contact the School University Research Relations (researchplacements@education.illinois.edu) for more information. Select one: ☐ Illinois schools **will** be used ☒ Illinois schools **will not** be used	

Section 9. SUBJECT ENROLLMENT GOAL & EQUITABLE SELECTION OF SUBJECTS

9A. For each performance site, indicate the estimated total number of participants.			
Performance Site	**# Male**	**# Female**	**Total**

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#1	Comprehensive Behavioral Health Center 505 South 8th Street- East St. Louis, Illinois 62201, approved IRB for another study	64	64	128
#2				
#3				
TOTALS				

If additional performance sites are included on an attachment, check here: ☐

9B. Select all participant populations that will be recruited.

Age:

☒ Adults (18+ years old)
☐ Minors (≤17 years old)
☐ Specific age range, *please specify*:

Gender:

☒ No targeted gender (both men and women will be recruited/included)
☐ Targeted gender, *please indicate*: ☐ Men/boys ☐ Women/girls ☐ Other, *please specify*:

Race/Ethnicity:

☒ No targeted race or ethnicity (all races and ethnicities will be recruited/included)
☐ Targeted race or ethnicity, *please specify*:

College Students:

☒ No targeted college population
☐ UIUC general student body
☐ Targeted UIUC student population, *provide the instructor or course information, name of the departmental subject pool, or other specific characteristics*:
☐ Students at institution(s) other than UIUC, *please specify*:

Any research with students on UIUC's campus needs to be registered with the Office of the Dean of Students.

Other:

☒ Inpatients
☒ Outpatients
☐ People who are illiterate or educationally disadvantaged
☐ People who are low-income or economically disadvantaged
☐ People with mental or cognitive disabilities or otherwise impaired decision-making capacities
☐ Adults with legal guardians
☐ People who are non-English speaking
☐ People with physical disabilities
☐ Pregnant or lactating women, human fetuses, and/or neonates
☒ Prisoners or people with otherwise limited civil freedoms
☐ Other, *please specify*:

9C. Describe additional safeguards included in the protocol to protect the rights and welfare of the populations selected above.

We will enroll people who are under parole, probation, drug court, or methadone maintenance treatment. These individuals have limited civil freedoms and are often mandated to attend SUD treatment. To minimize potential coercion, we will not notify participants supervisors about who was enrolled in the study. Although we will encourage participants to disclose their participation to their supervisor to avoid problems related to their availability to attend groups. For supervisors willing to accept participation in our intervention as sufficient to meet their clients' requirement to attend a SUD intervention, we will emphasize that CW is one intervention option among others such as medications, psychotherapy, attending alcoholics anonymous among others. We will engage Drug Court, parole, probation, and SUD treatment supervisors by explaining the nature of the study and asking them to help disseminate flyers among their clients. Potential participants will contact the study directly to indicate their willingness to participate and complete the study screen. Participants will attend a study orientation where we will present the study, describe the intervention, experimental conditions, randomization, participants rights, and expectations. At orientation people will be able to engage with other potential participants to explore pros and cons of participation, ask the study team questions, and review the informed consent form. Those interested, will complete the baseline assessment, and sign the IC online. All data will remain confidential and supervisors will not have access to the data. We have applied for a Certificate of Confidentiality to further protect participants.

Section 10. INCLUSION/EXCLUSION

10A. List specific criteria for inclusion and exclusion of subjects in the study, including treatment and control groups.

Eligibility criteria: Over 18 years of age; living in St. Clair County; 64 people will be under supervision (parole, probation, drug court or methadone maintenance) and 64 people will not be under supervision; having a SUD; English-speaker; and able and willing to provide informed consent.

10B. Explain how the inclusion/exclusion criteria will be assessed and by whom. If special expertise is required to evaluate screening responses or data, list who will make this evaluation and describe their training and experience.

A trained master's level clinician will conduct a brief phone screening to obtain self-reported eligibility on SUD, age, contact information, and whether they are currently under supervision.

10C. Drafts or final copies of all screening materials are attached. ☒ Yes ☐ Not Applicable

10D. Describe procedures to assure equitable selection of subjects. Justify the use of the groups marked in Section 9B. Selection criteria that target one sex, race, or ethnic group require a clear scientific rationale.

