ILLINOIS

OFFICE OF THE VICE CHANCELLOR
FOR RESEARCH & INNOVATION

Office for the Protection of Research Subjects
805 W. Pennsylvania Ave., MC-095
Urbana, IL 61801-4822

Notice of Approval: Continuing – Data Analysis Only

November 15, 2021

Principal Investigator	Liliane Windsor
CC	Ellen Benoit, Carol Lee
Protocol Title	*Community Wise: An Innovative multi-level intervention to reduce alcohol and illegal drug use*
Protocol Number	16574
Funding Source	National Institute on Minority Health & Health Disparities Grant Number: 5U01MD010629
Review Type	Expedited 8
Approved Subparts	BB
Status	Data Analysis Only
Risk Determination	No more than minimal risk
Approval Date	November 15, 2021
Expiration Date	November 14, 2022

This letter authorizes the use of human subjects in the above protocol. The University of Illinois at Urbana-Champaign Institutional Review Board (IRB) has reviewed and approved the research study as described.

The Principal Investigator of this study is responsible for:

- Conducting research in a manner consistent with the requirements of the University and federal regulations found at 45 CFR 46.
- Using the approved consent documents, with the footer, from this approved package.
- Requesting approval from the IRB prior to implementing modifications.
- Notifying OPRS of any problems involving human subjects, including unanticipated events, participant complaints, or protocol deviations.
- Notifying OPRS of the completion of the study.

University of Illinois at Urbana–Champaign

Office for the Protection of Research Subjects [OPRS]
528 East Green Street, Suite 203, MC-419
Champaign, IL 61820
tel: 217-333-2670 fax: 217-333-0405
E-mail: irb@illinois.edu Web: www.irb.illinois.edu

IRB Application

Application for Review of Research Involving Human Subjects

This Section is for Office Use Only	
UIUC IRB Protocol No. 16574	Track: _____
Exempt under 45 CFR §46.101(b) ☐(1) ☐(2) ☐(3) ☐(4) ☐(5) ☐(6)	Reviewer 1: _____
Expedite, Category ☐(1) ☐(2) ☐(3) ☐(4) ☐(5) ☐(6) ☐(7) ☐(8) ☐(9)	Reviewer 2: _____

All forms must be completed, signed by the RPI, and submitted by FAX, Email, or single-sided hard copy.
Please type responses, handwritten forms will not be accepted.
Please, no staples!

☐ Initial Submission, date of submission _____
☒ Revised IRB-1, date of revised IRB-1 1/15/2020

1. RESPONSIBLE PROJECT INVESTIGATOR (RPI) The RPI must be a non-visiting member of UIUC faculty or staff who will serve as project supervisor at UIUC. **For other research team members [including those from other institutions], please complete the Research Team Attachment and provide with the completed application.** Include all persons who will be 1) directly responsible for the project's design or implementation, 2) recruitment, 3) obtain informed consent, 4) involved in data collection, data analysis, or follow-up.

Last Name: Windsor	First Name: Liliane		Academic Degree(s): PhD
Dept. or Unit: School of Social Work	Office Address: 1010 W. Nevada St.		Mail Code:
Street Address: 1010 W. Nevada St.	City: Urbana	State: IL	Zip Code: 61801
Phone: 217-300-1782	**Fax:**	E-mail: lwindsor@illinois.edu	
UIUC Status: Non-visiting member of (Mark One) ☒ **Faculty** ☐ **Academic Professional/Staff**			
Training ☒ **CITI Training, Date of Completion, 02/10/21** ☐ **Additional training, Date of Completion[1],**			

2. PROJECT TITLE

[1] Additional CITI modules may be required depending on subject populations or types of research. These include: (i) research enrolling children; (ii) research enrolling prisoners; (iii) FDA regulated research; (iv) data collected via the internet; (v) research conducted in public elementary/secondary schools; and, (vi) researchers conducted in international sites

Community Wise: An innovative multi-level intervention to reduce alcohol and illegal drug use

3. FUNDING Indicate whether this research is funded by, or application has been made for, a grant, contract, or gift.

3A. STATUS ☐ Research is **not funded** and is **not pending** a funding decision (Proceed to Part 4).

☒ Research is **funded** (funding decision has been made).
☐ Funding decision is **pending**. Funding proposal submission date:

3B. SOURCE(S) If the research is funded or pending a funding decision, mark and name all sources:

	Type of Funding—check all that apply	**Name of Source**
☐	**UIUC Department, College, or Campus** (includes Research Board and Campus Fellowship Training Grants)	
☒	**Federal** (from federal agencies, offices, departments, centers)	**National Institute on Minority Health & Health Disparities**
☐	**Commercial Sponsorship & Industry**[2][3] (from corporations, partnerships, proprietorships)	
☐	**State of Illinois Department or Agency** (from any state office or entity)	
☐	**Gift or Foundation (including UIF)** (public or private foundations, not-for-profit corporations, private gifts)	

→ Check here if the funding is through a Training Grant: ☐

3C. PROPOSAL Attach a complete copy of the funding proposal or contract. ☒ Attached

Sponsor-assigned grant number, if known: **1U01MD010629 - 01**

Title of Funding Proposal or Contract, if different from Project Title in Part 2:

3D. FUNDING AGENCY OFFICIAL, IF ANY, TO BE NOTIFIED OF IRB APPROVAL

Last Name: Griffith	First Name: Carla	Salutation: Ms.	
Agency: **National Institute on Minority Health & Health Disparities**	Office Address: 6707 Democracy Boulevard, Suite 800		Mail Code:
Street Address:	City: Bethesda	State: MD	Zip Code: 20892-5465

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

Phone: (301) 594-8944	Fax: (301) 480-4049	E-mail: Griffithcp@mail.nih.gov

4. FINANCIAL INTERESTS: Indicate below if any investigators or any members of their immediate families have any relationships, commitments, or activities with the sponsor of this research that might present or appear to present a conflict of interest with regard to the outcome of the research. (If a financial conflict of interest exists, please submit the UIUC approved conflict management plan. If you have questions about conflict of interest contact the Office of the Vice Chancellor for Research at 217-333-0034.)

☐ Ownership, equity or stock options
☐ Has been disclosed to the UIUC campus **OR** ☐ has not been disclosed to the UIUC campus

☐ Personal compensation such as royalties, consulting fees etc.
☐ Has been disclosed to the UIUC campus **OR** ☐ has not been disclosed to the UIUC campus
☐ Intellectual property such as patents, trademarks, copyright, licensing, etc.
☐ Has been disclosed to the UIUC campus **OR** ☐ has not been disclosed to the UIUC campus

☐ Other conflict of interest:
☐ Has been disclosed to the UIUC campus **OR** ☐ has not been disclosed to the UIUC campus

☒ No conflicts exist

5. SUMMARIZE THE RESEARCH. In **LAY LANGUAGE**, summarize the objectives and significance of the research.

Rates of alcohol and illicit drug use (AIDU) among residents of distressed communities with concentrations of African Americans (DCAA- i.e., localities with high rates of poverty and crime) are similar to the general population. Yet AIDU has significantly higher consequences for residents in DCAAs (e.g., higher incarceration and HIV/HCV infection rates), who also have considerably less access to effective treatment of substance use disorders. This project will continue to develop and test *Community Wise*, an innovative multi-level intervention created in partnership with service providers, residents of DCAAs and individuals with histories of substance use disorders and incarceration, to reduce health inequalities related to AIDU. We used community-based participatory research (CBPR) to develop and pilot test *Community Wise,* achieving 75% intervention completion rates, despite great participant challenges (such as homelessness, AIDU, and poverty). Note that substance use disorder intervention completion rates in the literature are much lower among populations with fewer challenges (often 30 to 40%). We believe that this success is due to the CBPR model used to develop an intervention that is relevant to participants' needs.

Community Wise addresses social determinants of health (e.g., stigma, poverty, lack of treatment access, housing, and meaningful employment) and inequalities related to AIDU at the micro level (e.g., cognitive and behavioral processes), meso level (e.g., relationships with individuals and organizations) and macro level (e.g., political and cultural processes). *Community Wise* builds on critical consciousness theory, which empowers individuals, organizations, and communities to address social determinants of health while changing individual behaviors (e.g., reducing AIDU). We propose

to apply the Multiphase Optimization Strategy (MOST) - an innovative and rigorous framework that employs factorial designs - to optimize *Community Wise.* Specifically, using MOST we will identify the most efficient, scalable, and sustainable components of *Community Wise* so that we can refine the intervention protocol by including only components that significantly reduce AIDU. The long-term goal of *Community Wise* is to reduce health inequalities related to AIDU between men with substance use disorders and a history of incarceration residing in DCAAs and the general population through an intervention that is congruent with DCAA world views and grounded in scientific and indigenous knowledge. Data from this study will culminate in an optimized *Community Wise* manual; enhanced methodological strategies to develop multi-component scalable interventions using MOST and CBPR; and a better understanding of the application of critical consciousness theory to the field of health inequalities related to AIDU.

6. PERFORMANCE SITES

Including UIUC sites, describe ALL the research sites for this protocol. For each non-UIUC site, describe: Whether the site has an IRB. Whether the site has granted permission for the research to be conducted. Contact information for the site. If the site has an IRB, whether the site's IRB has approved the research or planned to defer review to a UIUC IRB.		For non-UIUC sites, documentation of IRB approval is:
1.	National Development & Research Institutes, Inc. FWA00002853 Carol Tarzian: 212-845-4405; tarzian@ndri.org	☒ Attached ☐ Will Follow ☐ N/A
3.	The University of Michigan FWA00004969	☒ Attached ☐ Will Follow ☐ N/A
4	North Jersey Community Research Initiative (NJCRI) FWA00001870	☒ Attached ☐ Will Follow ☐ N/A

List and describe any additional Performance Sites information on an attachment and check here: ☐

7. DESCRIBE THE HUMAN SUBJECTS

7A. SECONDARY DATA ONLY? If this research *only* involves the analysis of data that *has already been collected* from human subjects and *no new data collection will occur,* check here: ☐

7B. MATERIALS OF HUMAN ORIGIN? Will this research involve the collection, analysis, or banking of human biological materials (*e.g.,* cells, tissues, fluids, DNA)? ☒ **Yes** ☐ **No** If yes attach **Appendix C**, the *Biological Materials Form*.

7C. ANTICIPATED NUMBERS How many subjects, including controls, will you study in order to get the data that you need?

If you plan to study disproportionate numbers of a given sex, race, or minority group, provide scientific rationale in Part 11.

Performance Site		# Male	# Female	Total
1.	NJCRI - RCT	592	0	592
2.	NJCRI - NCCB	08	12	20

3.				
TOTALS		600	12	612

List Anticipated Numbers for additional Performance Sites on an attachment and check here: ☐

7D. AGE RANGE Mark all that apply. Researchers planning to include children in research projects involving *more than minimal risk* must provide written documentation of the benefits that are likely to accrue to a child participating in the project. This should include information gathered on adults, if it exists, or an explanation about why it does not exist.

☐ 0–7 years ☐ 8–17 years ☒ 18–64 years ☒ 65+ years

→ ☐ If applicable, written documentation of benefits for including children in ***more than minimal risk*** research is attached.

7E. SPECIAL OR VULNERABLE POPULATIONS Mark groups that will be targeted by design. Also indicate groups likely to be involved in the research even though they are not targeted by design.

☐ None of the following special populations will be targeted

☐ Children (age < 18
☐ Neonates
☐ Fetuses *(in utero)*
☐ *in vitro* fertilization
☐ Pregnant or lactating
☐ Inpatients
☒ Outpatients
☐ Elderly (age > 65
☐ Other (describe here):

☐ Mentally disabled or cognitively impaired persons
☐ Adults with legal guardians
☐ Persons with limited civil freedom (*e.g.,* prisoners)
☐ Specific racial or ethnic group(s)—
☒ Low income or economically disadvantaged persons
☐ UIUC Students—name subject pool, if
☐ Other College Students—name subject

7F. If you checked any of the groups in question 7E, describe additional safeguards included in the protocol to protect the rights and welfare of special or vulnerable populations.

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 and all Newark Community Collaborative Board (NCCB) members will be required to undergo 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 informed consent forms and locator forms (used for follow-up interviews after the baseline). These forms will be kept electronically in box, in a folder separate from the data. Only full time, trained staff in the project including the outreach works, group facilitators, PD and PIs will have access to these files. Peer facilitator and licensed facilitator will not have access to data from the individuals that are randomized into their groups.

The electronic files generated through data collection will be identified by code numbers and codenames only and kept in password-protected devices/servers, separate from identifying information and available only to 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. Signed consent forms will be kept for 3 years after study completion. De-identified electronic data will be kept indefinitely. NCCB participants may ask at any time to have recordings of their interview destroyed by calling/e-mailing one of the Principal Investigators at the numbers provided in the informed consent forms. RCT voice recordings will be kept indefinitely for data analysis. However, if we have reason to believe that any of these recordings contain information that can put any of our participants in danger of being hurt or being incarcerated, we will destroy the recording.

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 NJCRI in the event that someone may need immediate assistance, whether it is during data collection or during the intervention sessions.

Dr. Windsor, Dr. Benoit, and project director will be available by phone at all times in case an emergency occurs. Any adverse event will be reported to the IRB and funding agency within 24 hours. Through our NCCB 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, legal support clinic at Rutgers University, Newark campus, 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, we will conduct the MINI suicidality screen and if we find anyone at risk, 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.

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.

8. RECRUITMENT

8A-1 RECRUITING PROCEDURES Specifically describe the systematic procedures for finding and recruiting subjects or requesting pre-existing data or materials. 1) State whether any of the researchers are associated with the subjects (*e.g.,* subjects are students, employees, patients). 2) Name any specific agencies or institutions that will provide access to subjects or subject data. 3) Who will contact the prospective subjects? 4) Who gives approval if subjects are chosen from records? 5) Describe solicitation through the use of advertising (*e.g.,* posters, flyers, announcements, newspaper, radio, television, Internet), face-to-face interaction, direct mail or phone contact, classrooms, subject pools, health care registries, patient referrals, and institutional "gatekeepers," as applicable.

This study will include up to 20 participants who will serve a dual role as researchers and human subjects through their membership in the Newark Community Collaborative Board (NCCB). All NCCB members are also research participants because NCCB meetings are recorded and board members complete an anonymous annual survey, both to monitor the study for compliance with principles of community-based participatory research and satisfaction. No NCCB member will be a participant in the *Community Wise* clinical trial. No NCCB member except the project director and the principal investigators, will have access to any identifying information about participants.

The NCCB is a diverse group of service providers, consumers of substance abuse treatment, individuals with a history of incarceration, researchers, and government employees who work together to improve health conditions in the City of Newark, NJ. The NCCB developed and pilot tested *Community Wise* and they will oversee all phases of the current study. At this time we have a total of 15 members. Anyone can apply to become a NCCB member at any time. Since the NCCB will oversee the research (e.g., recruitments, data collections, analysis, dissemination) all members are required to complete the CITI training prior to engaging in any study activities.

NCCB members bring a variety of skills to the table. Together, the NCCB is the overall directing body or the research, but outside of monthly meetings to get a big picture update on the research, it will function through sub-committees. All activities are voluntary (meaning no one is required to participate in any given activity). Subcommittees are formed to conduct specific and time limited research tasks. Membership in subcommittees is based on individual members' skills and interest in participating. For instance, clinical screening for the clinical trial requires that screeners have clinical training at the master level. Hence, only NCCB members who are clinicians are eligible to join the clinical screening sub-committee. In the event that NCCB clinicians are not interested in conducting clinical trial screens, we can hire and train outside clinicians to perform that task. Thus, NCCB members participate in all aspects of the research; however, not every NCCB member participates in every task. This is done on a case by case basis under the supervision of the project director and PIs.

Our clinical trial participants will be recruited from various venues in the community and using a variety of approaches. We will post fliers at reentry, substance abuse, and HIV/HCV service agencies throughout the community (e.g., Integrity House; La Casa de Don Pedro; NJCRI). Individual service providers and *Community Wise* alumni will be asked to help disseminate information about the study by distributing study fliers to people who may meet the eligibility criteria. These agencies and Community Wise alumni will not engage in recruitment; they will simply distribute fliers about the study. We will train the partner agency staff not to answer any questions that their clients may have about the study. We will provide them with the partner agency flier dissemination instruction sheet so that they can help us avoid potential coercion. We will pay NCCB members $5 per eligible participant referred into the project who successfully enrolls. NCCB members will distribute the fliers and encourage people they believe may be eligible and interested to contact the study outreach worker to complete the phone screening. During the screening, we ask participants to tell us who referred them to the study. NCCB members will receive a lump sum per wave for the number of people that name them as a referral source and that were admitted into the study. NCCB members will not have access to the information about who did not enter the study and why. Once the wave sample is randomized, the outreach worker will cross check the list of referee names in the phone screen with the list of people enrolled and submit the dollar amount that is due to each NCCB member. The outreach worker is not a member of the NCCB and only the outreach worker will have contact with

potential study participants which will include conducting the phone screen, and scheduling the clinical screen, the orientation session, and the baseline.

In addition, research staff will encourage potential participants to help distribute the study's fliers in their neighborhoods, churches and other meeting places. Men interested in participating will call the study's cell phone number to receive information about the study. **A trained master's level clinician** will conduct a brief phone screening to obtain self-reported eligibility information including substance use disorder, date of last prison release, age and contact information. Those meeting phone screening eligibility will be invited to complete the clinical screen. Those meeting the clinical screen eligibility criteria (see below) will be consented into the study. In this process we will explain the randomization process, the study risks and benefits, what we will ask them to do and their rights as research participants. Those consenting will be randomized into one of the eight experimental conditions.

It is possible the NCCB members may know some of the potential clinical trial participants as these individuals live and work in Newark, NJ. Potential clinical trial participants may be clients, family members, or a friend of any NCCB member. The standard protocol for such situations is to ensure that any NCCB member or staff person who has a personal relationship with a potential participant does not recruit or interact with that person in any capacity as part of the study. This is acknowledged in the NCCB informed consent which will be signed by NCCB members.