The proposed study does not include children because the intervention will focus on adult behaviors and it would not be appropriate to include children. Recruitment will be open to all residents of St. Clair County, IL, but given the location of the study sites, we expect that the vast majority of participants will come from East St. Louis, IL. As such, we estimate that our sample will approximate the demographics of East St. Louis in terms of race and ethnicity. Because of this, we anticipate that Black participants will be overrepresented in our sample. We will recruit an equal number of self-identified men and women to allow for gender-based comparisons (64 men and 64 women). We will recruit 50% of the sample under

supervision and 50% not under supervision to examine what intervention delivery strategy may be more efficacious in increasing attendance in the intervention in each of these groups.

Section 11. RECRUITMENT

11A. Select all recruitment procedures that will be used.

- ☐ Student subject pool, *please specify*:
- ☒ Email distribution
- ☐ MTurk, Qualtrics Panel, or similar online population, *please specify*:
- ☐ US Mail
- ☒ Flyers/brochures
- ☐ Website ad, online announcement (e.g. eWeek), or other online recruitment, *please specify*:
- ☐ Newspaper ad
- ☐ Verbal announcement
- ☐ Other, *please specify*:
- ☐ Not applicable (secondary data only)

11B. Drafts or final copies of all recruitment materials (including verbal scripts) are attached.

☒ Yes ☐ Not Applicable

11C. For each group of participants, describe the details of the recruitment process.

3CB members and study staff will post fliers at reentry, SUD, and HIV/HCV service agencies, probation and parole offices, drug courts, and throughout the community. Individual service providers will be asked to disseminate information about the study. In addition, research staff will encourage potential participants to help distribute the study's fliers in their neighborhoods, churches, and other meeting places. Men and women interested in participating will call the study's cell phone number. Only members of the research team listed in the IRB will have contact with study participants. Members of the 3CB will only see de-identified and aggregated data results or help disseminate the study in the community.

Section 12. REMUNERATION AND PLAN FOR DISTRIBUTION

Refer to the University Business and Financial Policies and Procedures for further guidance on the compensation process and reporting requirements.

12A. Will subjects receive inducements or rewards before, during, or after participation?

☒ Yes ☐ No

If yes, complete the rest of Section 12. If no, proceed to Section 13.

12B. Select all forms of remuneration that apply.

- ☒ Cash*, please specify amount:* Up to $250
- ☐ Check, *please specify amount:*
- ☐ Gift Certificate, *please specify amount:*
- ☐ Lottery, *please specify amount:* *and odds:*
- ☐ Course Credit, *please specify amount:* *and specify equivalent alternative activity:*
- ☐ Other, *please specify*:

12C. Will payment be prorated before, during, or after participation?

☒ Yes, *please specify how:* All participants will receive $20 for baseline completion and $30 for follow-up completion. Those randomized to receive cash incentive to attend intervention sessions will receive $20 per session attended. See study's flowchart attached.
☐ No

12D. For each group of participants, describe the details of the remuneration plan, including how, when and by whom they will be notified.
Once participants complete the baseline or follow-up on RedCAP, the research assistant will receive a RedCAP notification and they will submit the cash payment via Cashapp if the participant is remote or in cash if the participant is in person. Participants will receive cash payment from the research assistant at the end of each intervention group they attend. All sessions will be held at CBHC. Cash app uses participants e-mail or phone numbers to disburse payment. It is completely separate from the data. Once Redcap notifies the research assistant that a survey was completed, the research assistant retrieves the participants' email or phone from Redcap and uses Cash app, a completely separate app from Redcap, to transfer the funds. The research assistant notes in Redcap the date the payment was made. Cashapp records what payments were made when to what cash ap account. The business office just needs a list of what cash payments were made to what participant ID. Only the RA will have access the information linking the participant's e-mail to the study ID. This information will be destroyed as soon as data collection is complete. We have used this strategy in several other studies successfully and participants, especially from low income Black communities, often prefer Cash app over any other options, including cash.