NJCRI will be the main recruitment and performance site where experimental groups will run and all data will be collected. NJCRI has been our partner for over 6 years and it has served as a site for the intervention during our pilot testing. NJCRI is New Jersey's largest and most comprehensive HIV/AIDS community-based organization. NJCRI's mission is "to help people with HIV/AIDS and those at risk for HIV/AIDS." NJCRI conducts state-wide HIV clinical trials, and HIV treatment, care and prevention services in the Greater Newark Area. Populations served include youth and adults, men and women, men who have sex with men, people who acquire or who are at risk for HIV through injection drug use, and others. NJCRI also seeks to address the concerns and disparities of access to health care faced by minority populations. Some of the non-HIV related services offered include behavioral research, chronic illness management education, street outreach, substance abuse treatment, transportation, food pantry, and technical assistance to other community-based organizations. Approximately 5,000 people avail themselves of NJCRI's free and confidential services each year. NJCRI is located in a predominantly low-income African-American neighborhood in Newark, NJ. Another advantage of partnering with NJCRI is that they offer HIV/STDs counseling, testing and referrals services at no charge to people in the community. They house 1 of 5 syringe exchange programs in the state along with a drop-in center. Our participants will have access to all of these services at NJCRI.

We will also recruit participants through New Jersey parole officers. Specifically, parole officers will share the Community Wise study flier with their clients and inform them that they may choose to contact the study staff and participate in Community Wise as an optional and additional treatment service. Parole officers will not have access to information about who enrolled and who did not enroll unless the participant chooses to disclose this information themselves.

8 A-2 Attach final copies of recruiting materials including the final copy of printed advertisements and the final version of any audio/taped advertisements and check here: Attached ☒ Will Follow ☐

8B. WITHHELD INFORMATION Do you propose to withhold information from subjects prior to or during their participation?

☐ Yes ☒ No

If yes, describe what will be withheld, justify the withholding (address risks, provide rationale), describe the debriefing plan, and attach a labeled copy of a written debriefing form, to be provided to subjects. ☐ Debriefing Attached ☐ Will Follow

8C. PROTECTED HEALTH INFORMATION (PHI) The IRB must address the privacy and use of health information that is created, received, or housed by health care providers, health plans, or health care clearinghouses and that identifies or could be used to identify an individual. During *either recruiting or data collection*, will you use or have access to such information that is related to the past, present or future health or conditions of a *living or deceased* individual, provision of health care to the individual, or the payment for the provision of health care to the individual? ☐ Yes ☒ No

8D. SCHOOL-BASED RESEARCH If subjects will be recruited from Illinois public or private elementary or secondary schools, additional deadlines and procedures apply. Criminal background clearances might be required. Special consideration must be given to the exclusion of protected populations. Please contact the Office of School–University Research Relations (OSURR) (217.244.0515 or http://www.ed.uiuc.edu/BER/OSURR.html) for more information. Mark one:

☐ Illinois schools **will** be used ☒ Illinois schools **will not** be used

9. INCLUSION AND EXCLUSION CRITERIA Address all four of the following items in explaining who will and will not qualify for participation and how that determination will be made: (1) Describe procedures to assure equitable selection of subjects. Justify the use of any special or vulnerable groups marked in Part 9E. Selection criteria that target one sex, race, or ethnic group require a clear scientific rationale. (2) List specific criteria for inclusion and exclusion of subjects in the study, including treatment groups and controls. (3) Name and attach copies of measures and protocols that will be used to screen applicants. (4) Explain how the inclusion/exclusion criteria will be assessed and by whom. If special expertise is required to evaluate screening responses or data, tell who will make this evaluation and describe their training and experience.

All experimental participants will be males over the age of 18 and predominantly African Americans. Because we are dealing with health disparities related to AIDU and the intervention was developed at a DCAA and will take place in Newark, NJ, we anticipate that the vast majority of participants will be African American. However, we are not imposing race as an eligibility criterion.

Our pilot study included a balanced sample of men and women and our preliminary findings showed great improvements among the women. While we had hoped to conduct this experiment with both men and women, the reality of the population in Essex County made this impossible at this time.

Women represent only 6% of the populations being released from incarceration in Essex County, NJ. Therefore, unless we expanded the study to additional sites (which is unrealistic given the budgetary constraints), recruiting enough women would not be feasible. We discussed this challenge at our NCCB meeting and collaboratively made the difficult decision to exclude women from the current study. Once the intervention is optimized using a male sample, we will be in a better position to design a larger, multi-site study where we will be able to adapt and test the intervention with women.

We do not anticipate that we will have enough power to conduct significant racial comparisons as we expect that approximately 80% of our sample will be African American. We will, however, conduct valid analysis and explore potential moderation effects on the AIDU outcome to inform planning of future studies that could adapt *Community Wise* for use with other populations.

Women currently make up the majority of the NCCB. The NCCB is racially diverse with African Americans, Latinos, and Whites represented. The only female participants in the study will be members of the NCCB.

Participants in this study are not expected to be under custody, court order to attend the treatment, or any form of limited civil freedom; thus this is not part of the inclusion or exclusion criteria. **No research will be conducted with any subject who becomes incarcerated after enrollment until a research amendment discussing the specific procedures of access to the facility is filed and approved by the IRB.**
Master or doctoral level social workers or psychologists will conduct the clinical screens to assess participant eligibility. All recruitment will take place at Integrity House. Staff will be supervised by our co-investigator project director and the PI Ellen Benoit.

Inclusion criteria for the factorial experiment participants in the study will include:

- Men age 18 or older
- Residence in Essex County, NJ
- Willingness to be voice recorded during group sessions
- Ability to speak English
- Having a substance use disorder measured by the Global Appraisal of Individual Needs-Substance Problem Scale (GAIN-SPS).
- Having been released from incarceration in the past 4 years. This is due to research that shows that people are more likely to be re-incarcerated within the first 4 years of release from incarceration.

Exclusion criteria for RCT participants will include:

- Severe psychiatric disorders in the prior 6 months not stabilized (schizophrenia, depression with psychotic features, bipolar disorder, any psychosis), as measured by the MINI International Neuropsychiatric Interview 6 psychoticism and suicidality modules
- Gross cognitive impairment as measured by the Mini Mental State Exam.
- Sexual identification as female

Inclusion criteria for the focus group participants in the study will include:

- Being randomly selected from the study's intent to treat sample
- Being willing to be voice recorded
- Having attended at least one intervention session

Inclusion criteria for the NCCB members include:

- Men and women age 18 or older
- Knowledge about Essex County, NJ
- Ability to speak English
- Being invited to become a NCCB member after a majority favoring vote

We will use a screening script and a signed consent form to obtain permission to conduct the screening and use the data as part of the study, regardless of establishment of final eligibility. Participants will be informed that the information will be confidential and they can choose to stop participating at any time and we will destroy their data upon receiving their request. Note that voice recordings of Community Wise are exceptions as this will include data from entire groups of participants. We will only destroy voice recordings if there is reason to believe the recording has content that can put participants in danger of being hurt or re-incarcerated.

10. RESEARCH PROCEDURES: Using LAYMAN'S LANGUAGE, specifically describe what the participants (treatment groups and controls) will do and where the research activities will take place. Give approximate dates and durations for specific activities, including the total number of treatments, visits, or meetings required and the total time commitment.
(For schools-based research where class time is used, describe in detail the activities planned for nonparticipants and explain where (*e.g.,* in a classroom, in a private area) both participants and nonparticipants will be located during the research activities. Include a concise description of procedures, locations, time commitments, and alternate activities on the relevant consent and assent forms.)

All research activities will take place at NJCRI. Drug screening will take place at baseline and follow-up assessments conducted by trained full time staff supervised by the project director. Participants will be told by the RA that they have a right to refuse to complete the drug screen and that results will not be shared with staff at NJCRI. Results will be used to enhance the rigor of the study as an added source of information about drug use.

Intervention groups will be held at NJCRI. The research team is being hired through NJCRI and will have offices in the building. Mr. Morris and Mr. Iwuala will be the contact people at NJCRI. NJCRI will provide the research team with an office space for each project full time employee (project director, outreach worker, and group facilitators) in addition to conference rooms where the research groups will take place.

The project applies community based participatory research (CBPR) principles to the multiphase optimization strategy (MOST) framework in implementing a 2x2x2 factorial design in which 592 men with substance use disorders and a history of incarceration residing in Essex County, NJ will be randomized into one of sixteen conditions: 1) Critical Dialogue (CD) only, facilitated by a licensed facilitator (LF). 2) Critical Dialogue (CD) only, facilitated by a peer facilitator (PF). 3) Quality-of-Life-Wheel (QLW) only, facilitated by LF. 4) Quality of Life Wheel only, facilitated by PF. 5) Capacity building project (CBP) only, facilitated by LF. 6) CBP only, facilitated by PF. 7) CD+QLW facilitated by LF. 8) CD+QLW facilitated by PF. 9) CD+CBP facilitated by LF. 10) CD+CBP facilitated by PF. 11) QLW+CBP facilitated by LF. 12) QLW+CBP facilitated by PF. 13) CD+QLW+CBP facilitated by LF. 14) CD+QLW+CBP facilitated by PF. 15) Core Component facilitated by LF and 16) Core Component facilitated by PF. All groups will receive the core component of the intervention which includes introduction, critical thinking session and graduation.

Facilitators, whether licensed or peer, may or may not be members of the NCCB. In the event a NCCB member is selected to be a group facilitator, they will not have access to any of the research data collected in the groups they are facilitating and they will need to leave any portion of the NCCB meetings where we may discuss their groups. This will be done to avoid bias in the group facilitation and in the data.

Core component includes an introduction session, a critical thinking session, and the graduation. This is designed to give participants tools to assess their own thinking and hence, their assumptions that may contribute to substance use;

Critical Dialogue consists of group conversations prompted by thematic images. It 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;

Quality-of-Life-Wheel consists of individual and group exercises to develop individual goals. It aims to increase self-efficacy and help participants develop a vision for their future, breaking this vision down into small, feasible, measureable goals they can implement on a weekly basis (e.g. quitting smoking, improving relationships with family members, paying down debt);

Capacity Building Projects consist of projects created by the groups to address a community problem. The capacity building projects are 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.

Facilitation by both licensed clinician and peer facilitator will provide an opportunity to test not only the efficacy of delivering the intervention through peers but will also determine the cost effectiveness of peer delivery vs. licensed facilitators.

Prior to the being consented into the study at baseline, participants will have the opportunity to attend an orientation session where we will explain the research design, the different conditions available, the randomization process, and the risks and benefits of participation in the study. We will emphasize the difference between the intervention and the research (mainly group sessions and data collection sessions). We hope that this make the participants better informed about the study and minimize contamination by explaining the importance to keep their activities in each group private. Data will be collected in six waves and will include a baseline and five monthly follow-up interviews. These interventions were developed and pilot tested by our team. We will also randomly select 24 groups to participate in focus groups and provide their feedback about their experience participating in the intervention. We will randomly select one group per intervention condition and only participants who attended at least one intervention session will be eligible to participate. We will keep track of other services that participants seek during follow-up assessments and we will control for the impact of these services statistically.

Below is a table displaying research activities. Note that for follow-up, depending on which condition someone is randomized into, they may complete between 1 to 5 follow-ups post intervention, receiving $20 per follow-up plus $2.50 for each intervention session they attend. This occurs because of the variance in the number in intervention sessions among the different conditions.:

Activity	Cost per participant	Time	Professional Assigned
Clinical screens	$10	30 minutes	Licensed NCCB clinicians
Baselines	$20	90 minutes	NCCB, research assistants
Follow-ups during intervention	$20 + $2.50 per intervention group attended in the past month for a maximum of $30 per follow-up	90 minutes	
Focus groups	$20	90 minutes	
NCCB Meetings	$50	120 minutes	Online survey
NCCB retreat	$100	4 hours	Research assistants

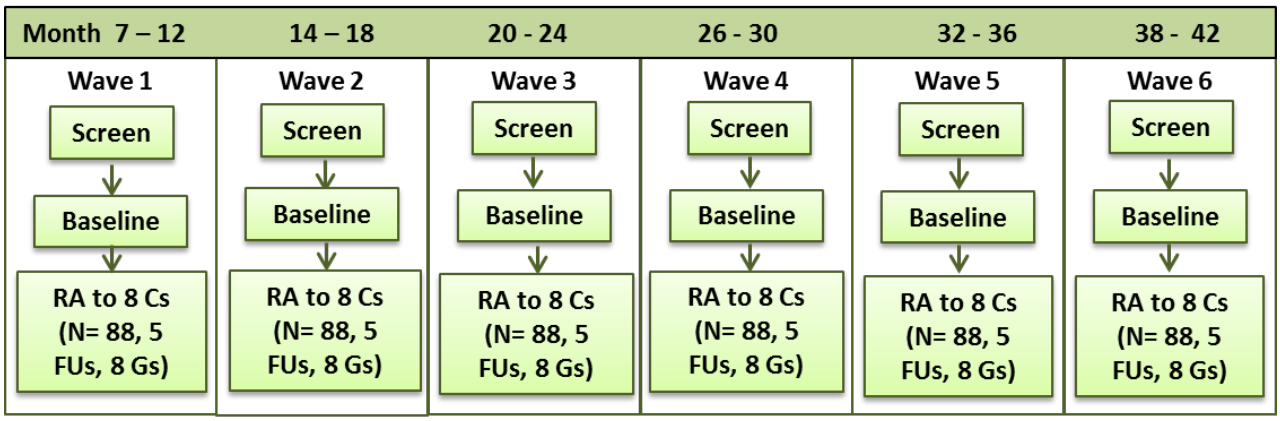
Below is a table summarizing the participation of 592 men in the different experimental conditions. Note participants may stop participating at any time or skip any sessions without penalty:

Study condition with number of sessions and total cost estimate to deliver each condition					
Experimental Condition	Critical Dialogue (CD)	Quality of Life Wheel (QLW)	Capacity Building Project (CBP)	Facilitated By*	# 120 minute sessions
1: CD alone	Present	Absent	Absent	LF	9
2: CD alone	Present	Absent	Absent	PF	9
3:QLW alone	Absent	Present	Absent	LF	6
4:QLW alone	Absent	Present	Absent	PF	6
5:CBP alone	Absent	Absent	Present	LF	6
6:CBP alone	Absent	Absent	Present	PF	6
7: CD+QLW	Present	Present	Absent	LF	12
8: CD+QLW	Present	Present	Absent	PF	12
9: CD+CBP	Present	Absent	Present	LF	12
10: CD+CBP	Present	Absent	Present	PF	12
11: QLW+CBP	Absent	Present	Present	LF	9
12: QLW+CBP	Absent	Present	Present	PF	9
13: Full intervention	Present	Present	Present	LF	15
14: Full intervention	Present	Present	Present	PF	15
15: Core component	Absent	Absent	Absent	LF	0

*LF = Licensed facilitator; PF = Peer facilitator

Below is a table describing the research process:

Figure 4: Study's procedures



RA = randomization; C=Conditions; FU=monthly follow-ups; G= intervention groups

Measures:

Clinical Screen: Mini Mental State Exam, MINI International Neuropsychiatric Interview 6 psychoticism and suicidality modules, and the Global Appraisal of Individual Needs-Substance Problem Scale (GAIN-SPS).

Baseline and follow-ups: Timeline Follow Back to measure drug use, a urine toxicology screen, the Crime and Violence Scale (part of the GAIN scale), the States of Engaged Awareness about Health Inequalities (SEAHI-unpublished and developed by us-see baseline and follow-up packet). The SEAHI will be administered through the computer along will all the other measures. During the baseline assessment, we will ask participants permission to take a digital photograph of them during the baseline to assist with finding them during follow-ups. The photo will be in the master file along with the name and identifying information, but not linked to any data. Photographs will be used by the outreach workers to recognize participants on the streets and they will be destroyed as soon as the participant completes follow up 5. Participants will have the option to refuse without penalty and they may ask us to destroy their photo at any time during the study.

Additional follow-up measures: Use of Treatment Skills measure to track participants' use of specific tools learned; measures of participants' perceptions of helpful intervention components, and the Treatment Service Review.

A trained research assistant (most likely a MSW student) will schedule the data collection with up to eight participants at a time. Participants will be asked to take a urine collection sterile cup when they are ready to use the restroom. The RA will ask them to collect ½ inch of urine privately in the restroom, close the container and hand it to the RA who will be working near the data collection room. The RA will use rubber gloves to handle the sample. A drug test will be inserted in the urine and the results can be read within 3 minutes. The RA will empty the cup in a toilet and dispose the cup and gloves in a dedicated trash bin in a private area. The results will be recorded directly into redcap using the participant's codename. No identifying information will be attached to the results or the discarded materials. The RA will pay the participant when they complete the survey and they will be free to go. While she is in collecting the drug test, she will tell participants still working on the computer to wait for her to return in case they finish or have questions. The urine drug test procedure takes 5 minutes to complete. We used this strategy successfully in our pilot study.

Facilitators complete a checklist at the end of each *Community Wise* group session to list the activities completed and group attendance. Facilitators will upload the checklists directly to a facilitator-assigned folder in Box, the study's secured server, where they will be reviewed by the PIs and the PD.

Participants will use both codenames and code numbers, which will be connected in the electronic key list, but not in the database. We use this strategy to facilitate (and humanize) participants as we talk about them in meetings (including clinical supervision, NCCB meetings, and in Community Wise groups). Participants can request that we destroy their data (except group voice recordings) at any time until data collection is completed by notifying one of the PIs by phone or e-mail. After that we will destroy the electronic key and we will be unable to determine what data belongs to whom. Note that voice recordings will be kept indefinitely.

The clinical screen will be an in-person interview conducted by the study local PI, the licensed facilitator, or the project director who will be properly trained by Dr. Windsor.
Urine screens will be collected in person by a trained staff person. Baseline and follow-up will be administered through Redcap on the laptop during the small group sessions and administered by trained full time staff. The peer facilitator will only be allowed to collect data from participants in the licensed facilitator groups and vice versa.

Focus groups will be facilitated in person by the local PI or trained staff members who did not facilitate the group being interviewed.

NCCB members and project staff will recuse themselves from interacting with anyone they personally know as a part of study activities. We will have study interviewers review the name of the person they are interviewing prior to the interview to make sure they do not personally know them. If they do, we will find someone else to conduct the interview. If a NCCB member unexpectedly encounters someone they know at a study related activity, they will recuse themselves and notify the project director and the principal investigators. The project director will keep a list of participants that we identify as having a personal relationship with NCCB members or staff and we will make sure these individuals are not booked together for any study related activities.

Due to randomization, we cannot schedule the group time and date before the participant enrolls in the study. Thus, it is likely that many participants will be randomized into a group that is being held during a time when they are no available. Thus, we will offer, as a courtesy, The opportunity for people who are enrolled in the study to participate in a full intervention group after they complete their participation in the study. These groups will be provided by the licensed facilitator and it will not be a part of the study. No data will be collected and this will be offered solely to give participants the option to engage in the intervention.

11. EQUIPMENT Will any physical stimulation or physiological data acquisition equipment be used with the subjects?

☒ Yes ☐ No If yes, attach **Appendix A**, the *Research Equipment Form*.

12. DEVICES Will any devices be used with the subjects?

☐ Yes ☒ No If yes, attach **Appendix B-1.**

13. DRUGS AND BIOLOGICS Will any drugs or chemical or biological agents be used with the subjects?

☐ Yes ☒ No If yes, attach **Appendix B-2**.

14. 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 (217.244.0600; bmrf@bmrl.bmrf.uiuc.edu) and use BIC-approved screening and consent forms. Attach:

BIC approval ☐ Attached
BIC screening form ☐ Attached
BIC consent form ☐ Attached

15. MEASURES If subjects will complete questionnaires, surveys, interviews, psychological measures, or other measures, however administered, the IRB must review and approve the measures. List all such measures here and attach complete, labeled copies (including translations, if applicable) to this application:

CLINICAL SCREEN ☒ Attached	
Measure 1:	Mini Mental
Measure 2:	Mini suicidality screen
Measure 3:	Mini Psychotic Assessment
Measure 4:	GAIN
BASELINE ☒ Attached	
Measure 5:	Demographics
Measure 6:	Timeline Follow-back
Measure 7:	Crime and violence scale (part of GAIN)
Measure 8:	States of Engaged Awareness about Health Inequalities(developed by us)
FOLLOW-UP ☒ Attached	
Measure 9:	Demographics
Measure10:	Timeline Follow-back
Measure11:	Crime and violence scale

Measure 12:	States of Engaged Awareness about Health Inequalities (developed by us)
Measure 13:	Treatment Services Review (TSR)
Measure 14:	Yalom Group Scale
Measure 15:	Use of Treatment Skills (UTS- developed by use)
Measure 16:	End of treatment questionnaire (ETQ- Developed by us)

List additional Measures on an attachment and check here: ☐

16. SUBJECT REMUNERATION

Will subjects receive inducements or rewards before, during, or after participation? ☒ Yes ☐ No

If yes, will payment be prorated for partial participation? ☒ Yes ☐ No

If remuneration will be given, for each subject group:

(1) specify the form of remuneration, including $, course credit, lottery, gift certificate, or other;
(2) state the $ amount or the approximate $US value, or the course credit and its percentage of the final grade;
(3) explain the remuneration plan, including whether and how prorating will be made for partial participation;
(4) for lotteries, include (a) the number of prizes, (b) the nature and value of each prize, (c) the approximate odds of winning, (d) the date(s) of the drawing(s), and (e) how winners will be notified, by whom, and by when; and
(5) include all this information on the relevant consent forms.

Incentives will be distributed in cash at the completion of each study tasks described in the table above. Participants may earn as much as $187.5 over 5 months if they complete all study activities. For instance, someone randomized into condition 14 (full intervention) who completes all study activities will receive: $10 for clinical screen, $20 for baseline, $20 for the all follow-ups plus $10 for each of the first 3 follow-ups for attending 4 intervention sessions per month, $7.50 for attending 3 intervention sessions in follow up 4 $20 for focus group if they are randomized to complete the focus group = $187.5. Someone randomized to receive condition 15 (core component only) and randomized not to complete the focus group who completes all study activities will receive $10 for clinical screen, $20 for baseline, $20 for each follow-up, in addition to $7.50 for follow-up 1 only will earn $137.50 over the course of the study.

NCCB members will receive $20 per hour worked, generally in meetings of 2 hours each. They will also receive $100 per 4 hour long retreat they attend. NCCB retreats are, for the most part, long NCCB meetings. Retreats can be more informal and build in opportunities for members to simply engage with one another, bring family and friends, and increase our bond. No confidential materials are discussed during open session retreats where non-NCCB members are present. If there is an agenda of items we need to discuss more formally, we use the same exact procedures as those described for meetings and collect the same data (video recording of the meeting). NCCB members

may also receive compensation for referring participants to the Community Wise randomized controlled trial. They will receive $5 per enrolled participant they refer. NCCB members will not know the identity of those they referred who successfully enrolled. Participants will contact the outreach worker directly and during the phone screen, we will ask them who referred them to the study. Those NCCB members who are named by the enrolled participants will receive a lump sum once recruitment is ended.

17. SUBJECT OUTLAY Will subjects incur costs for research-related procedures (*e.g.*, longer hospitalization, extra tests), use of equipment, lost compensation, or transportation (over 50 miles)?
☐ Yes ☒ No If yes, describe here:

18. CONFIDENTIALITY OF DATA Answer each of the following to describe methods that will ensure the confidentiality of individually identifiable data. Confidentiality is required unless subjects give express, written permission to have their identifiable information published, presented, or shared.

18A. CHECK IF USED IN DATA COLLECTION: ☒ Audio tapes/ ☒ Video tapes ☐ Still photos ☐ Other imaging

Digital voice

18B. DATA COLLECTION Explain how the data will be collected. If anonymous data collection is proposed, provide details of how investigators *will not have the ability to trace responses to subject identities.* For multiphase data collection or if multiple contacts will be made with subjects, specifically explain the subject tracking and coding systems.

Address the confidentiality of data collected via e-mail, databases, Web interfaces, computer servers, and other networked information, as applicable.

Data will be generated and collected through face-to-face computer assisted interviews, computer assisted self-interviews, focus groups, and group session audio recordings. This will include brief telephone screenings, clinical screenings, baseline, five post baseline follow-ups, focus groups and intervention sessions. Interested individuals will call the study's confidential phone number and complete a brief telephone screen with a research assistant who will obtain self-reported identifying and eligibility information such as birth date, complete name, last incarceration date and place, gender, current AIDU, and whether they reside in Essex County, NJ. Before completing the phone screen, participants will be given a brief description of the study and they will be informed that the information they release on the phone will be kept confidential and will be used only to verify eligibility (including verification of their last incarceration place and date based on public records). This information will be kept in a password secured Excel file in a password secured laptop at a

locked office at NJCRI. Those found to be eligible will be invited to complete the clinical screen with a licensed clinician at NJCRI. Prior to completing the clinical screen, participants will learn more about the study and the clinical screen. They will sign an informed consent to participate in the clinical screen which will include Mini Mental State Exam, MINI International Neuropsychiatric Interview 6 psychoticism and suicidality modules, and the Global Appraisal of Individual Needs-Substance Problem Scale (GAIN-SPS). Those found to be eligible will learn about the randomization process and the study procedures. The clinician will go through the informed consent and those who agree will be randomized into one of eight experimental conditions and we will schedule the baseline. Participants may take the informed consent with them and think about whether to participate or not, as long as we are still recruiting. Paper data will be kept at a locked file cabinet at NJCRI. A code number and a codename will be assigned to each participant completing the clinical screen and only this code number and codename will be used in the paper and electronic data collection. A master list will be created linking names with code numbers and this list will be kept in a password protected excel file in the PD's computer in a locked office at NJCRI.

Baseline and follow-up data will be collected at NJCRI by assistant staff member. *Community Wise* group participants will be scheduled to complete the data collection on the same day and time. Each participant will work independently on a private tablet using RedCap data collection management software. We will collect outcome, process, and safety monitoring measures (e.g. MINI suicidality) including AIDU, use of treatment skills measure, and their perceptions about helpful components. This electronic data will only contain the code numbers and codenames and it will be stored in a secured server at the University of Illinois at Urbana Champaign. Data will be securely uploaded into the server immediately after data collection. Only authorized personnel will have access to it.

During the baseline assessment, we will ask participants permission to take a digital photograph of them during the baseline to assist with finding them during follow-ups. The photo of those who consent will be taken by the RA and immediately uploaded into the master file along with the name and identifying information, but not linked to any data. Photographs will be used by the outreach workers to recognize participants on the streets and they will be destroyed as soon as the participant completes follow up 5. Participants will have the option to refuse without penalty and they may ask us to destroy their photo at any time during the study.

No research will be conducted with any subject while they are incarcerated.

Focus groups

Sixteen out of 48 *Community Wise* groups of up to eleven participants each will be randomly selected in advance during year 1 to be included in the focus groups throughout the six waves. Participants from selected groups who attended at least one Community Wise session will be invited to attend the focus group at the end of each data collection wave. The focus groups will be conducted at NJCRI by a trained RA, and will be audio-recorded and transcribed for analysis. Focus group sessions will be structured and the RA will be trained to keep the discussion focused on clients' satisfaction with the intervention. If a participant starts to talk about personal issues, the RA will stop them and offer to refer them to talk to an Integrity House counselor if appropriate (see focus group script). Data will be uploaded into a password-secured server at the University of Illinois at Urbana-Champaign. Only code numbers will be included with the electronic data.

Audio Recordings

All *Community Wise* sessions will be voice-recorded for the purposes of treatment fidelity and quality control. Agreement to be voice-recorded is a requirement for eligibility and it will be fully explained

during the informed consent process. Session audio files will be kept in a password secured server at the University of Illinois at Urbana-Champaign. The files will be accessed only by and the PIs, the PD, and research assistants who will listen to randomly selected sessions to complete the treatment fidelity and participant safety measures. These measures will only include code numbers and they will be stored in the server at the University of Illinois where the data analysis will take place.

NCCB meetings

The NCCB is a diverse community collaborative board of up to 20 community residents, consumers, researchers, service providers and government representatives working together to build a safer and healthier city through the implementation of a comprehensive community based health program that fosters advocacy of health and community reentry issues at the government level. Over the past 5 years, the NCCB has developed and pilot tested *Community Wise*. The NCCB will meet as a full board 6 times each year for 2 hours each time, to monitor the current research progress including training, recruitment, data collection, services delivery, data analysis, and dissemination. Members will also meet in committees, to work on specific aspects of the study (e.g., revising manuals, developing capacity building projects). Only NCCB members who are not listed in the current research budget will be compensated for attending meetings ($20 per hour). NCCB meetings will be video recorded so that detailed minutes can be taken and the research team can collect data on how decisions were made among NCCB members. Detailed meeting minutes are taken and approved each meeting. Videos are available at a private Blackboard virtual collaboration site to be reviewed by any NCCB member. Each NCCB member has a password and login ID to access the collaboration site. NCCB members will also participate in annual evaluations of the NCCB and its chair, which will be overseen by Dr. Pinto, the project's co-investigator. Dr. Pinto is at the University of Michigan and he is responsible for evaluating our adherence to CBPR principles and the quality of communication and satisfaction among NCCB members. Anonymous evaluation data will be collected via Qualtrix and only Dr. Pinto will have access to it. Results will be used to gage the health of collaboration within the NCCB and the application of CBPR principles. Participation will be voluntary.

We will use a REDCap to track participants' progress throughout the project. We will keep one password protected file that will contain participants' names, phone number, e-mail address, residence address, Facebook page, permission to contact them, and specific instructions about what type of message we may or may not leave. We will also collect information about friends and family members that we may contact if we lose communication with participants.

We will find out about participants being incarcerated in one of three ways: 1) someone tells us about it while we are attempting to contact the person, 2) the person themselves find a way to notify us, 3) we run a public search for incarceration in state and federal websites. Once we find someone who was incarcerated, we will check to see if they granted authorization for us to pursue them. If authorization was given, we will find out who is the appropriate authority and we will call them to make a formal request to visit the participant. We will simply state that the person is a participant in a health research study and that we would like to schedule a time to collect the follow up data in the facility. We will explain that the data will be collected using the REDCap and that once it is submitted by the participants in the tablet, it is encrypted. The data is completely confidential and protected by the COC. We will only schedule the interview if the responsible official grants us permission and agrees to provide us with a private room (incarceration officers can see us, but not hear us) for up to 1.5 hours, and agrees that the data collected will be confidential. The tablet does not have internet connection and it will not have any other programs or information installed outside of the Redcap interview. We will not conduct the urine drug screen as that is not safe or feasible in an incarceration setting. These interviews will be conducted personally by the local PI or the PD.

18C. DATA SECURITY Describe how and where the data be kept so that the data remain confidential.

We will use the same strategy we developed during our pilot study to store hard paper data, including informed consent forms, papers completed during the clinical screen, and incentive receipts. This data will be organized into separate folders and locked into file cabinets that will be in the project director's locked office. Forms containing identifying information will not contain either the codename or the code numbers and they will be stored separately from the data. All paper forms will be kept for at least 3 years after study completion.

Electronic files containing identifying information will be stored in Box . A master list will be created linking code numbers to identifying information. Only fulltime staff will have access to participants identifying information. Participants will have the choice to use their real names in the group or request that they only use their codenames. This information will be deleted at study completion (once analysis is complete).

Facilitators will have contact information for the participants so that they can contact them to schedule/cancel meetings/ data collection, and check in during the week if needed. This information will be kept in the facilitator's password protected study cell phone and will include instructions on whether it is all right to leave a message and under what circumstance for each participant.

All de-identified electronic data, including NCCB videos and focus group and Community Wise session group voice recordings will be stored in a Box cloud contracted through the University of Illinois (see https://www.box.com/business/). Folders for specific content will be created and permissions will be assigned accordingly to members of the NCCB who are assigned to work with specific data files. The PIs and the project director will have access to all files. Other team members will gain access based on the tasks they are assigned and cleared to complete. All team members will receive training on each task they are to perform by the PIs or the PD and they will not receive access to data until they have been cleared by one of the PIs or the PD. Dr. Windsor will be responsible for tracking who has access to what at any given time. This data will be kept indefinitely for the purposes of data analysis.

The University of Illinois at Urbana-Champaign has applied for a single *Certificate of Confidentiality*, which will apply to all collaborating institutions. With this Certificate, the researchers cannot be forced to disclose information that may identify a participant, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. However, the Certificate cannot be used to resist a demand for information from United States Government personnel that is used for auditing or evaluation of federally funded projects. Researchers may also disclose the identity of participants who report intentions to harm themselves or others or if researchers have knowledge those participants are abusing children or elderly persons.

18D. STAFF TRAINING Describe the training and experience of all persons who will collect or have access to the data.

All members of the research team (including all members of the NCCB) will complete IRB certification training prior to starting to work on the project. Drs. Windsor and Benoit will be responsible for training NCCB members on project specific tasks, and on human subjects protocol. Both Dr. Windsor and Dr. Benoit are experienced researchers who have worked with this population before and who have conducted several projects that were higher than minimal risk. Dr. Windsor served as a member of the IRB at Rutgers University for 3 years and Dr. Benoit is currently a member of the IRB at National Development & Research Institutes, Inc. project director and Dr. Windsor will train clinicians on the delivery of the intervention on IRB protocol.

We recognize that peer facilitators will need enhanced training, supervision, and support. The NCCB is currently reviewing the literature on peer group facilitation and we have created a committee who will be responsible for developing the peer training. This will include an all-day training conducted by a member of the NCCB who is a licensed practitioner. The training will cover our safety and ethical protocols, training on group facilitation techniques, and role play where they will be able to practice these skills. Peer and licensed facilitators will participate in weekly supervision with Dr. Windsor to discuss each group and address potential problems. We will hire and train four peer facilitators to ensure that if someone needs to be replaced, we will have a back up facilitator.

No research will be conducted with any subject while they are incarcerated.

18E. DATA RETENTION How long will the data be kept?

All paper forms will be kept for at least 3 years after study completion.

Electronic files containing identifying information and focus group voice recordings will be deleted at study completion (once analysis is complete).

Facilitators will have contact information for the participants in their groups so that they can contact them to schedule/cancel meetings and check in during the week if needed. Once the group is completed, the information will be deleted by the facilitator.

All de-identified electronic data, including NCCB videos and Community Wise session group voice recordings will be stored in a Box cloud contracted through the University of Illinois (see https://www.box.com/business/). This data will be kept indefinitely for the purposes of data analysis.

An identity key along with participants photo in electronic form will be kept until data collection is completed. At that time, the electronic key will be destroyed. Participants will be able to request that their data be destroyed (with the exception of voice recordings) as long as the electronic key is stored by the project director. Once the electronic key is destroyed at the conclusion of data collection, we will no longer be able to destroy any data because we will no longer be able to track what part of the data belongs to what participant.

18F. DISSEMINATION OF RESULTS What is(are) the proposed form(s) of dissemination (*e.g.,* journal article, thesis or academic paper, conference presentation, sharing within industry or profession)?

Research context, findings, and interpretation will be disseminated to policymakers, clinicians, members of the community, and researchers through publication of study results in peer-reviewed journals, periodicals, professional presentations at conferences (e.g., CPDD, APHA, ASA, SSWR, Paulo Freire Institute), and the media. However, individuals may want to access the data directly, either for the purpose of replicating published findings or to use the data to explore new or related research questions.

UIUC and NDRI researchers are bound by professional ethics and maintenance of professional standards overseen by an Institutional Review Board. The investigators have historically made data from previous projects available to other researchers, including graduate students, and other early-career individuals. We will continue to make every effort to comply with reasonable requests for access. The investigators in collaboration with members of the Newark Community Collaborative Board (NCCB) will develop a plan for sharing data and associated documentation with outside researchers. Regardless of specifics, will require a data- sharing agreement that provides for the following conditions at minimum: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate tools and computer technology; and (3) a commitment to destroying or returning the data after analyses are completed.

All data will be stripped of personal identifiers so as to be suitable for use by other investigators. Even though the database will be stripped of identifiers prior to any sharing, however, we will make the data and associated documentation available to users only under a data-sharing agreement that provides for the above-stated commitments.

18G. PRIVACY Describe provisions to protect the privacy interests of subjects.

Participation is voluntary and participants may stop participation at any time. 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 NJCRI in the event that someone may need immediate assistance, whether it is during data collection or during the intervention sessions.

It is possible the NCCB members or group facilitators may know some of the potential clinical trial participants as these individuals live and work in Newark, NJ. Potential clinical trial participants may be clients, family members, or friends of any NCCB member. The standard protocol for such situations is to ensure that any NCCB member who has a personal relationship with a potential participant does not interact with that person as part of the study or does not have access to data that includes their family/friend/client. To further protect privacy, NCCB members will not have access to the session voice recordings. Before assigning facilitators to specific groups, we will make sure that the facilitator does not personally knows any of the group members.

Session voice files will be stored in the secured server and only the PIs, PD, and RAs at the University of Illinois coding the files for analysis will have access to them.