12E. The information listed above is provided on the relevant consent forms.
☒ Yes

Section 13. RISKS & BENEFITS

13A. Describe all known risks to the participants for the activities proposed, such as risks to the participants' physical well-being, privacy, dignity, self-respect, psyche, emotions, reputation, employability, and criminal and legal status. Risks must be described on consent forms.
Potential risks of this study include inadvertent violation of confidentiality, emotional distress on the part of participants, and coercion. The use of code names and numbers along with other procedures described below are intended to prevent violations of confidentiality. It is important to be aware that participants may be disturbed by sensitive questions raised during data collection and intervention sessions. Questions and discussions regarding drug use may cause anxiety, anger, suspicions, or other emotions. While this is a predominantly African American sample, there will be some White and Latino participants as well and talking about racism in the group will elicit strong emotions. We welcome homosexual participants and discuss sexuality in groups that may include members who are opposed to homosexuality. Each of these differences has the potential to harm or cause discomfort for the participant or revive psychological dynamics that could threaten to renew old conflicts. We designed CW very carefully so that these discussions happen in a safe way, where everyone is encouraged to challenge their own assumptions by

analyzing the evidence they have that supports or challenges their positions. This starts with operational components where the intervention is clearly described so that people know what to expect, and ground rules are collaboratively created and enforced during group discussions. In our previous research testing CW with over 700 participants, there were many instances where the critical questions posed led to a heated dialogue where people were able to express their conflicting views while respecting each other and considering the possibility of changing their point of view. We carefully selected peers who successfully worked in our prior COVID-19 research with this population at CBHC. They show a deep understanding about the challenges of managing a group discussion and we will carefully train them on how to handle potential conflict in the group. Facilitators will participate in weekly supervision meetings with Dr. Windsor where we will process any challenges they may experience so that we can provide them with feedback on how to improve their performance. In the unlikely event a discussion escalates to the point that it may challenge the safety of the group, or if during a session something happens and the facilitator needs assistance, there are trained CBHC staff that include licensed clinicians and security in place who can intervene and deflect potential violence. Moreover, during the prior CW studies no adverse events occurred as a result of study participation.

Another risk to confidentiality refers to the fact that participants who participate in CW groups will learn information about other participants that are shared 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 share information about peers with other individuals. We disclosed this risk to participants in the informed consent.

Clinical trial participants will be randomized into eight conditions. It is possible that participants may not be randomized into their study condition of choice, particularly those that receive payment to attend intervention sessions and those who do not. We will clearly explain to participants at the orientation session that we do not know which condition each person will receive and we will emphasize that half of the sample will receive $20 for each session they attend and the other half will not. We will describe each condition with a great amount of detail and emphasize the importance to conduct the research properly so that we can find out what is best possible intervention package. We will ensure that prior to consenting to the study, participants will be fully aware that they will not be able to choose what condition they will receive and that they will agree to participate in whatever condition they are randomized to. Those who are set on only participating in a specific condition will be discouraged from entering the study prior to the randomization. We will also tell participants that they have the right to stop participating without penalty at any time during the study.

Finally, some participants, particularly those under supervision (Drug court, methadone maintenance, or parole/probation) may believe that their participation in the study is expected by

their supervisors. We will not inform supervisors about study participation or share data with supervisions or staff at CBHC. We will emphasize the voluntary nature of participation. Finally, those under Drug Court supervision who are mandated to SUD treatment will be able to use the program completion to satisfy their treatment mandates. These participants will be notified that there are many other treatment modalities (e.g., support groups, alcoholic anonymous) available and also accepted by Drug Court. If they choose to use CW as their mandated treatment, they will sign the attached release to grant us permission to inform Drug Court about their program completion status.

13B. Describe the steps that will be taken to minimize the risks listed above.

To avoid possible violations of confidentiality, project staff are trained to carefully follow detailed procedures designed to assure that no information about any participant (or others they may mention) will be given to law enforcement, other government agencies, or anyone but research staff. Every member of the research team completed human subject protection training and provide a certificate of completion to the IRB prior to any contact with human subjects. Standards of confidentiality include the use of code numbers and code names for participants and other individuals they may mention. The only place participants' names or other identifying information will appear is on locator forms (used for follow-up interviews after the baseline). These forms will be kept separate from the data and stored in RedCAP, a HIPPA approved software. We will apply for a certificate of confidentiality from the NIH to further protect participants.