18H. INDIVIDUALLY IDENTIFIABLE INFORMATION Will any individually identifiable information, including images of subjects, be published, shared, or otherwise disseminated? ☒ Yes ☐ No Only NCCB members whose membership in the NCCB will be public and displayed in our website.

If yes, subjects must provide explicit consent or assent for such dissemination. Provide appropriate options on the relevant consent documents.

19. INFORMED CONSENT: University policy requires the execution of a comprehensive, written document that is signed by the subject (or the subject's authorized representative) as the principal method for obtaining consent from subjects. The language in the document must be understandable to the subject or the subject's legally authorized representative.

An investigator may request a Waiver or Alteration of Informed Consent or a Waiver of Documentation of Informed Consent (e.g., online consent, oral consent). If requesting a waiver please complete the appropriate waiver form at: www.irb.illinois.edu and submit it with the IRB Application for review.

Children must *assent* (or, voluntarily agree) to participation and a parent must separately consent on behalf of their child (*i.e.,* two different forms are generally required). Children under age 8 may assent either orally or passively, depending on their level of maturity. Children 8–17 years old should sign a written form unless the UIUC IRB approves a different process.

19A. TYPE OF CONSENT Check all that apply and attach one copy of each relevant form, letter, or script on university letterhead. Include translations, if consent will be obtained in a foreign language. Use headings, headers, or footers to uniquely identify each document and associate it with the subject group for which it will be used.

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

☐ **Waiver or Alteration of Informed Consent (Attach waiver form.)**
☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

☐ **Waiver of Documentation (signature) of Informed Consent (Attach waiver form.)**
☐ adult subjects ☐ parent(s) or guardian(s) ☐ adolescents aged 8–17 years

19B. USE OF PROXY Will others (*e.g.,* next of kin, legal guardians, powers of attorney) act on behalf of adult subjects in giving consent to participate in this research? ☐ Yes ☒ No if yes, describe in Section 20D.

19C. USE OF PROXY OUTSIDE THE UNITED STATES If a proxy is used in research conducted outside Illinois, provide justification (e.g., statement of an attorney or copy of applicable law) that the proxy is authorized under the laws of the jurisdiction in which the research will be conducted to consent to the procedures involved in this protocol.

19D. CONSENT PROCESS Describe when and where voluntary consent will be obtained, how often, by whom, and from whom. If cognitively impaired subjects (including children under age 8) will be involved, explain how the subject's understanding will be assessed and how often; include the questions that will be asked or actions that will be taken to assess understanding.

Describe any waiting period between informing the prospective subject and obtaining the consent. Describe steps taken to minimize the possibility of coercion or undue influence. Indicate the language used by those obtaining consent.
Indicate the language understood by the prospective subject or the legally authorized representative.

If the research involves pregnant women, fetuses, or neonates, indicate whether consent will be obtained from the mother, father, or both. If the research involves children, indicate whether consent will be obtained from: Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child; or from one parent regardless of the status of the other parent.

We will obtain 4 separate consents:

1) NCCB members will be asked to sign a consent to participate in the study
2) RTC participants will be asked to sign a consent to complete the clinical screen
3) RTC participants will be asked to sign a consent to participate in the study (including focus groups)
4) Half of RCT participants will be randomly selected and asked to sign a consent to participate in a focus group about the intervention

Participants will be recruited by project staff in the field and by referral from NCCB members and participants themselves. We will post study fliers throughout the city including parks, health service agencies, and places that provide services to people with histories of incarceration and substance abuse treatment. NCCB members will promote the study in the community and help encourage potential participants to consider participating. We will also attend community events where we will distribute flyers and ask participants themselves to encourage others to participate. Those interested will be able to call or e-mail the study's private phone or e-mail to complete the phone screen. All potential participants will be screened for eligibility and will provide written informed consent before answering any questions. Project staff will inform each research subject in detail about the nature of the study, its sponsors, sources of funding, objectives, and goals, duration of the study, and the extent of participation sought. The purpose and sponsorship of the research will be thoroughly explained and procedures for confidentiality will be clearly understood by respondents prior to beginning interviews.

It will be stressed that participation is voluntary and that participants are able to withdraw their consent and participation at any time during study data collection without explanation or repercussion, that respondents will be eligible to receive payments for their participation, and that payment is not

linked to completion of the interviews or complete abstinence from AIDU. The data provided by the participants will be used for research purposes only and will be kept confidential and not shared except among research staff. Respondents will be assured that their participation in the research will not lead to investigations by welfare or social workers, law enforcement and other governmental agencies unless there is reason to suspect imminent harm to oneself (i.e., suicidal ideation with intent or plan) or immediate danger to another individual (i.e., homicidal idea) that is reported during a session or at the intake interview. Such clinical emergencies will be handled by the appropriate NJCRI staff in accordance with their guidelines for triage and needs assessment of high-risk behavior (see Data and Safety Monitoring Plan below for more detail on handling clinical emergencies). Participants will sign informed consent forms prior to engaging in any research activities.

Participants will be asked to grant permission for us to take a digital photograph of them during the baseline when they are enrolled in the study and sign the informed consent. Their photo will be stored in connection to the real names and separate from the data. Only the PIs, project director, and outreach worker will have access to the photos. These will be used to help project staff identify participants that lose contact with the study. Participants can request that their photo be destroyed at any time and the project staff will destroy the photos with 24hours of the participant's request. A separate request for the photo was added to the informed consent.

Participants will also be asked to provide consent for us to contact them to complete the follow-up in the event they are re-incarcerated. Those refusing to consent to this will not be contacted. Participants will be informed that if they provide consent for us to contact them in case they become re-incarcerated, we may disclose their participation in the study to prison officials in order to obtain permission to complete the follow-up. The exact procedures will depend upon the facility's policies and will be cleared with the IRB prior to any data collection taking place. Data will be collected by trained NCCB members and research assistants. No research will be conducted with any subject who becomes incarcerated until a research amendment discussing the procedures is filed and approved by the IRB. A new consent document will be used for re-consent for incarcerated subjects. A letter of permission from the relevant correctional facility (local, state, federal jail or prison) will also be submitted prior to conducting research with incarcerated subjects.

20. RISKS

20A. DESCRIPTION Specifically describe all known risks to the subjects for the activities proposed and describe the steps that will be taken to minimize the risks. Include any risks to the subject's 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 1) inadvertent violation of confidentiality, 2) emotional distress on the part of participants, 3) potential discord during group sessions, given the sensitive topics we discuss. 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, HIV risk behavior including sexual activity, HCV infection, social and family relationships, and discrimination 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 *Community Wise* 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 the pilot, 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. In half of the conditions, we are using licensed facilitators who have a great deal of experience dealing with these sensitive topics and with this marginalized population. The other half will be facilitated by trained peers. We will carefully select peers that 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. The hiring process will be conducted by Drs. Benoit and Windsor, and project director. Facilitators will participate in weekly supervision meetings where we will process any challenges they may experience and sessions will be taped 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 NJCRI staff that include licensed clinicians and security in place who can intervene and deflect potential violence. Moreover, during the *Community Wise* pilot study and first year of the current study no adverse events occurring as a result of study participation were observed.

Another risk to confidentiality refers to the fact that participants who participate in Community Wise 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 you with other individuals. We disclosed this risk to participants in the informed consent noting this risk for Community Wise Groups and research focus groups.

It is possible the NCCB members and group facilitators may know some of the potential clinical trial participants as these individuals live and work in Newark, NJ. Potential clinical trial participants may be clients, family members or friends of any NCCB member. The standard protocol for such situations is to ensure that any NCCB member or group facilitator who has a personal relationship with a potential participant does not interact with that person as part of the study or does not have access to data that identifies their family/friend/ client.

Clinical trial participants will be randomized into the 16 conditions. It is possible that participants may not be randomized into their study condition of choice (e.g., some people prefer peer facilitators while others prefer a licensed clinician). We will clearly explain to participants at the orientation

session that we do not know which condition is the most effective since this research has not been done before. 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.

Because NCCB members may have multiple roles in the study, we will employ procedures to manage power differentials and role boundaries. We address issues of power imbalance by ensuring transparency (e.g., budgets are shared and collaboratively developed), anonymous evaluations (which include measures of trust) and adherence to the bylaws, which were developed collaboratively by the NCCB and which require decision-making by consensus and voting. We maintain role boundaries through subcommittees dedicated to performing specific research tasks. Roles are selected for NCCB members based on their expertise, interest, availability and performance. Some roles automatically preclude others (e.g., group facilitators may not collect data from their groups). Finally, each task assigned to the NCCB includes training specific to that task. The PIs and PD are responsible for developing and conducting all research-related training.

20B. 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**

20C. Data Monitoring Plan: If you checked that the research is more than minimal risk, describe the provisions for monitoring the data to ensure the safety of subjects (Who will periodically monitor harms and benefits experienced by subjects to ensure that the relationship of risks to potential benefits remains unchanged? How often will monitoring occur? What analyses will be performed? If appropriate, what criteria will be used to stop the research based on monitoring of the results?)

The DSMP was reviewed and approved by the assigned Project Officer and the University of Illinois at Urbana-Champaign IRB, who will continue to monitor the study as it progresses. Data will be collected at NJCRI. All data will be stored in password protected devices and/or locked in a filing cabinet in a locked office space where only authorized members of the research team have access. A database will be set up at a password protected University of Illinois at Urbana-Champaign server 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. Immediately after data entry, all data will be filed at University of Illinois at Urbana-Champaign for safekeeping. Project director and Drs. Benoit and Windsor will be responsible for overseeing all data collection and processing. All identifying electronic data will be destroyed immediately after data analysis is completed. Signed consent forms and session videos will be kept for 3 years after study's completion. De-identified electronic data will be kept indefinitely.

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 new 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 will create a Data Safety and Monitoring Board (DSMB) in keeping with the protocol as approved by the designated NIH Program Official to conduct periodic independent analyses of the pilot evaluation data in the data collection phase. The DSMP is as follows:

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

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 interviewer or facilitator, and are free to withdraw from the program. Interviewers will be trained to observe signs of discomfort and check with participants if they want to continue. Licensed facilitators and peer 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 at the Clinical Screen and throughout the intervention. Monthly assessments will test levels of AIDU and suicidality. Staff at Integrity House, Inc. and NJCRI, as well as group facilitators are highly trained to recognize and recommend courses of action for current or potential withdrawal symptoms, and will consult with project director at Integrity House, Inc. Integrity House, Inc. offers a variety of substance abuse treatment services and staff there are fully trained to recognize and address signs of withdrawal. Dr. Windsor will be available to consult with project director and the group 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 facilitator will refer the participant to the appropriate staff at NJCRI. for admission to inpatient or ambulatory detoxification. Dr. Windsor and the project director will review each intake for risk of withdrawal symptoms, level of care needs, and appropriate action plan. Members of the NCCB who are service providers will be available to provide consultation to any challenges that may arise with participants. Member service providers include social workers experienced in the field of substance abuse.

c. Clinical emergencies will be handled by the NJCRI treatment team of experienced staff under supervision of project director and at NJCRI under the supervision of Henry Iwuala and Corey DeStefano, who will be available by phone to all facilitators. Appropriate assessments will be conducted; treatment options will be recommended and followed through as necessary. NJCRI routinely provide services to individuals with substance use disorders and they are fully equipped to address any potential emergencies either themselves or via referrals. NJCRI, project director, and the NCCB have longstanding relationships with all substance abuse treatment facilities in Newark, NJ. NJCRI project director or on-call service providers will be available 24 hours a day to handle health-related emergencies. 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 project director and/or Dr. Windsor regarding appropriate course of action using NJCRI guidelines.

e. Relapse and Referral for Further Treatment. As the participant nears the end of the intervention, our intervention will include relapse prevention, and what to do in the event of relapse. Each participant therefore will leave the intervention with a plan for handling relapse during the follow-up period and beyond. If further treatment is indicated, we will provide the participant with several outpatient referrals. After the intervention, should the participant request a referral for treatment, study personnel will refer the participant to NJCRI where staff can provide appropriate care or referrals.

f. Deterioration. Clients who are deteriorating during treatment will be reviewed by project director and Dr. Windsor. Clients may be withdrawn from the study and/or referred to a higher level of care if they meet specific indicators 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 *Community Wise* 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 *Community Wise* is possible. The facilitators, project director, 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. All cases will be monitored closely on a weekly basis by the responsible members of the research team (Dr. Windsor, project director, Dr. Benoit, NCCB, research assistants) and the facilitators. All participants will be supervised by the facilitators, at least one other clinical expert (including Dr. Windsor), and by research assistants through coding of video sessions, ongoing data analysis, and weekly clinical and staff meetings.

i. Any research staff member who learns of an adverse event is responsible for reporting the event to the Principal Investigators (PI), who are in turn responsible for discussing the event to make a joint decision about whether the event is serious or non-serious. Events will be categorized as adverse or serious adverse according to NIH guidelines: "Adverse events (AEs) are defined as any untoward medical occurrence that may present itself during treatment or administration of an intervention, and which may or may not have a causal relationship with the treatment. Serious adverse events (SAEs) are defined as any medical occurrence that results in death; is life-threatening; requires inpatient hospitalization or prolongation of existing hospitalization; creates persistent or significant disability/incapacity, or a congenital anomaly/birth defects." As such, adverse events (AEs) occurring during the course of the study will be collected, documented, and reported to the PIs or a designated co-investigator. The occurrence of AEs will be assessed during the intervention phase of the study at baseline and each group visit through clinical observation. Each week a study investigator will review the AE Forms from the previous week for events that were reported as new or continuing. The study investigators will follow all AEs to the point of a satisfactory resolution. A study participant may be withdrawn from the study if the responsible

investigator or group facilitators determine it is the best decision in order to protect the safety of a participant. All AEs will be assessed to determine if they meet criteria for an SAE. If an AE meets criteria for serious adverse event (SAE), as defined by the FDA, they will be systematically evaluated at each clinic visit and treated in a similar fashion as AEs with regards to monitoring and reporting.

Any SAE will be reported to each of the three IRB's and to the assigned NIH Project Officer within 48 hours of the occurrence. The report of SAEs will include whether they were expected or unexpected, a rating of severity of the event, a brief narrative summary of the event, a determination of whether a causal relationship existed between the study procedures and the event, whether the informed consent should be changed as a result of the event and whether all enrolled participants should be notified of the event. Finally, as part of the annual progress report (noncompeting continuation application) to NIH, we would provide summary information on all SAEs that have occurred during that year.

j. Any actions taken by any of the IRBs will be reported promptly to NIH via the Project Officer or appropriate parties.

k. The PIs and Dr. Smith will closely monitor the validity and integrity of the data on an on-going basis. The DSMB with also conduct biannual monitoring of the data through spot checks and independent preliminary analysis of the data. For instance, the PIs and the Project Director will meet regularly with project interviewers to review assessments and coding of incoming data. The PIs will be responsible for ensuring that data are being coded, entered and cleaned appropriately. The full research team will meet every week for 120 minutes to review all aspects of the research study.

l. Data collected from NCCB members is anonymous and does not include sensitive information. It will be reviewed by the IRB, but this data will not be included in the oversight of the DSMP

21. BENEFITS 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 a manual-based optimized 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 NCCB 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 inequalities between distressed communities with concentrations of African Americans (DCAA) and their wealthier and

predominantly White counterparts. Major obstacles to the adoption of evidence-based interventions by DCAAs 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 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 inequalities.

22. RISK/BENEFIT ASSESSMENT 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, Project Officer, funding agencies and the IRBs of the University of Illinois at Urbana-Champaign, NDRI, NJCRI, and Michigan University within 48 hours. Adverse events will be tracked in a database and reviewed at each DSMB meeting. Our CBPR pilot 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.

If additional Risk/Benefit information is attached, check here: ☐

23. Is this a multi-center study in which the UIUC investigator is the lead investigator of a multicenter study, or the UIUC is the lead site in a multi-center study. **Yes** ☒ **No** ☐

If yes, describe the management and communication of information obtained that might be relevant to the protection of subjects, such as: unanticipated problems involving risks to subjects or others, interim results and protocol modifications.

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 and all NCCB members will be required to undergo 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 informed consent forms and locator forms (used for follow-up interviews after the baseline). These forms will be kept in a locked filing cabinet at NJCRI, which will be kept separate from data. The Project Director, and Dr. Benoit, a Principal Investigator, are the only people who will have access to the filing cabinet.

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 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. Signed consent forms and session videos will be kept for 3 years after study completion. De-identified electronic data will be kept indefinitely. NCCB participants may ask at any time to have recordings of their meetings destroyed by calling/e-mailing one of the Principal Investigators at the numbers provided in the informed consent forms.

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 NJCRI in the event that someone may need immediate assistance, whether it is during data collection or during the intervention sessions.

Dr. Windsor, Dr. Benoit, and project director will be available by phone at all times in case an emergency occurs. Any adverse event will be reported to the IRB and funding agency within 24 hours. Through our NCCB 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, we will conduct the MINI suicidality screen and if we find anyone at risk, 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.

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.

24. INVESTIGATOR ASSURANCES: The signature of the Responsible Project Investigator is required (scanned or faxed signatures are acceptable). Other investigators are also responsible for these assurances and are encouraged to sign.

I certify that the information provided in this application, and in all attachments, is complete and correct.

I understand that I have ultimate responsibility for the protection of the rights and welfare of human subjects, the conduct of this study, and the ethical performance of this project.

I agree to comply with all UIUC policies and procedures, the terms of its Federal Wide Assurance, and all applicable federal, state, and local laws regarding the protection of human subjects in research.

I certify that

- the project will be performed by qualified personnel according to the UIUC IRB-approved protocol.
- the equipment, facilities, and procedures to be used in this research meet recognized standards for safety.
- no change will be made to the human subjects protocol or consent form(s) until approved by the UIUC IRB.
- legally effective informed consent or assent will be obtained from human subjects as required.
- Unanticipated problems, adverse events, and new information that may affect the risk–benefit assessment for this research will be reported to the UIUC IRB Office (217.333.2670; irb@illinois.edu) and to my Departmental Executive Officer.
- I am familiar with the latest edition of the UIUC *Handbook for Investigators*, available at www.irb.illinois.edu, and I will adhere to the policies and procedures explained therein.
- student and guest investigators on this project are knowledgeable about the regulations and policies governing this research.
- I agree to meet with the investigator(s), if different from myself, on a regular basis to monitor study progress.
- if I will be unavailable, as when on sabbatical or other leave, including vacation, I will arrange for an alternate faculty sponsor to assume responsibility during my absence. I will advise the UIUC IRB by letter of such arrangements.