The electronic files generated through data collection will be identified by code numbers only and kept in password-protected devices/servers, separate from identifying information and available only to authorized project staff. This helps to ensure that no identifying information will be disclosed in the unlikely event that computerized data are stolen or otherwise seen by unauthorized persons.) All identifying electronic data will be destroyed immediately after data analysis is completed. Identifying information will be deleted immediately after data collection De-identified electronic data will be kept indefinitely.

Our interviewers are trained to watch participants carefully and will stop questioning if an individual appears uneasy. At every interview, participants will be informed that they may ask the interviewer to stop if they are feeling uncomfortable. Referrals to counselors are available if participants wish and trained clinical counselors are available at CBHC in the event that someone may need immediate assistance, whether it is during data collection or during the intervention sessions.

Dr. Windsor and Ms. Ellis will be available by phone or e-mail within 24 hours of its report Monday through Saturday. Through our 3CB collaboration, we have excellent relationships with

the community, including community members and agencies that we can mobilize in case the need arises (e.g., access to providers that provide detox and emergency services, free legal support clinics, community members who learned from participants about their engagement in the study may reach out to us for help in case they know one of our participants may be in trouble).

In addition to this extensive network, we will collect data during the baseline and follow-up assessments to monitor participant safety. For instance, if we find participants with severe ASM, we will have the appropriate group clinician reach out to the participant individually and make sure they are linked to the mental health services they need.

To avoid coercion, we will not inform supervisors about study participation or share data with supervisions or staff at CBHC. We will emphasize the voluntary nature of participation. Finally, for those under supervision who are mandated to SUD treatment, they will be notified that there are many other treatment modalities available and CW is simply one of them.

Finally, the research team and the clinical team will engage in weekly project meetings to discuss the progress of the study and identify, discuss, and address any potential issues. Peer facilitators will have bi-weekly clinical supervision with Dr. Windsor. The 3CB will meet monthly to receive updates on the study and provide oversight and feedback.

13C. Indicate the risk level.

☐ **No more than minimal risk**
(The probability and magnitude of harm or discomfort anticipated for participation in the proposed research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

☒ **More than minimal risk** (answer 13D)

13D. If you checked that the research is <u>more than minimal risk</u>, describe the provisions for monitoring the data to ensure the safety of subjects, such as who will monitor data and how often, what criteria will be used to stop the research, etc.

While the proposed study does not seek to test the effectiveness of drugs or a medical devise delivered in multiple sites, the proposed study will be testing a behavioral intervention in the community with a marginalized population and there is potential for harm. Thus, we developed a Data and Safety Monitoring Plan (DSMP) and the 3CB will serve as a Data Safety and Monitoring Board (DSMB) to conduct periodic independent analyses of the data during the data collection phase. The DSMP will be reviewed by the University of Illinois at Urbana-Champaign IRB, who will continue to monitor the study as it progresses.

Data will be collected at CBHC. All data will be stored in password protected devices to which

only authorized members of the research team have access. A database will be set up in RedCAP in such a way that all authorized members of the research team will be able to access specific files remotely. Each member will be assigned a password protected account that will allow them to access the database. Dr. Windsor will be responsible for overseeing all data collection and processing. All identifying electronic data will be destroyed immediately after data analysis is completed. De-identified electronic data will be kept indefinitely.

The DSMP is as follows:

1. The participants are fully informed of the study requirements throughout the study and are allowed the opportunity to withdraw from participation, at no penalty to themselves or their ability to receive other treatment at regular cost to them. This is written in the consent form, which will be approved by the IRB.

2. Risks of the study and steps taken to minimize risk and protect the participants as outlined in the consent form are as follows:

a. Possible discomfort from answering personal questions. If the participants experience such discomfort at any time, they are free to inform the research assistant or facilitator, and are free to withdraw from the program. Facilitators will be trained to observe signs of discomfort and check with participants if they want to continue. Facilitators are trained to address discomfort during the sessions and participants are able to leave whenever they need.

b. Discomfort or risk of minor or major substance withdrawal symptoms. This will be carefully assessed throughout the intervention. CBHC offers a variety of SUD treatment services and staff there are fully trained to recognize and address signs of withdrawal. Dr. Windsor will be available to consult with Ms. Ellis and the peer facilitators via phone and e-mail, and she will provide on-going, remote clinical supervision and monitoring of each case. In the event of acute withdrawal symptoms or high risk behaviors (i.e., suicidal or homicidal ideation, intent, or plan), the peer facilitator will refer the participant to the appropriate staff at CBHC for admission to inpatient or referral to ambulatory detoxification. Dr. Windsor will review each survey for risk of withdrawal symptoms, level of care needs, and appropriate action plan.

c. Clinical emergencies will be handled by the CBHC treatment team of experienced staff under supervision of the Director of Addiction Services at CBHC and Ms. Ellis, who will be available by phone to all facilitators. Appropriate assessments will be conducted; treatment options will be recommended and followed through as necessary. CBHC routinely provides services to individuals with substance use disorders and they are fully equipped to address

any potential emergencies either themselves or via referrals. CBHC has longstanding relationships with all substance use disorder treatment facilities in St. Clair County. Any adverse event will be reported to the appropriate authorities within 48 hours and immediate action will be taken to minimize the likelihood of it occurring again.

d. Non-Response to Intervention. Close monitoring during the intervention allows us to determine if a participant develops increased risk or withdrawal symptoms or need of a higher level of care. At any time during the course of the intervention, any acute medical issues, non-response to treatment, or reported or observed withdrawal symptoms will result in the facilitator's consultation with Dr. Windsor regarding appropriate course of action using CBHC guidelines.

e. Relapse and Referral for Further Treatment. Our intervention includes information about relapse prevention. After the intervention, should the participant request a referral for treatment, study personnel will refer the participant to CBHC where staff can provide appropriate care or referrals.

f. Deterioration. Clients who are deteriorating during the intervention will be reviewed by Dr. Windsor. Clients may be withdrawn from the study and/or referred to a higher level of care if they have signs of deterioration that will be discussed during clinical supervision (e.g., become suicidal, regularly arrives high to participate in group discussions, consistently displays disruptive behavior during group).

g. Potential harm done by involvement in *CW* groups. Typically intervention groups lead to a positive outcome. However, given the sensitive nature of the topics we discuss, the diversity of the groups, and the innovative nature of the intervention, harm as a result of participation in *CW* is possible. The facilitators and Dr. Windsor will closely monitor the course of the intervention through ongoing data collection, observations, and weekly supervision and staff meetings to monitor and address any issues that may arise.

h. Any research staff member who learns of an adverse event is responsible for reporting the event to Dr. Windsor and Ms. Ellis, who are in turn responsible for discussing the event to make a joint decision about whether the event meets OPRS criteria for advance events. The PIs will report adverse events that may represent unanticipated problems involving risks to participants or others to the IRB and funders within one week of its occurrence.

i. Dr. Windsor will closely monitor the validity and integrity of the data on an ongoing basis. The DSMB with also conduct monthly monitoring of the data through spot checks and

independent preliminary analysis of the data. For instance, Dr. Windsor and Ms. Ellis will meet regularly with project interviewers to review assessments and coding of incoming data. Dr. Windsor and Ms. Ellis will be responsible for ensuring that data are being coded, entered and cleaned appropriately. The full research team will meet every week for 60 minutes to review all aspects of the research study.

13E. Describe the expected benefits of the research to the subjects and/or to society.

The potential benefits to participants in this study and other members of the community are significant and long lasting if the proposed research results in increased intervention attendance in an intervention that is truly community-based, culturally congruent, effective, and scalable. In the near term, participants may experience increased feelings of empowerment, connection with their community, sense of purpose in life and self-esteem, all of which have been associated with reduced health-risk behaviors. The community itself is likely to benefit from the various capacity building projects that participants will implement during the intervention. In the near term, participation itself can be beneficial when individuals are able to share their lived experiences and concerns about health needs and community problems in a secure and unthreatening environment. Community member participants will also be compensated materially for participating in interviews, focus groups and the pilot intervention. In addition, if participants express a need for professional assistance at any time, the project team and the CBHC are well equipped to either provide service or make appropriate referrals.