I further certify that the proposed research has not yet been done, is not currently underway, and will not begin until IRB approval has been obtained.

03/03/2019

Responsible Principal Investigator	Date	Investigator	Date
Investigator	Date	Investigator	Date

25. (OPTIONAL) DEPARTMENTAL ASSURANCE To be completed by the RPI's Departmental Executive Officer or their designee.

The activity described herein is in conformity with the standards set by our department and I assure that the principal investigator has met all departmental requirements for review and approval of this research.

Departmental Executive Officer (or designee) Date

***** For units that conduct **scientific merit review,** the signature above documents the following:

☐ 1. The research uses procedures consistent with sound research design.
☐ 2. The research design is sound enough to yield the expected knowledge.

ILLINOIS
Office for the Protection of Research Subjects

Research Team

For Listing Additional Researchers who are Involved in the Project

All forms must be typewritten and submitted via email to irb@illinois.edu.

When to use this form: If there are collaborating researchers participating in a research study, including those from other institutions, complete this form by listing all collaborating researchers. Include all persons who will be: 1) directly responsible for project oversight and implementation, 2) recruitment, 3) obtaining informed consent, or 4) involved in data collection, analysis of identifiable data, and/or follow-up. **Please copy and paste text fields to add additional research team members.**

Note:

- Changes made to the Principal Investigator require a revised Protocol Form and an Amendment Form.
- A complete Research Team form with all research team members included needs to be submitted every time the research team is updated.

Section 1. PROTOCOL INFORMATION

1A. Principal Investigator: Liliane Windsor
1B. Protocol Number: 16574
1C. Project Title: Community Wise: An Innovative multi-level intervention to reduce alcohol and illegal drug use

Section 2. ADDITIONAL INVESTIGATORS

Full Name: Carol Lee	**Degree: MSW**	**Dept. or Unit: School of Social Work**
Professional Email: carolal2@illinois.edu		**Phone: 5184773204**
Campus Affiliation: ☒ University of Illinois at Urbana-Champaign ☐ Other, *please specify*: **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☒ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☐ Other, *please specify*: Research staff		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 05/28/2020 ☐ Additional training, **Date of Completion:**		
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☒ Handling identifiable data ☒ Other, *please specify*: Handling deidentified data		
☒ **This researcher should be copied on OPRS and IRB correspondence.**		
☐ **This researcher is no longer an active research team member.**		
Date added to research team: 05/2016	**Date removed from research team:**	

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Research Team

Full Name: Dora Watkins	**Degree: LLMSW**	**Dept. or Unit: School of Social Work**
Professional Email: dnw6@illinois.edu		**Phone: 313-463-0093**
Campus Affiliation: ☒ University of Illinois at Urbana-Champaign ☐ Other, *please specify*: **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☒ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☐ Other, *please specify*: Research staff		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 07/2021 ☐ Additional training, **Date of Completion:**		
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☒ Handling identifiable data ☒ Other, *please specify*: Handling deidentified data		
☐ **This researcher should be copied on OPRS and IRB correspondence.**		
☐ **This researcher is no longer an active research team member.**		
Date added to research team: 07/2021	**Date removed from research team:**	

Full Name: Peter Treitler	**Degree:** MSW	**Dept. or Unit:** IFH
Professional Email: peter.treitler@rutgers.edu		**Phone:** 848-932-6896
Campus Affiliation: ☐ University of Illinois at Urbana-Champaign ☒ Other, *please specify*: Rutgers University **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☒ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☐ Other, *please specify*:		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 4/5/2018 ☐ Additional training, **Date of Completion:**		
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☐ Handling identifiable data ☒ Other, *please specify*: Secondary analysis of de-identified data		
☐ **This researcher should be copied on OPRS and IRB correspondence.**		
☐ **This researcher is no longer an active research team member.**		
Date added to research team: 12/21/2020	**Date removed from research team:** 11/9/2021	

Full Name: Sierra Wollen	**Degree:** MSW	**Dept. or Unit:** Social Work
Professional Email: slwollen@uw.edu		**Phone:** 253-569-7271

ILLINOIS
Office for the Protection of Research Subjects

Research Team

Campus Affiliation: ☐ University of Illinois at Urbana-Champaign ☒ Other, *please specify*: University of Washington **Campus Status:** ☐ Faculty ☒ Academic Professional/Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☐ Other, *please specify*:
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 1/31/19 ☐ Additional training, **Date of Completion:**
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☐ Handling identifiable data ☒ Other, *please specify*: Secondary analysis of de-identified data
☐ **This researcher should be copied on OPRS and IRB correspondence.**
☐ **This researcher is no longer an active research team member.**
Date added to research team: 12/21/20 **Date removed from research team:**

Full Name: Sophia Gawron	**Degree:** BS	**Dept. or Unit:** School of Social Work
Professional Email: sgawron2@illinois.edu		**Phone:** 319-457-0885
Campus Affiliation: ☒ University of Illinois at Urbana-Champaign ☐ Other, *please specify*: **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☒ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☐ Other, *please specify*:		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 12/01/2020 ☐ Additional training, **Date of Completion:**		
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☒ Handling identifiable data ☒ Other, *please specify*: Cleaning deidentified data		
☐ **This researcher should be copied on OPRS and IRB correspondence.**		
☐ **This researcher is no longer an active research team member.**		
Date added to research team: 12/26/2020 **Date removed from research team:** 10/21/2021		

Full Name: Ashley Masengale	**Degree:** BSW	**Dept. or Unit:** School of Social Work
Professional Email: amasen2@illinois.edu		**Phone:** 217-497-0511
Campus Affiliation: ☒ University of Illinois at Urbana-Champaign ☐ Other, *please specify*: **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☒ Graduate Student ☐ Undergraduate Student		

Research Team

☐ Visiting Scholar ☐ Other, *please specify*:
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 12/01/2020 ☐ Additional training, **Date of Completion:**
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☒ Handling identifiable data ☒ Other, *please specify*: cleaning deidentified data
☐ **This researcher should be copied on OPRS and IRB correspondence.**
☐ **This researcher is no longer an active research team member.**
Date added to research team: 12/26/2020 **Date removed from research team:** 10/21/2021

Full Name: Kang Sun	**Degree:** PhD	**Dept. or Unit:** School of Social Work
Professional Email: kangsun2@illinois.edu		**Phone: 419-494-2123**
Campus Affiliation: ☒ University of Illinois at Urbana-Champaign ☐ Other, *please specify*: **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☒ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☐ Other, *please specify*:		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 09/29/2018 ☐ Additional training, **Date of Completion:**		
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☒ Handling identifiable data ☒ Other, *please specify*: Cleaning deidentified data		
☐ **This researcher should be copied on OPRS and IRB correspondence.**		
☐ **This researcher is no longer an active research team member.**		
Date added to research team: 12/26/2020 **Date removed from research team:** 10/21/2021		

Full Name: Kimberly Garcia	**Degree:** High School	**Dept. or Unit:** School of Social Work
Professional Email: kimberlyg_christina@yahoo.com		**Phone:** 7324875646
Campus Affiliation: ☒ University of Illinois at Urbana-Champaign ☐ Other, *please specify*: **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☒ Other, *please specify*: Research staff		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 12/2020 ☐ Additional training, **Date of Completion:**		

ILLINOIS
Office for the Protection of Research Subjects

Research Team

Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☐ Handling identifiable data ☒ Other, *please specify*: Handling deidentified data
☐ **This researcher should be copied on OPRS and IRB correspondence.**
☐ **This researcher is no longer an active research team member.**
Date added to research team: 12/26/2020 **Date removed from research team:**

Full Name: Julia Gold	**Degree: BFA**	**Dept. or Unit: School of Social Work**
Professional Email: juliarg2@illinois.edu		**Phone: 847-769-8152**
Campus Affiliation: ☒ University of Illinois at Urbana-Champaign ☐ Other, *please specify*: **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☒ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☐ Other, *please specify*:		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 12/2020 ☐ Additional training, **Date of Completion:**		
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☐ Handling identifiable data ☒ Other, *please specify*: Handling deidentified data		
☐ **This researcher should be copied on OPRS and IRB correspondence.**		
☐ **This researcher is no longer an active research team member.**		
Date added to research team: 12/26/2020 **Date removed from research team:** 10/21/2021		

Full Name: Marlene Pena	**Degree: BS**	**Dept. or Unit: School of Social Work**
Professional Email: mpena21@illinois.edu		**Phone: 872-233-5308**
Campus Affiliation: ☒ University of Illinois at Urbana-Champaign ☐ Other, *please specify*: **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☒ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☐ Other, *please specify*:		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 09/2020 ☐ Additional training, **Date of Completion:**		
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☒ Handling identifiable data ☒ Other, *please specify*: Handling deidentified data		
☐ **This researcher should be copied on OPRS and IRB correspondence.**		

ILLINOIS
Office for the Protection of Research Subjects

Research Team

☐ **This researcher is no longer an active research team member.**	
Date added to research team: 12/26/2020	**Date removed from research team:**

Full Name: Vitalis Im	**Degree:** MSW	**Dept. or Unit:** School of Social Work and Department of Anthropology
Professional Email: vitalis@umich.edu	**Phone:** 7348001961	

Campus Affiliation:
☐ University of Illinois at Urbana-Champaign ☒ Other, *please specify*: University of Michigan

Campus Status:
☐ Faculty ☐ Academic Professional/Staff ☒ Graduate Student ☐ Undergraduate Student
☐ Visiting Scholar ☐ Other, *please specify*:

Training:
☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 11/04/2020 (PEERS Certification)
☐ Additional training, **Date of Completion:**

Role on Research Team (check all that apply):
☐ Recruiting ☐ Consenting ☐ Administering study procedures ☐ Handling identifiable data
☒ Other, *please specify*: Analyzing deidentified data

If administering biomedical study procedure (e.g., blood draws, scans, etc.), please specify the procedure(s):

☐ **This researcher should be copied on OPRS and IRB correspondence.**

☐ **This researcher is no longer an active research team member.**

Date added to research team: 10/21/2021 **Date removed from research team:**

Full Name: Evan Hall	**Degree:** BS	**Dept. or Unit:** School of Social Work
Professional Email: ejdhall@umich.edu	**Phone:** 248-882-7113	

Campus Affiliation:
☐ University of Illinois at Urbana-Champaign ☒ Other, *please specify*: University of Michigan

Campus Status:
☐ Faculty ☐ Academic Professional/Staff ☐ Graduate Student ☒
☐ Visiting Scholar ☐ Other, *please specify*:

Training:
☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 3/22/2021
☐ Additional training, **Date of Completion:**

Role on Research Team (check all that apply):
☐ Recruiting ☐ Consenting ☐ Administering study procedures ☐ Handling identifiable data
☒ Other, *please specify*: Analyzing deidentified data

ILLINOIS
Office for the Protection of Research Subjects

Research Team

If administering biomedical study procedure (e.g., blood draws, scans, etc.), please specify the procedure(s):
☐ **This researcher should be copied on OPRS and IRB correspondence.**
☐ **This researcher is no longer an active research team member.**
Date added to research team: 10/21/2021 **Date removed from research team:**

Full Name: Annabella Vidrio	**Degree:** BS	**Dept. or Unit:** School of Social Work
Professional Email: bellanv@umich.edu		**Phone:** 562-977-7308
Campus Affiliation: ☐ University of Illinois at Urbana-Champaign ☒ Other, *please specify*: University of Michigan **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☐ Graduate Student ☒ ☐ Visiting Scholar ☐ Other, *please specify*:		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 3/22/2021 ☐ Additional training, **Date of Completion:**		
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☐ Handling identifiable data ☒ Other, *please specify*: Analyzing deidentified data		
If administering biomedical study procedure (e.g., blood draws, scans, etc.), please specify the procedure(s):		
☐ **This researcher should be copied on OPRS and IRB correspondence.**		
☐ **This researcher is no longer an active research team member.**		
Date added to research team: 10/21/2021 **Date removed from research team:**		

Full Name: Marc Arthur	**Degree: PhD**	**Dept. or Unit:** School of Social Work
Professional Email: marcarth@umich.edu		**Phone:** 415-425-4690
Campus Affiliation: ☐ University of Illinois at Urbana-Champaign ☒ Other, *please specify*: University of Michigan **Campus Status:** ☐ Faculty ☒ Academic Professional/Staff ☐ Graduate Student ☐ ☐ Visiting Scholar ☐ Other, *please specify*:		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 3/22/2021 ☐ Additional training, **Date of Completion:**		

ILLINOIS
Office for the Protection of Research Subjects

Research Team

Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☐ Handling identifiable data ☒ Other, *please specify*: Analyzing deidentified data
If administering biomedical study procedure (e.g., blood draws, scans, etc.), please specify the procedure(s):
☐ **This researcher should be copied on OPRS and IRB correspondence.**
☐ **This researcher is no longer an active research team member.**
Date added to research team: 10/21/2021 **Date removed from research team:**

Full Name: Ellen Benoit	**Degree: PhD**	**Dept. or Unit: NJCRI**
Professional Email: e.benoit@njcri.org		**Phone: 973-483-3444 ext. 281**
Campus Affiliation: ☒ University of Illinois at Urbana-Champaign ☐ Other, *please specify*: **Campus Status:** ☐ Faculty ☐ Academic Professional/Staff ☐ Graduate Student ☐ Undergraduate Student ☐ Visiting Scholar ☒ Other, *please specify*: 0% employee		
Training: ☒ Required CITI Training, **Date of Completion** (valid within last 3 years): 02/17/2020 ☐ Additional training, **Date of Completion:**		
Role on Research Team (check all that apply): ☐ Recruiting ☐ Consenting ☐ Administering study procedures ☒ Handling identifiable data ☐ Other, *please specify*:		
☒ **This researcher should be copied on OPRS and IRB correspondence.**		
☐ **This researcher is no longer an active research team member.**		
Date added to research team: 05/2016 **Date removed from research team:**		

ILLINOIS
UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN

FWA No. 00008584

IRB #1 Authorization Agreement

1. Parties and Purpose. THE BOARD OF TRUSTEES OF THE UNIVERSITY OF ILLINOIS ("ILLINOIS"), for its University of Illinois at Urbana-Champaign IRB #1 ("IRB #1"), and National Development & Research Institutes, Inc.(NDRI), FWA# **00002853** ("INSTITUTION"), enter into this Institutional Review Board ("IRB") Authorization Agreement for review and continuing oversight of the following INSTITUTION human subjects research ("Research"):

Name of Research Project: Community Wise: An innovative multi-level intervention to reduce alcohol and illegal drug use
Name of Principal Investigator: Liliane Cambraia Windsor/UIUC and Ellen Benoit/NDRI
Sponsor or Funding Agency: National Institute on Minority Health & Health Disparities
Award Number, if any: 1U01MD010629 - 01
Other information: UIUC IRB #16574

This agreement applies to the described Research only and to no other research in which INSTITUTION may be engaged now or in the future.

2. Request to Consider Alteration to or Waiver of HIPAA Authorization. ☐ **Check if applicable.** The Research may require INSTITUTION researchers to use or disclose *protected health information* ("PHI") as defined by the Health Insurance Portability and Accountability Act ("HIPAA") and its regulations. Pursuant to 45 CFR §164.512(i), INSTITUTION requests that IRB #1 approve either an alteration to, or waiver, in whole or in part, of the HIPAA authorization required for INSTITUTION's use or disclosure of PHI for the Research.

3. INSTITUTION Representations. INSTITUTION represents that it: (a) shall remain responsible for ensuring compliance with IRB #1's determinations, with the terms of INSTITUTION's OHRP-approved FWA, and with all laws governing the Research; and (b) shall immediately report to IRB #1 in writing upon becoming aware of any new or continuing noncompliance with any relevant contract, law or institutional policy governing the Research, including but not limited to human subject protections, conflicts of interest, and research misconduct. INSTITUTION's obligation to report under 3(b) is in addition to, and in no way replaces, a principal investigator's duty to report any matters such as unanticipated problems involving risks to subjects and others. INSTITUTION shall make all such reports to the Director of IRB #1.

4. ILLINOIS Representations. In performing its review and continuing oversight of the Research, ILLINOIS represents that it shall: (a) comply with the requirements of the Common Rule as codified in regulation; (b) meet the human subject protection requirements of INSTITUTION's OHRP-approved FWA; (c) follow written procedures for reporting its findings and actions to appropriate officials at INSTITIUTION; and (d) make available to INSTITUTION upon its request relevant minutes of IRB #1 meetings.

5. Notice of Agency Action. Each party will immediately report to the other if any oversight agency or organization initiates any action or investigation that may adversely affect the Research.

6. Record Retention. Each party shall keep this document on file for no less than six years after completion of the Research and shall provide a copy of it to OHRP upon request.

7. Liability. Neither party assumes liability for the acts or omissions chargeable to the other party unless otherwise imposed by law. By entering into this agreement, ILLINOIS does not waive the immunities and defenses afforded to it under both Illinois and federal laws.

This agreement is effective on the last signature date and expires on the date the Research is closed by IRB #1.

For ILLINOIS:

The Board of Trustees of the University of Illinois

By: _____ Date: 5/2/16
Walter K. Knorr, Comptroller

By: _____ Date: 4-25-2016
Peter Schiffer, Ph.D., FWA Signatory Official

For INSTITUTION B:

By: _____ Date: 04/22/2016
Printed Name: Andrew Rosenblum, PhD
FWA Signatory Official

Approved for legal form /LMP/10-2012

Date: Mon, Mar 11, 2019 at 1:43 PM
Subject: eResearch Notification: Scheduled Continuing Review Approved
To: <ropinto@umich.edu>, <krber@umich.edu>, <yunch@umich.edu>

Health Sciences and Behavioral Sciences Institutional Review Board (IRB-HSBS) • 2800 Plymouth Rd., Building 520, Room 1170, Ann Arbor, MI 48109-2800 • phone (734) 936-0933 • fax (734) 998-9171 • irbhsbs@umich.edu

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To: Dr. Rogerio Pinto

From:

Thad Polk

Cc:

Rogerio Pinto
Kathryn Berringer
Yun Chen

Subject: IRB HSBS Acknowledgement of Scheduled Continuing Review for Study Conducted Under a Non-UM IRB (University of Illinois), [CR00074677] for [HUM00115022]

SUBMISSION INFORMATION:
Study Title: Community Wise
Full Study Title (if applicable): Community Wise: An Innovative multi-level intervention to reduce alcohol and illegal drug use.
Study eResearch ID: HUM00115022
SCR eResearch ID: CR00074677
SCR Title: HUM00115022_Continuing Review - Wed Jan 30 10:37:25 EST 2019
Date of this notification from IRB HSBS: 3/11/2019
Review: Expedited
Date of IRB HSBS Registration Review: 3/11/2019
Non-UM IRB ID Number: 16574
Current Non-UM Approval Period: **Staff Insert Approval Date - **Staff Insert Expiration Date****
Current UM Acknowledgement Period: **Staff Insert UM Acknowledgement Period**
UM Federalwide Assurance: FWA00004969 (For the current FWA expiration date, please visit the UM HRPP Webpage)

NOTICE OF IRB APPROVAL AND CONDITIONS:
Following applicable internal review(s), this application to conduct human subjects research is acknowledged as meeting the criteria of the University of Michigan for ceding oversight to a non-UM IRB and is considered to be registered with IRB HSBS for purposes of institutional record-keeping. You must conduct this study in accordance with the approval criteria of the external IRB.

APPROVAL PERIOD AND EXPIRATION DATE:
The updated UM acknowledgement period for this study is listed above. Please note the UM expiration date as it may differ from the IRB approval period of the non-UM IRB. If the external IRB approval lapses, you may not conduct work on this study until appropriate approval has been re-established, except as necessary to eliminate apparent immediate hazards to research subjects or

others. Should the latter occur, notify the external IRB and the IRB HSBS Office as soon as possible.

IMPORTANT REMINDERS AND ADDITIONAL INFORMATION FOR INVESTIGATORS

AMENDMENTS, RENEWALS, AND TERMINATIONS:
The non-UM IRB is now the IRB of Record for the conduct of this study at the University of Michigan. However, you must utilize eResearch to:

- Submit amendments to the registered application if any changes to the protocol will require re-review by an ancillary committee (e.g., IDS, CRAO, RDRC/SHUR)
- Annually renew (SCR) the registration of this research study with IRB HSBS
- Terminate the IRB HSBS registration of this study when the study is terminated at the non-UM IRB

AEs/ORIOs:
Although the non-UM IRB is now the IRB of Record for the conduct of this study, you must report related Serious Adverse Events and Unanticipated problems in accordance with the division of labor as agreed upon by the University of Michigan and the non-U-M IRB.

This should be done through eResearch following the same procedures as for an IRB HSBS-approved study. These include, but are not limited to, events and/or information that may have physical, psychological, social, legal, or economic impact on local research subjects.

APPROVED STUDY DOCUMENTS:
You must use the study documents approved by the non-UM IRB.

SUBMITTING VIA eRESEARCH:
The online forms for continuing review, amendments, and AE/ORIO reporting can be accessed in the eResearch workspace for this Non-UM IRB-approved, IRB HSBS-accepted study, referenced above.

MORE INFORMATION:
You can find additional information about UM's Human Research Protection Program (HRPP) in the Operations Manual and other documents available at http://research-compliance.umich.edu/human-subjects.

Thad Polk
Chair, IRB HSBS

Institutional Review Board (IRB) Authorization Agreement

Name of organization providing IRB review: The University of Illinois at Urbana-Champaign (UIUC)

Federalwide Assurance (FWA) #: 00008584

Name of Institution relying on the designated IRB: North Jersey Community Research Initiative, Inc. (NJCRI)

The officials signing below agree that NJCRI may rely on UIUC, the designated IRB for review and continuing oversight of its human subjects research described below:

☒ This agreement is limited to the following specific protocol:

Name of research project: Community Wise: An innovative multi-level intervention to reduce alcohol and illicit drug use IRB # 16574

Name of Principal Investigator: Liliane Cambraia Windsor and Ellen Benolt

Sponsor or funding agency: National Institute on Minority Health and Health Disparities

The review performed by UIUC will meet the human subject protection requirements of NJCRI's OHRP-approved FWA. The IRB at UIUC will follow written procedures for reporting its findings and actions to appropriate officials at NJCRI. Relevant minutes of IRB meetings will be made available to NJCRI upon request. NJCRI remains responsible for ensuring compliance with IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

James Oleske/ IRB Chairman
Signatory Official (NJCRI)

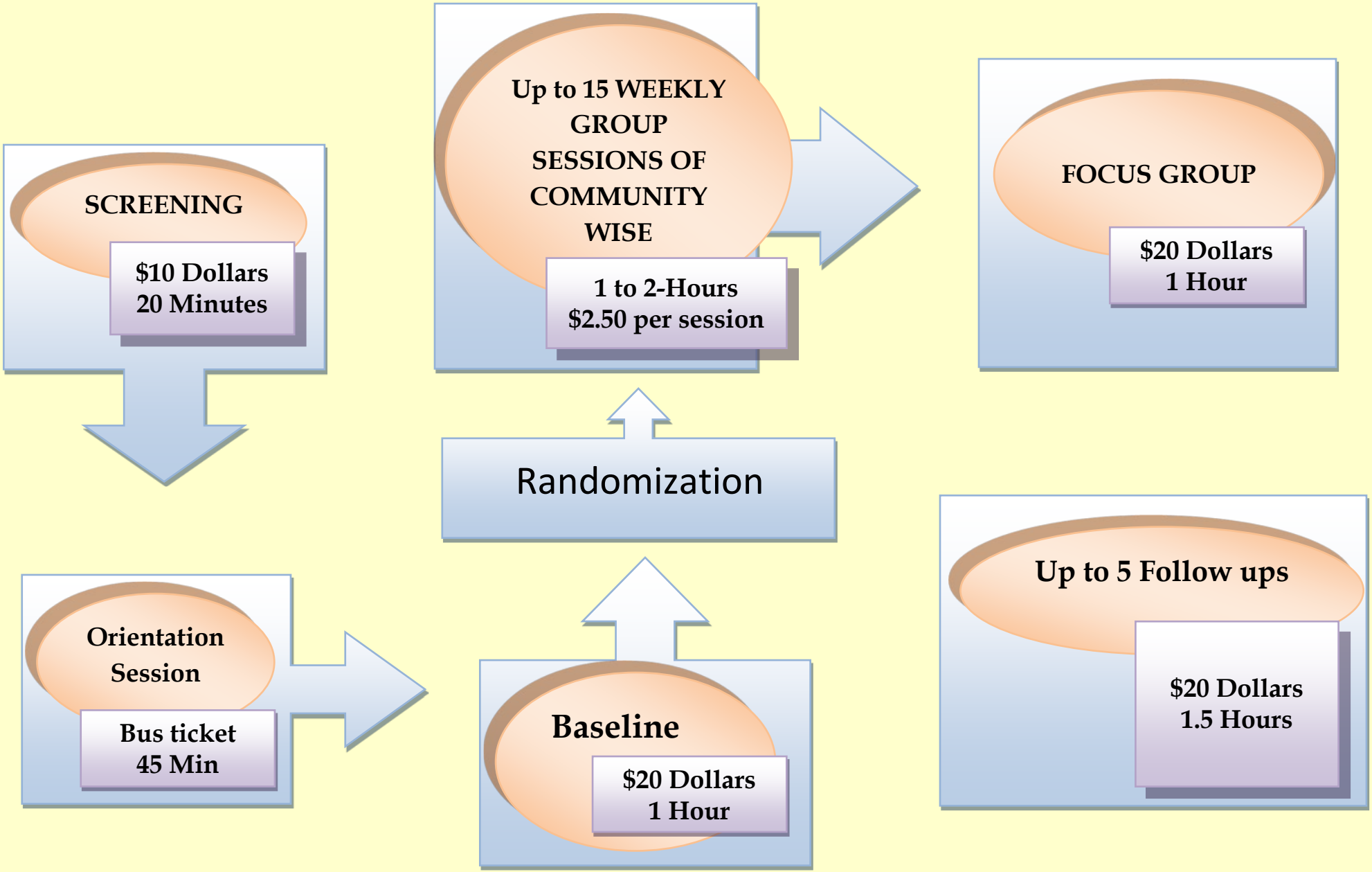
Date: 1/4/2017

Walter K. Knorr/ Comptroller
Signatory Official (UIUC)

Date: 2/8/17

Peter Schiffer/ Vice-Chancellor for Research
Signatory Official (UIUC)

Date: 1/23/2017


SCREENING
$10 Dollars
20 Minutes
Up to 15 WEEKLY GROUP SESSIONS OF COMMUNITY WISE
1 to 2-Hours
$2.50 per session
FOCUS GROUP
$20 Dollars
1 Hour
Randomization
Orientation Session
Bus ticket
45 Min
Baseline
$20 Dollars
1 Hour
Up to 5 Follow ups
$20 Dollars
1.5 Hours

NEWARK COMMUNITY COLLABORATIVE BOARD

Seeking men with a history of substance use disorders transitioning into Newark from incarceration (up to 4 years since release date) to participate in the evaluation of *Community Wise*, a new community based intervention to reduce substance use:

THE INTERVENTION: You will be randomized into receiving all or a combination of:

1) Group dialogue.

2) Personal goal development and implementation.

3) Engagement on community capacity building projects.

Participants must be 18 or older, speak English, live in Essex County, NJ, and be willing to be voice recorded.
Participation is confidential and voluntary

Participants may receive anywhere from $10 to $187.50 over 5 months depending upon the number of study interviews completed. Participants will also receive the potential benefits of the free intervention which may include improved health, mental health, networking opportunities, and community engagement.

Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927	Email: outreach@newarkccb.org Tel.: (973) 803-1927

University of Illinois at Urbana-Champaign
Institutional Review Board

Approval Date: November 15, 2021
IRB #16574

NEWARK COMMUNITY COLLABORATIVE BOARD

Thank you for agreeing to help spread the word about the Community Wise study. We are currently seeking men with a history of substance use disorders transitioning into Newark from incarceration (up to 4 years since release date) to participate in the evaluation of *Community Wise*, a new community based intervention to reduce substance use.

We are asking you to help distribute our study fliers to your client who may meet our eligibility criteria. In an effort to minimize potential coercion (e.g. a client may want to please you by participating in in the study when in fact they do not want to), we ask you to follow the recommendations below:

- ***Hand in fliers at the end of your session with your client***
- ***Do not encourage clients to participate in the study, rather mention to them that there is a study going on that they can consider joining if they want to.***
- ***Do not answer any of their questions about the study. Simply tell them to call the study number if they have any questions.***

If you have any questions about this request, please contact the project director at the e-mail or phone number below:

Leticia Mcbride

Email: outreach@newrkccb.org

Tel.: (973)803-1927

Dos and Don'ts of Recruitment

If you do all of these things, you should go into every group with approximately 12 confirmed men in order to get 8 of each.

-Ask for Multiple phone numbers for each participant, not just one. This is more important than family/friend numbers. Some people have different cells that are turned off but will be back on. And house lines too, get as many as possible.

-Ask people when they give a phone number during the phone screening, "is this # you're giving me YOUR number?" If not, def ask for additional numbers!!

- Friend and family numbers are only useful if they are people they live with or see every day so when asking for alternate numbers for family/friends, request this specifically. Anything else is a waste of time.

-on the spreadsheet, keep track of who is friends or related to whom. Some participants are friends or related and this will be very helpful in getting in touch with people.

-If someone sounds very unsure/confused or does not have a phone number or permanent living address, schedule them 5-7 days from the date of their call and do not remind them of their appointment. Some people will surprise you and show up and these people will end up being reliable. For the others it is just a good way of weeding them out without rejecting them.

-For all others, schedule them for the following day or the day after whenever possible. Same day is not good and two days you start losing people. Don't confirm appointments that are within this time frame. People are able to remember without reminders and people who end up needing a lot of reminders end up disappearing and taking up too much time re-scheduling over and over. But if the appointment needs to be more than 2 days away, you should remind people.

-If two people are friends, schedule them back to back so they are more likely to come together and one of them will remember their apt or that they have group.

-Before the suicidal/psychotic questionnaires let people know there is no right or wrong answer and just because they say yes to certain questions doesn't mean they can't participate. Tell them the questions are just to see how they are doing right now. If you don't do this people won't feel comfortable answering honestly and you'll get a lot of conflicting information.

-Stress that the research and intervention are SEPARATE throughout the screenings and baselines.

-For people who miss an appointment with a no call and then call later wanting to reschedule, tell them we have a 2 appt unexcused miss policy and that they will need to call beforehand next time.

-Give yourself a full hour for each screening appt because some people arrive late or early and getting backed up is not fun.

- Ask people how they are doing, always offer them a comfortable chair, a place to put their bags, lots of snacks and drinks, etc. Make them feel welcome and comfortable.

-Do not take walk-ins. They will usually disappear. Even if you have time to see them, schedule them for the next day if possible. Generally people who insist on being seen the same day are hoping for fast cash and will not be back to attend the groups.

-every time you see someone, give them a bunch of flyers AND business cards and ask them to please tell everyone they know who might be a good fit for the groups. This is how we recruited most people for the pilot.

-Weed people out by their availability during the phone screening so you aren't wasting your time screening someone in person who is not available for the exact group you need to put them in.

-Know the day/time/location of the group by the time you meet with a participant for the first time. Tell them once you what group they were randomized into, date and location of the first group. Give them a business card with this information during the baseline as they leave.

-Ask people if they seem like they might not come to the first group if they are definitely interested. Tell them there are other people waiting to get in if they aren't and it's totally okay if they don't want to come. I found that most people become more committed once they hear they are doing something other people want to do. And if they really don't want to be in it they will tell you.

-If someone is too high to do the baseline or is obviously not taking the questions seriously, waitlist them.

-People call the phone mostly between 8:30am-10:30am. Try to keep this time free during the day to take calls.

-Nobody shows up to 9am appointments so only schedule 10am and after.

NEWARK COMMUNITY COLLABORATIVE BOARD

Incentive and Study Activities
Condition 1 or 2 – Full Intervention

Session	# of sessions	Length in minutes	Who	Where	How much per session
Phone screen	1	5	Research Assistant	Phone	$0
Clinical Screen	1	20	Clinician	NJCRI	$10
Baseline	1	90	Research Assistant	NJCRI	$20
Community Wise Sessions	15	120	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Follow-up during intervention	5	60	Research Assistant	NJCRI	$20
Focus group	1	90	Research Assistant	NJCRI	$20
Total earned over 5 months	---	---	---	---	$187.50

Group #:

Group Meeting Dates:

Group Meeting Time:

Name of Group Facilitator:

Meeting place address:

Office Phone Number:

NEWARK COMMUNITY COLLABORATIVE BOARD

Incentive and Study Activities
Condition 3 or 4 – Critical Dialogue (CD) and Quality of Life Wheel (QLW)

Session	# of sessions	Length in minutes	Who	Where	How much per session
Phone screen	1	5	Research Assistant	Phone	$0
Clinical Screen	1	20	Clinician	NJCRI	$10
Baseline	1	90	Research Assistant	NJCRI	$20
Community Wise CD and Core Sessions	9	120	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Community Wise QLW Sessions	6	60	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Follow-ups	5	60	Research Assistant	NJCRI	$20
Focus group (possible)	1	90	Research Assistant	NJCRI	$20
Total earned over 5 months	---	---	---	---	$187.50

Group #:

Group Meeting Dates:

Group Meeting Time:

Name of Group Facilitator:

Meeting place address:

Office Phone Number:

NEWARK COMMUNITY COLLABORATIVE BOARD

Incentive and Study Activities
Condition 5 or 6 – Critical Dialogue (CD) and Capacity Building Project (CBP)

Session	# of sessions	Length in minutes	Who	Where	How much per session
Phone screen	1	5	Research Assistant	Phone	$0
Clinical Screen	1	20	Clinician	NJCRI	$10
Baseline	1	90	Research Assistant	NJCRI	$20
Community Wise CD and Core Sessions	9	120	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Community Wise CBP Sessions	6	60	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Follow-ups	5	60	Research Assistant	NJCRI	$20
Focus group (possible)	1	90	Research Assistant	NJCRI	$20
Total earned over 5 months	---	---	---	---	$187.50

Group #:

Group Meeting Dates:

Group Meeting Time:

Name of Group Facilitator:

Meeting place address:

Office Phone Number:

NEWARK COMMUNITY COLLABORATIVE BOARD

Incentive and Study Activities
Condition 7 or 8 – Critical Dialogue

Session	# of sessions	Length in minutes	Who	Where	How much per session
Phone screen	1	5	Research Assistant	Phone	$0
Clinical Screen	1	20	Clinician	NJCRI	$10
Baseline	1	90	Research Assistant	NJCRI	$20
Community Wise Sessions	9	120	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Follow-ups	5	60	Research Assistant	NJCRI	$20
Focus group (possible)	1	90	Research Assistant	NJCRI	$20
Total earned over 5 months	---	---	---	---	$172.50

Group #:

Group Meeting Dates:

Group Meeting Time:

Name of Group Facilitator:

Meeting place address:

Office Phone Number:

NEWARK COMMUNITY COLLABORATIVE BOARD

Incentive and Study Activities
Condition 9 or 10 – Quality of Life Wheel (QLW) and Capacity Building Projects (CBP)

Session	# of sessions	Length in minutes	Who	Where	How much per session
Phone screen	1	5	Research Assistant	Phone	$0
Clinical Screen	1	20	Clinician	NJCRI	$10
Baseline	1	90	Research Assistant	NJCRI	$20
Community Wise Sessions	9	120	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Follow-ups	5	60	Research Assistant	NJCRI	$20
Focus group (possible)	1	90	Research Assistant	NJCRI	$20
Total earned over 5 months	---	---	---	---	$172.50

Group #:

Group Meeting Dates:

Group Meeting Time:

Name of Group Facilitator:

Meeting place address:

Office Phone Number:

NEWARK COMMUNITY COLLABORATIVE BOARD

Incentive and Study Activities
Condition 11 or 12- Quality of Life Wheel (QLW)

Session	# of sessions	Length in minutes	Who	Where	How much per session
Phone screen	1	5	Research Assistant	Phone	$0
Clinical Screen	1	20	Clinician	NJCRI	$10
Baseline	1	90	Research Assistant	NJCRI	$20
Community Wise Core Sessions	3	120	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Community Wise QLW Sessions	6	60	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Follow-ups	5	90	Research Assistant	NJCRI	$20
Focus group (possible)	1	90	Research Assistant	NJCRI	$20
Total earned over 5 months	---	---	---	---	$172.50

Group #:

Group Meeting Dates:

Group Meeting Time:

Name of Group Facilitator:

Meeting place address:

Office Phone Number:

NEWARK COMMUNITY COLLABORATIVE BOARD

Incentive and Study Activities
Condition 13 or 14 – Capacity Building Projects (CBP)

Session	# of sessions	Length in minutes	Who	Where	How much per session
Phone screen	1	5	Research Assistant	Phone	$0
Clinical Screen	1	20	Clinician	NJCRI	$10
Baseline	1	90	Research Assistant	NJCRI	$20
Community Wise Core Sessions	3	120	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Community Wise CBP Sessions	6	60	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Follow-ups	5	60	Research Assistant	NJCRI	$20
Focus group (possible)	1	90	Research Assistant	NJCRI	$20
Total earned over 5 months	---	---	---	---	$172.50

Group #:

Group Meeting Dates:

Group Meeting Time:

Name of Group Facilitator:

Meeting place address:

Office Phone Number:

NEWARK COMMUNITY COLLABORATIVE BOARD

Incentive and Study Activities
Condition 15 or 16- Core

Session	# of sessions	Length in minutes	Who	Where	How much per session
Phone screen	1	5	Research Assistant	Phone	$0
Clinical Screen	1	20	Clinician	NJCRI	$10
Baseline	1	90	Research Assistant	NJCRI	$20
Community Wise Core Sessions	3	120	Group facilitators	NJCRI	$2.50 each attended session (paid at month follow-up)
Follow-ups	5	90	Research Assistant	NJCRI	$20
Focus group (possible)	1	90	Research Assistant	NJCRI	$20
Total earned over 5 months	---	---	---	---	$157.50

Group #:

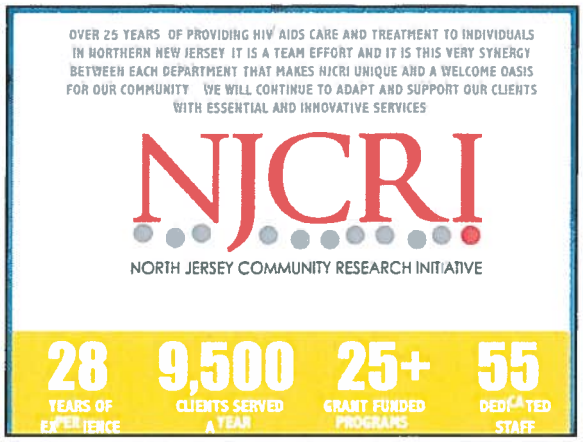
Group Meeting Dates:

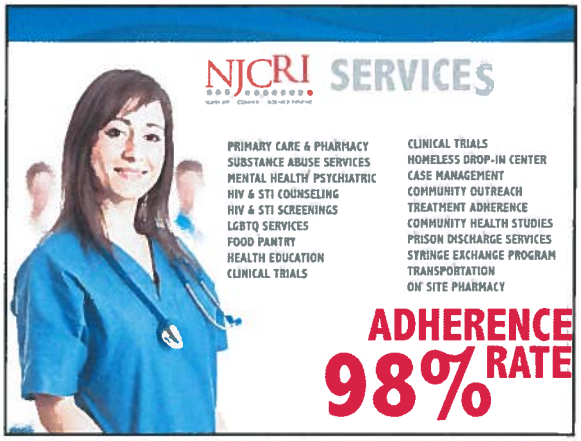
Group Meeting Time:

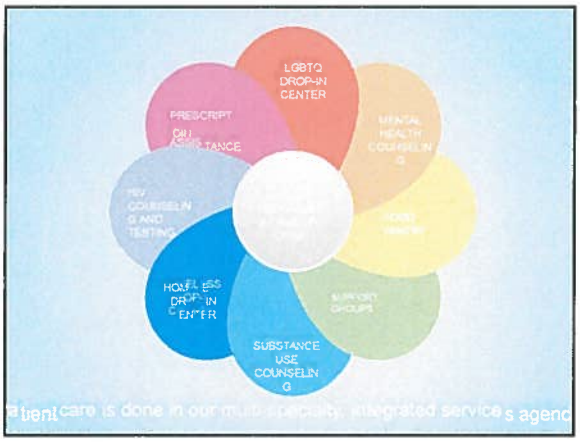
Name of Group Facilitator:

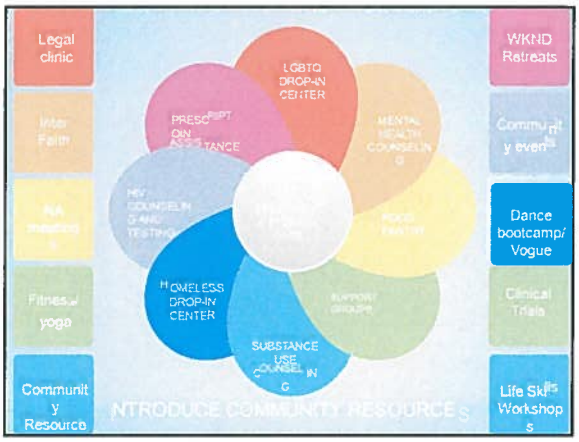
Meeting place address:

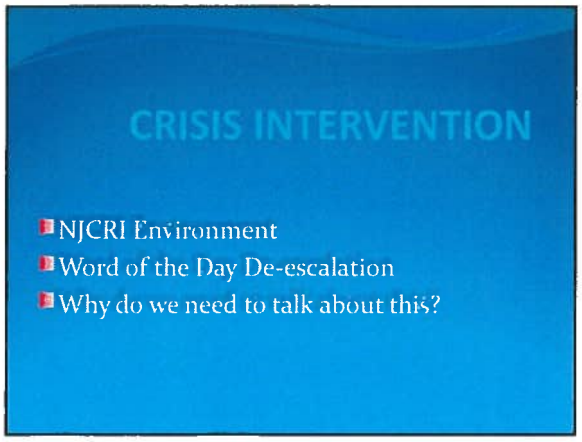
Office Phone Number:

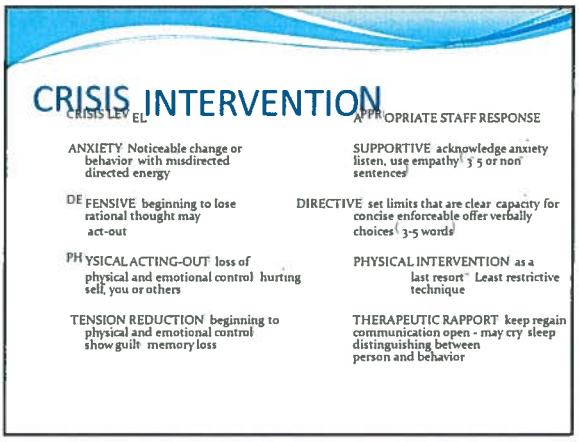












CRISIS INTERVENTION:

DO'S AND DON'TS

NON VERBAL COMMUNICATION (85%)

A. PERSONAL SPACE (18" to 3' or leg length) size, height, sex appearance, relationship

B. BODY LANGUAGE
Signs when personal space invaded: blushing, tension, position of arms or fists
* WHY THE "L" STANCE?
1. Respect personal space (distance)
2. Less challenging or threatening (position of arms, hands, torso)
3. Increase personal safety (less exposed) better balance)

C. PARAVERBAL COMMUNICATION: how we say it, not what we say
1. Tone of voice-avoid condescending, sarcastic, abusive patronizing
2. Volume
3. Cadence - rate of speech

VERBAL COMMUNICATION

VERBAL ESCALATION CONTINUUM	APPROPRIATE INTERVENTION LEVEL
1. QUESTIONING a. seeking information b. challenging authority	Rational response Redirect, focus on topic
2. REFUSAL - "no" mode	SET LIMITS that are a. clear - no jargon b. concise - to the point c. reasonable - appropriate d. Avoid power struggle, ally with patient
3. VERBAL RELEASE	Allow venting Isolate *situation - remove *individual or audience Get assistance
4. INTIMIDATION - threat against self, you or others	Take seriously Isolate situation Make environment safe Get assistance
5. TENSION REDUCTION	THERAPEUTIC RAPPORT Opportunity for learning and growth

TIPS FOR VERBAL INTERVENTION

DO:	DON'T:
• remain calm	• overreact
• be aware of non-verbals	• ignore signals
• isolate situation	• be threatening
• listen - at all stages	• make false promises
• be consistent	
• take time	

LISTENING SKILLS

1. Remain non-judgmental
2. Don't ignore or fake attention
3. Read between the lines, note mixed messages
4. Reclarify, reflective listening
5. Use silence - shows listening, allows individual time to go on

FACTORS WHICH CAN PRECIPITATE CRISIS IN PATIENTS

- Fear
- Guilt
- Loss of control (health, housing, income)
- Social situation (loss of family, friends, sex partner)
- Holidays, anniversaries
- Staff attitude and behavior
- No one acts out in a vacuum, behavior is reciprocal. If we mirror anxious behavior, we can escalate the situation.
- Psychological -- delusions, hallucinations
- Physiological -- drugs, alcohol, meds, hunger, fatigue, illness

Staff Issues That Affect Work With Clients

- Client's behavior and actions:
  - attendance
  - Follow-through
- Upset with co-workers, supervisors or job in general
- Own personal experience:
  - Substance use recovery
  - View of abstinence vs. harm reduction
  - Years in the field – new or experience
  - Years with same client, same problems
- Expectations of
  - Client
  - Job
  - Co-workers
  - Personal growth

HOW STAFF CAN COPE WITH FEAR AND ANXIETY

- Know what frightens you (self awareness).
- Fear and frustration often cause of anger.
- Use a team (case conference, individual supervision)
- Know personal safety

STAFF REACTIONS TO FEAR ANXIETY CAN BE

UNPRODUCTIVE

1. Overreact – feelings, actions
2. Freeze
3. Inappropriate behaviors verbally, physically

PRODUCTIVE

1. Increased sensory acuity and awareness
2. Shorter reaction time
   * Seeking assistance
   * Creating a safe place

Respect

Privacy, Security and Confidentiality

Red/Blue Folder

Policy & Procedure

NJCRI
393 Central Avenue
Newark, NJ 07103
973-483-3444
973-485-7080 (fax)

Issued By:	**Policy #**
Brian McGovern, L.S.W.	Effective Date:
Prepared By:	Updated 06/14/16
Lore De DeStefano	
Approved By:	

Policy Title:

CRISIS INTERVENTION Response to Emergency in the Building

CODE BLUE: will be for medical or mental health emergencies throughout the building.

PURPOSE: To define the procedure to defuse a medical or mental health emergency situation.

POLICY: It will be the policy of NJCRI that by using the over-head page and announcing the code phrase **"Blue Folder" and the Area** (e.g., 2nd floor waiting area, lobby, etc.), would activate the existing response team, who in turn would assist any staff member that may be experiencing a potential medical emergency or mental health crisis with a client or other staff member. The phrase **"Blue Folder"** coupled with the location will instruct/alert security and other key staff members that a response is warranted in the designated area of our building. Emergencies will include, but not be limited to: physical bodily harm, medical emergencies, suicidal or homicidal threat, etc.

PROCEDURE:

1. Staff or Security who witness, are involved, are informed of an medical or mental health emergency or in potential imminent danger will dial page (an overhead page for the entire building).

2. Staff or Security will state **"Blue Folder"** and where they are in the building. Be as specific as possible. Example: Blue Folder, 2nd floor Gym Staff or Security calling for a Blue Folder Code should repeat this three times.

3. The pre-designated Emergency Response Team will assemble upon the location mentioned in the announcement.

4. The Emergency Response Team will consist of the following staff (when available): Joe Kiper, RN, Candace Tobin, RN, Paul Iyhen, RN, Any Physicians in the building at the time of the medical emergency, including Jack Boghossian, MD, Kevin O'Connor, MD, Ronald Poblete, MD, Sue Willard, NP or any other NP in the building at the time, Juan Torres, CMA,

Vieshia Morales, CMA, Corey DeStefano, Clinical Director, Mary Pillarella, LSW, Sidsel Venger, LCSW, Dorinda Coleman, CADC,

5. The Emergency Response Team will secure the area; first respondents will determine who the team leader would be and team leader will identify themselves.

6. Team leader (first on the scene) will direct emergency response team member to medically difuse the situation by conducting; crowd control tactics, secure building, stabilize medically, remove/isolate individual(s) from potentially explosive situations, and/or call 911 for assistance, etc.

7. The Blue Folder Team should have met and make policies and procedures for any medical related community outbreak (IE. Ebola, Zika Virus)

Approved by:

Executive Director Date

NJCRI 393 Central Avenue Newark, NJ 07103 973-483-3444 973-485-7080 (fax)	**Issued By**: Brian McGovern, L.S.W. **Prepared By**: Cuthbert E. Ashby, M.S. **Approved By**:	**Policy #** Effective Date: 03-01-2006 Page 1 of 1 Updated 01-04-08 5-1-2012. 6-14-16
Policy Title: **CRISIS INTERVENTION Response to Emergency in the Building**		

PURPOSE: To define the procedure to defuse emergency situations that may or may not cause physical harm, threats or medical emergency to another client or staff member.

POLICY: It will be the policy of NJCRI that by using the over-head page and announcing the code phrase **"Red Folder" and the Area** (e.g., 2nd floor waiting area, lobby, etc.), would activate the existing response team, who in turn would assist any staff member that may be experiencing a potential crisis. The phrase **"Red Folder"** coupled with the location will instruct/alert security and other key staff members that a response is warranted in the designated area of our building. Emergencies will include, but not be limited to: physical bodily harm, medical emergencies, suicidal or homicidal threat, etc.

PROCEDURE:

1. Staff or Security who witness, are involved, are informed of an emergency or in potential imminent danger will dial page (an overhead page for the entire building).

2. Staff or Security will state **"Red Folder"** and where they are in the building. Be as specific as possible. Example: Red Folder, 2nd floor Project ReNew, suite, Jill's cubical.

3. Staff or Security calling for a Red Folder Code should repeat this three times.

4. The pre-designated Emergency Response Team will assemble upon the location mentioned in the announcement.

5. The Emergency Response Team will consist of the following staff (when available):
Julio Roman, Henry Godette, Angelo Adams, Brian McGovern, Henry Iwuala, Joe Kiper, Keith Williams, Viesha Morales, Candy Tobin, Juan

Torres, Charles Evens, Shawn Ekwall, Corey DeStefano, Paul Iyahen, Steve Morris

6. The Emergency Response Team will secure the area; first respondents will determine who the team leader would be and team leader will identify themselves.

7. Team leader will direct emergency response team member to defuse and deescalate the situation by conducting; crowd control tactics, secure building, remove/isolate individual(s) from potentially explosive situations, and/or call 911 for assistance, etc.

Approved by:

Executive Director Date

Ok to leave messages/instructions	Third preferred contact	Ok to leave message/ instructions	Ok to mail letters?	What is the best way to find you if we lose you?	ok to contact in jail/prison
(Contact Sheet)					

University of Illinois at Urbana-Champaign
Institutional Review Board

Approved: 4/4/16
IRB #: 16574

RECEIVED
MAR 21 2016
INST REVIEW BOARD

University of Illinois at Urbana-Champaign
Institutional Review Board

Approved: 4/4/16
IRB #: 16574

Drug use	Released in past 4 years	English	Eligibility	Clinical screen date	Refused	Reason for refusing

RECEIVED
MAR 21 2016
INST REVIEW BOARD

Phone Screen Sheet

Participant Sheet includes the following column headers:

Gender	Subject #	Code Name	Notes	Group #	Research Assistant for Screening	Number of No Shows	Date of Completed Screening	Computer #
Bio Test selected	Anticipated Date(s) of Bio Test	Screening Informed Consent Completed	Incentive Receipt Filed (LJ)	Eligible (y/n)	Randomized condition	Date of Scheduled Baseline (put on outlook Calendar)	Anticipated Date(s) of Bio Test	Anticipated Date(s) of Bio Test
Screening Informed Consent Completed	Incentive Receipt Filed (LJ)	Eligible (y/n)	Randomized condition	Date of Scheduled Baseline (put on outlook Calendar)	Research Assistant for Baseline	Number of No Shows	Date of Baseline Completed	Computer #
Informed Consent Submitted	Incentive Receipt Filed	Follow up 1	Incentive Receipt Filed	Follow up 2	Incentive Receipt Filed	Follow up 3	Incentive Receipt Filed	Follow up 4
Incentive Receipt Filed	Follow-up 5	Incentive Receipt Filed	Dropped Out (Record Date & Stage of Intervention)	Comments				

RECEIVED
MAR 22 2016
INST REVIEW BOARD

University of Illinois at Urbana-Champaign
Institutional Review Board
Approved: 4/4/16
IRB #: 16574

Waitlisted Sheet includes the following column headers:

Gender	Subject #	Code Name	Notes	Group #	Research Assistant for Screening	Number of No Shows	Date of Completed Screening	Computer #
Anticipated Date(s) of Bio Test	Screening Informed Consent Completed	Incentive Receipt Filed (LJ)	Eligible (y/n)	Date of Scheduled Baseline (put on outlook Calendar)	Research Assistant for Baseline	Number of No Shows	Date of Baseline Completed	Computer #
Computer #	Informed Consent Submitted	Incentive Receipt Filed	Follow up 1	Incentive Receipt Filed	Follow up 2	Incentive Receipt Filed	Follow up 3	Incentive Receipt Filed
Informed Consent Submitted	Incentive Receipt Filed	Med sheet filed	Date of Individual Interview with Facilitator	Monthly Assessment 1	Incentive Receipt Filed	Monthly Assessment 2	Incentive Receipt Filed	Monthly Assessment 3
Incentive Receipt Filed	Date of Focus Group	Incentive Receipt Filed	Date of Follow-up	Incentive Receipt Filed	Dropped Out (Record Date & Stage of Intervention)	Comments		

Biotesting Sheet includes the following column headers:

Subject #	Code Name	Notes	Group #	Research Assistant for Screening	Number of No Shows	Date of Completed Screening	Computer #	Anticipated Date(s) of Bio Test

Screening Informed Consent Completed	Incentive Receipt Filed (LJ)	Eligible (y/n)	Date of Scheduled Baseline (put on outlook Calendar)	Research Assistant for Baseline	Number of No Shows	Date of Baseline Completed	Computer #	Informed Consent Submitted
Incentive Receipt Filed	Med sheet filed	Date of Individual Interview with Facilitator	Monthly Assessment 1	Incentive Receipt Filed	Monthly Assessment 2	Incentive Receipt Filed	Monthly Assessment 3	Incentive Receipt Filed
Date of Focus Group	Incentive Receipt Filed	Date of Follow-up	Incentive Receipt Filed	Dropped Out (Record Date & Stage of Intervention)	Comments			

Ineligible or not Interested Sheet includes the following column headers:

Anticipated Date(s) of Bio Test	Screening Informed Consent Filed (AJ)	Incentive Receipt Filed (LJ)	Eligible (y/n)	Date of Scheduled Baseline (put on outlook Calendar)	Research Assistant for Baseline	Number of No Shows	Date of Baseline Completed	Computer #
Informed Consent Submitted	Incentive Receipt Filed							

Data Processing Sheet includes the following column headers:

Subject #	Code Name	date screen completed	computer #	Date Screening Data in Data Manager & SPSS	date baseline completed	computer #	Date Baseline Data in Data Manager & SPSS	Date Baseline Data Removed
Date Follow up 1 completed	Computer #	DateFollow Up 1 uploaded to box drive	Date Followup Data Entered into Data Manager & SPSS	Date Followup Data Removed	DateFollow Up uploaded to box drive	Date Followup Data Entered into Data Manager & SPSS	Date Followup Data Removed	DateFollow Up uploaded to box drive
Date Followup Data Entered into Data Manager & SPSS	Date Followup Data Removed	DateFollow Up uploaded to box drive	Date Followup Data Entered into Data Manager & SPSS	Date Followup Data Removed	DateFollow Up uploaded to box drive	Date Followup Data Entered into Data Manager & SPSS	Date Followup Data Removed	

Dropout Sheet includes the following column headers:

Subject #	**Code Name**	**Status**	**Research Assistant for Screening**	**Number of No Shows**	**Date of Completed Screening**	**Computer #**	**Screening Informed Consent Filed (AJ)**	**Incentive Receipt Filed (AJ)**
Eligible (y/n)	**Date of Scheduled Baseline (put on Google Calendar)**	**Research Assistant for Baseline**	**Number of No Shows**	**Date of Baseline Completed**	**Computer #**	**Informed Consent Filed**	**Incentive Receipt Filed**	**Group #**
Anticipated Date(s) of Bio Test	**Dropped Out (Record Date & Stage of Intervention)**	**Comments**						

Correction to Make Sheet includes the following column headers:

Date Correction was made Correction to be made

Recruitment Screening

This is a recruitment screening instrument. Please answer all required questions carefully. You will be able to edit any responses later if necessary.