Knowledge to be gained from this investigation is important for deepening our understanding of structural environmental challenges as contributors to racial and economic health inequities between distressed communities with concentrations of African Americans and their wealthier and predominantly White counterparts. Major obstacles to the adoption of evidence-based interventions by these marginalized communities include distrust and differences between community culture and the theoretical frameworks of many evidence-based interventions. Knowledge produced by community-based participatory research (CBPR) such as that proposed here can address these challenges while building community capacity and empowerment. This is the first study to apply the Multiphase Optimization Strategy (MOST) under CBPR principles to optimize the delivery of a multi-level intervention. This cutting edge research will help increase the number of rigorous methodologies available that can be used with CBPR principles to develop multi-level interventions targeting myriad health inequities.

13F. Weigh the risks with regard to the benefits. Provide evidence that benefits outweigh risks.

The value of the knowledge to be gained far outweighs the potential risks of participation described above, particularly when considering the precautions we have taken to minimize these risks. As explained earlier in this section, project staff will employ every effort to maintain confidentiality and to minimize any other potential risks; should a serious adverse event occur, it will be reported to the DSMB,

funding agencies and the IRB of the University of Illinois at Urbana-Champaign within 48 hours. Adverse events will be tracked in a database and reviewed at each DSMB meeting. Our previous research shows significant community support for this application and community members themselves are committed to assisting us in the successful and safe implementation of this project.

Section 14. INFORMED CONSENT PROCESS TO INCLUDE: WAIVERS, ASSENTS, ALTERATIONS, ETC.

14A. Indicate all that apply for the consent/assent/parental permission process.

☒ Written informed consent (assent) with a document signed by
☒ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

☐ Waiver of Documentation (signature) of Informed Consent *(include the relevant Waiver Form)*
☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

☐ Waiver of Informed Consent *(include the relevant Waiver Form)*
☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

☐ Alteration of Informed Consent *(include the relevant Alteration Form)*
☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

14B. List all researchers who will obtain consent/assent/parental permission from participants. This will be done online after the participant completes the Orientation. Dr. Windsor and Heather Perkins will deliver the Orientations.

14C. Describe the method for obtaining consent/assent/parental permission. After attending the study Orientation Session, participants will be able to read the informed consent form and decide whether they want to participant by checking a box in Redcap and completing the baseline assessment.

14D. Describe when consent/assent/parental permission will be obtained. Online, after the orientation and before completing the baseline assessment.

14E. Will participants receive a copy of the consent form for their records?

☒ Yes ☐ No, *if no, explain*:

14F. Indicate factors that may interfere or influence the collection of voluntary informed consent/assent/parental permission.

☐ No known factors
☐ Research will involve students enrolled in a course or program taught by a member of the research team
☐ Research will involve employees whose supervisor(s) is/are recruiting participants
☐ Participants have a close relationship to the research team
☒ Other, *specify any relationship that exists between the research team and participants*: The study will include 64 individuals who are under supervision (drug court, parole, probation, or methadone maintenance).

If applicable, describe the procedures to mitigate the above factors.

Some participants, particularly those under supervision (Drug court, methadone maintenance, or parole/probation) may believe that their participation in the study is expected by their supervisors. We will not inform supervisors about study participation or share data with supervisions or staff at CBHC. We will emphasize the voluntary nature of participation. Finally, those in Drug Court will be able to choose Community Wise as one of many other possible programs that are mandated by Drug Court. If they choose to use Community Wise as their mandated program, they will sign a release authorizing us to share program attendance information with Drug Court.

14G. Copies of the consent form(s) are attached. ☒ Yes ☐ Not applicable

14H. Will this project be registered as a clinical trial? ☒ Yes ☐ No
If yes, effective January 21, 2019, an informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit.

Section 15. DEVICES & DRUGS

Indicate if your research includes any of the following.

☐ Equipment [Researchers collecting physiological data, not testing the device]
(*include Appendix A, the Research Equipment Form*)

☐ Devices [Researchers planning to test devices on human subjects]
(*include Appendix B, the Device Form*)

☐ Materials of Human Origin
(*include Appendix C, the Biological Materials Form*)

☐ Drugs and Biologics
(*include Appendix D, the Drug and Chemical Usage Form*)

☐ MRI AT BIC To use the Beckman Institute Biomedical Imaging Center (BIC) in human subject's research, you must obtain prior approval from the BIC (217.244.0446; bic@beckman.illinois.edu) and use BIC-approved screening and consent forms. Attach:
☐ BIC approval ☐ BIC screening form ☐ BIC consent form

Section 16. CONFIDENTIALITY OF DATA & PRIVACY OF PARTICIPATION

16A. How is participant data, records, or specimens identified when received or collected by researchers? Identifiers include, but are not limited to, name, date of birth, email address, street address, phone number, audio or video recordings, and SSN.

☐ No identifiers are collected
☐ Direct identifiers are collected
☒ Indirect identifiers (e.g. a code or pseudonym used to track participants);
Does the research team have access to the identity key? ☒ Yes ☐ No

16B. Select all methods used to safeguard research records during storage:

☒ Written consent, assent, or parental permission forms are stored separately from the data
☐ Data is collected or given to research team without identifiers
☒ Data is recorded by research team without identifiers

Protocol Form

☒ Direct identifiers are removed from collected data as soon as possible ☒ Direct identifiers are deleted and no identity key exists as soon as possible ☒ Participant codes or pseudonyms are used on all data and the existing identity key is stored separately from the data ☒ Electronic data is stored in a secure, UIUC-approved location, *please specify* RedCAP and Box ☐ Hard-copy data is stored in a secure location on UIUC's campus, *please specify* ☐ Other, *please specify*:
16C. How long will identifiable data be kept? Until data collection is completed
16D. Describe provisions to protect the privacy interests of subjects. We will store identifying information separately from data, we will apply for a certificate of confidentiality, we will train staff to keep confidentiality, we will ask group participants to agree to keep group dialogues confidential. We will not disclose study participation or data to others without written approval of participants.
16E. Describe the training and experience of all persons who will collect or have access to the data. Dr. Windsor has been conducting sensitive research for over 20 years, including large NIH clinical trials, ethnographic studies, and international research. Ms. Ellis and the peer facilitators have been trained as staff in the CIVD-19 Study which is being conducted at CBHC under Dr. Windsor's supervision over the past year (UIUC IRB protocol 22606). Heather Perkins is the research assistant and she is a first-year doctoral student working under Dr. Windsor supervision. All research team has completed the IRB training certificate.

Section 17. DISSEMINATION OF RESULTS

17A. List proposed forms of dissemination (e.g. journal articles, thesis, academic paper, conference presentation, sharing within industry, etc.). Study findings will be disseminated in aggregate form and without any identifying information. We will write journal articles, publish findings on our website, and present at academic conferences.
17B. Will any identifiers be published, shared, or otherwise disseminated? ☐ Yes ☒ No **If yes, does the consent form explicitly ask consent for such dissemination, or otherwise inform participants that it is required in order to participate in the study?** ☐ Yes
17C. Do you intend to put de-identified data in a data repository? ☐ Yes ☒ No **If yes, explain how data will be de-identified.**

Section 18. INVESTIGATOR & DEPARTMENTAL ASSURANCES

- I certify that the information provided in this application is complete and correct.
- I certify that I will follow my IRB Approved Protocol.
- I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
- I will comply with all applicable federal, state and local laws regarding the protection of human subjects in research.

Protocol Form

- I will ensure that the personnel performing this study are qualified and adhere to the provisions of this IRB-certified protocol.

The original signature of the PI is required before this application may be processed (electronic signatures are acceptable).

1/29/2023

Principal Investigator Date

If the PI is not eligible to serve as PI under the Campus Administrative Manual, the applicable academic dean, institute director, or campus administrative officer indicates their approval of the researcher to act as Principal Investigator. Please note that departmental assurance only needs to be provided in the initial application.

Name of Authorizing Individual

Signature of Authorizing Individual Date