Notes _____

Wave number _____

Date of phone screen _____

Candidate ID # _____

How did you hear about the study? _____
(Ask for referring person's name)

Candidate First Name _____

Candidate Last Name _____

What is your home phone number? _____

What is your cell phone number? _____

Eligibility Questions

What is your gender? (Read all options and have them choose one)

- ○ Female
- ○ Male
- ○ Transgender M to F
- ○ Transgender F to M

Do you have or have you had problems because of alcohol or drug use?

- ○ No
- ○ Yes

What was the date when you last used any drug or alcohol? _____

Have you ever been incarcerated before?

- ○ Yes
- ○ No

(DO NOT ASK THINK QUESTION! The RA will verify this information) What were your charges? _____
(Do not ask this question. This will be verified by the RA.)

How long have you been incarcerated when you were last incarcerated? (Months) _____

What is the date of your last incarceration? (Let them know we will check in public records) _____

What is the date of your last release from incarceration? (Let them know we will check in public records) _____

Length since you were last released _____

What type of facility were you involved with?

- ○ Federal Facility
- ○ State Facility
- ○ Municipal

Which state were you incarcerated? _____

Which county were you incarcerated? _____

Are you in a waiting list for any inpatient treatment?

- ○ Yes
- ○ No

Are you currently under supervision such as parole, drug court, halfway house?

- ○ Yes
- ○ No

Please explain

_____

List the date and name of staff who verified record on public data _____

Residential Address

Do you live in Essex County? (I will need an address)

- ○ No
- ○ Yes

Street _____

Apt # / Suite # _____

City _____

State _____

Zip Code _____

Is it ok to mail you letters?

- ○ Yes
- ○ No

Additional Information

Does participant speak English?

- ○ No
- ○ Yes

What is your date of birth? _____

What is your e-mail address? _____

What is the best way to contact you? (check all that apply)

- ☐ Home Phone
- ☐ Cell Phone
- ☐ Email
- ☐ Facebook
- ☐ Text

Is it ok to leave a message? (check all that apply)

- ☐ Home Phone
- ☐ Cell Phone
- ☐ Email
- ☐ Facebook
- ☐ Text

Clinical Screening Scheduling

Was participant Eligible at Phone Screen?

○ No
○ Yes

Explain why the candidate was ineligible.

_____

Please remember to add the scheduled clinical screening date in the Redcap Calendar!!!!

When would you like to schedule the Clinical Screening appointment?

_____
(ALSO SCHEDULE ON REDCAP CALENDAR !!!!)

We are sorry. The candidate is ineligible for Community Wise Optimization study at this time. Please fill out the form below to indicate reason.

Reason ineligible at phone screen

☐ Gender
☐ Language
☐ Residence
☐ No substance use disorder
☐ Not incarcerated
☐ Released for more than 4 years ago
☐ Not willing to be voice recorded
☐ Refused to participate
☐ Other Reason

Explain why the candidate is not eligible.

_____

Clinical Screen Packet Checklist

Date of Interview: _____

Name of Interviewer: _____

Code Name of Interviewee: _____

Participant ID#: _____

- ✓ Clinical Screen Consent
- ✓ MINI Mental State Exam
  - o "Close your Eyes"
  - o Pentagon Drawing
  - o Wristwatch (not included)
- ✓ MINI Suicidality Assessment
- ✓ MINI Psychotic Assessment
- ✓ GAIN SCALE
- ✓ Script to Participate in Community Wise
- ✓ Full Study Informed Consent (2)
- ✓ Community Wise Flow Chart
- ✓ CW Referral List
- ✓ Incentive Receipt
- ✓ Cash Incentive ($10) (sign out)

Clinical Screening Survey

This is a recruitment survey. Please answer all required questions carefully. You will be able to edit any responses later if necessary.

Thank you!

Candidate ID # _____

Number of sessions participant missed before completing data collection _____

Date of Clinical Screening Interview _____

Name of Interviewer _____

Mini-Mental total score. _____
(Integer Only (Scores between 0-30))

Suicidality

During the past 12 months, have you thought about ending your life or committing suicide?
○ Yes
○ No

Would you be willing to agree not to attempt suicide for the duration of the treatment program (5 months) and let your counselor know if you need help keeping this agreement?
○ Yes
○ No

During the past 12 months, did you have a plan where you actually intended to commit suicide?
○ Yes
○ No

	Yes	No
During the past 12 months, have you gotten a gun, pills or other things to carry out your plan?	○	○
During the past 12 months, have you attempted to commit suicide?	○	○

Psychoticism

(If Yes, prob to determine plausibility. Only mark Yes if explanation is clearly not plausible.)

During the past 12 months, have you had significant problems with...

	Yes	No

thoughts that other people were taking advantage of you, not giving you enough credit, or causing you problems?	○	○
thoughts that someone was watching you, following you or out to get you?	○	○
seeing or hearing things that no one else could see or hear or feeling that someone else could read or control your thoughts?	○	○

Did the candidate have psychotic symptoms in the past 12 months?
- ○ Yes
- ○ No

When was the last time, if ever, your life was significantly disturbed by these symptoms?
- ○ 4 to 12 months ago
- ○ 1 to 3 months ago
- ○ 1 to 4 weeks ago
- ○ 3 to 7 days ago
- ○ Within the past two days

Determine if psychotic symptoms are due to drug use

Do these psychological problems happen only when or after you have been using alcohol or other drugs?
- ○ Yes
- ○ No

Do these psychological problems happen even when you have not been using alcohol or other drugs?
- ○ Yes
- ○ No

DO NOT ASK THIS, USE YOUR JUDGMENT TO ANSWER: Are psychotic symptoms drug induced?
- ○ Yes
- ○ No

Does participant have psychotic symptoms that are likely to intervene with participation in Community Wise?
- ○ Yes
- ○ No

Clinician notes to support their recommendation.

_____

(Notify participant that if they seek treatment for these symptoms they can become eligible in the future.)

Timeline Follow Back Alcohol Use Questions

Number of days on which alcohol was used in the past 30 days. _____

Average number of drinks per drinking day in past 30 days. (NOTE: MUST WRITE 1 DECIMAL PLACE. e.g. 0.0). To get this number, add the total number of drinks in the month, then divide it by the number of drinking days. _____

Number of heavy drinking days. (Heavy Drinking = 4 or more drinks in one occasion) _____

Timeline Follow Back Drug use questions

Number of days on which heroin was used in the past 30 days. _____

How much heroin do you typically use in a day? _____

Number of days on which cocaine was used in the past 30 days. _____

How much cocaine do you typically use on a day? _____

Number of days in which cannabis was used in the past 30 days. _____

How much cannabis do you typically use on a day. _____

Number of days on which prescription opiates was used in the past 30 days. _____

How much prescription opiates do you typically use on a day. _____

Number of days on which prescription downers (Benzos, Barbiturates) was used in the past 30 days. _____

How much prescription downers do you typically use on a day. _____

Number of days on which hallucinogens was used in the past 30 days? _____

How much hallucinogens do you typically use on a day? _____

Number of days on which synthetic marijuana was used in the past 30 days? _____

How much sythetic marijuana do you typically use on a day? _____

Number of days in which other drug was used in the past 30 days _____

How much other drugs do you typically use a day? _____

Specify other drug _____

Did the participant meet the weekly use in the past month threshold? (4 or more days using any drug or 4 or more days of binge drinking)
- ◯ Yes
- ◯ No

In the past year, did you use any drugs or drank any alcohol?
- ◯ Yes
- ◯ No

GAIN SPS-SII

Next we want to go over a list of common problems related to alcohol. After each of the following questions, we would like you to tell us the last time you had this problem.

		Past Month (3)	Past year (2)	Lifetime (1)	Never (0)
c.	c. When was the last time that you tried to hide that you were using alcohol or other drugs?	○	○	○	○
d.	d. When was the last time that your parents, family, partner, co-workers, classmates or friends complained about your alcohol or other drug use?	○	○	○	○
e.	e. When was the last time that you used alcohol or other drugs weekly or more often?	○	○	○	○
f.	f. ... your alcohol or other drug use caused you to feel depressed, nervous, suspicious, uninterested in things, reduced your sexual desire or caused other psychological problems?	○	○	○	○
g.	g. ...your alcohol or other drug use caused you to have numbness, tingling, shakes, blackouts, hepatitis, TB, sexually transmitted disease, or any other health problems?	○	○	○	○
h.	h. ... you kept using alcohol or other drug even though you knew it was keeping you from meeting your responsibilities at work, school, or home?	○	○	○	○
j.	j. ...you repeatedly used alcohol or other drugs when it made the situation unsafe or dangerous for you, such as when you were driving a car, using a machine, or when you might have been forced into sex or hurt?	○	○	○	○
k.	k. ...your alcohol or other drugs caused you to have repeated problems with law?	○	○	○	○
m.					

	m. ... you kept using alcohol or other drugs even though it was causing social problems, leading to fights, or getting you into trouble with other people?	○	○	○	○
n.	n. ... you needed more alcohol or other drugs to get the same high or found that the same amount did not get you as high as it used to?	○	○	○	○
p.	p. ... you had withdrawal problems from alcohol or other drugs like shaky hands, throwing up, having trouble sitting still or sleeping, or you used any alcohol to stop being sick or avoid withdrawal problems?	○	○	○	○
q.	q. ...you used alcohol or other drugs in larger amounts, more often or for a longer time than you meant to?	○	○	○	○
r.	r. ...you were unable to cut down on or stop using alcohol or other drugs?	○	○	○	○
s.	s. ... you spent a lot of time either getting alcohol or other drugs , using alcohol or other drugs , or feeling the effects of alcohol or other drugs (high, sick)?	○	○	○	○
t.	t. ... your use of alcohol or other drugs caused you to give up, reduce or have problems at important activities at work, school, home or social events?	○	○	○	○
u.	u. ...you kept using alcohol or other drugs even after you knew it was causing or adding to medical, psychological or emotional problems you were having?	○	○	○	○
ua.	ua. ... you wanted to use alcohol or other drugs so badly you couldn't think of anything else?	○	○	○	○

GAIN Substance use disorder

Number of symptoms coded 2 (past year) for Alcohol	
Number of symptoms coded 1 (lifetime) for Alcohol	
Number of symptoms coded 2 (past year) for heroin	
Number of symptoms coded 1 (lifetime) for heroin	
Number of symptoms coded 2 (past year) for cocaine	
Number of symptoms coded 1 (lifetime) for cocaine	
Number of symptoms coded 2 (past year) for cannabis	
Number of symptoms coded 1 (lifetime) for cannabis	
Number of symptoms coded 2 (past year) for opiates	
Number of symptoms coded 1 (lifetime) for opiates	
Number of symptoms coded 2 (past year) for downers	
Number of symptoms coded 1 (lifetime) for downers	
Number of symptoms coded 2 (past year) for hallucinogens	
Number of symptoms coded 1 (lifetime) for hallucinogens	
What is the participant's substance use disorder diagnosis (2 or more symptoms in the specific time frame)?	◯ None ◯ Past year ◯ Lifetime
FOR CLINICIAN TO ANSWER: Did the participant have a SUD disorder lifetime or past year AND used drugs last year OR met the weekly use threshold?	◯ Yes ◯ No

The Clinical Screening is complete.

The candidate is ELIGIBLE to participate in Community Wise Optimization study. Please notify the candidate about the result and proceed to next step to enroll the candidate as a participant of our study. Feel free to make any notes in the below section.

Make sure you press the SUBMIT button before closing your browser!

Field Note

The participant is NOT ELIGIBLE at this time.

Reason ineligible at clinical screening.

- ☐ More than 3 No shows for scheduled interview
- ☐ Mini-mental score
- ☐ Suicidality criteria
- ☐ Psychoticism criteria
- ☐ Alcohol usage criteria
- ☐ Substance usage criteria
- ☐ Refused
- ☐ Other Reason

Explain the reason for ineligibility at clinical screening.

Script for terminating the Clinical Screen:

If they do not qualify:

I am sorry but the screen is showing you are not eligible. The intervention has some components that could be more harmful to some people. Since the program is still new, we are not taking any risks and making sure your safety comes first. If ineligible due to MINI, let them know the screen captured a cognitive deficit and encourage them to contact their doctor for further screening. If they ask what that means, say they do not seem to be processing information properly. This could be due to an injury, age, genetics, drug use, or other illnesses. Thus, they should follow up with a doctor. If they are ineligible due to their drug use level, tell them their level of substance use disqualified them but do not provide further information. Refer them appropriately with the referral list.

If they say they are seeking residential treatment, let them know they do not qualify for the study. If they say they tried to get into residential but were unable to, ask how long the waiting list is. If longer than 5 months, admit them. If not, let them know they are not eligible.

If they qualify:

Congratulations, you qualify for the study. The next step will be to attend an orientation session where we will explain the study in detail to you. We will not pay you to attend but we will provide transportation tickets at the end. The orientation will last 30 minutes and we will offer light refreshments. You can only proceed in the study after you attend the orientation. There are several dates available and this card includes all of the information. After the orientation, if you are still interested, you will be invited to complete another questionnaire on the computer and after that you will start the intervention. We plan on starting Community Wise groups in two weeks or so. [Give them one copy of the full informed consent letter and encourage them to read it and write down their questions to ask at orientation]. Do you have any questions? [if they ask about the study, tell them to read the consent and attend the orientation]. Ask them if they would like a copy of our referral list.

Table 1. Study Measures, Points of Administration (FUs anchored to BL), minutes to administer

Area of assessment	Variables examined	Measures	Clinical Screen	Baseline	Monthly FUs 1,2,4	Mid FU 3	Last FU 5
		Maximum collection time	**35 min**	**70 min**	**50 min**	**72min**	**85mi**
SCREENING MEASURES							
Screen Consent		Consent Form	(02)	---	---	---	---
Organic Deficits	Cognitive Impairment	Mini Mental Screen (ratio)	(05)	---	---	---	---
Mental Health	Suicidality and Psychotic	MINI 6 modules (dichotomous)	(03)	---	---	---	---
	AIDU frequency	TLFB	(10)	---	---	---	---
SUDs	Screen (first 2 pages)	Gain SPS (ratio)	(15)	---	---	---	---
ORIENTATION SESSION							
Informed Consent	Obtained after participant attends the orientation session		---	---	---	---	---
OUTCOME MEASURES							
Demographics			---	(02)	---	---	(02)
Critical consciousness	Knowledge and action scales	Scale developed by us (ratio/scale);	---	(02)	(02)	(02)	(02)
		SEAHI (ratio/scale)	---	(10)	(10)	(10)	(10)
		CHAT (ratio/scale)	---	(08)	---	(08)	(08)
Mental health	Mental Health	General mental health GAIN	---	(04)	---	---	(04)
		PTSD GAIN	---	(02)	---	---	(02)
		General Self-Efficacy Scale (GSE-6)	---	(03)	(03)	(03)	(03)
		TOSCA (ratio/scale)	---	(08)	---	(08)	(08)
Substance use frequency and consequences	SUD severity	TLFB (ratio/scale)	---	(10)	(10)	(10)	(10)
		Smoking GAIN	---	(01)	(01)	(01)	(01)
		Gain 2 first pages (ratio/scale)	---	(04)	---	(04)	(04)
Biological marker	Substance use	Urine Toxicology Screen (IP) (dicho)	---	(05)	(05)	(05)	(05)
Health Risk Behaviors	Risky sex, HIV, and drug use	CHAT (ratio/scale)/ Gain	---	(05)	(05)	(05)	(05)
Offending	Types of drug related, property, and interpersonal crimes the respondent has committed.	Crime and Violence Scale (GAIN) (ratio/sc)	---	(01)	(01)	(01)	(01)
		Re-arrest in public data (dichotomous)	---	---	---	---	---
Other types of treatment	Control for other treatment received	TSR (IP) (ratio/scale)	---	(05)	(05)	(05)	(05)
PROCESS MEASURES							
Intervention application	Learned skills	Use of Treatment Skills (ratio/scale)	---	---	(03)	(03)	(03)
Group Process	Group satisfaction 12 item scale	Group climate questionnaire (Redcap, by participant & RATER) (ratio/scale)	---	---	(02)	(02)	(02)
	Rapport with group and facilitator12 item scale	Working Alliance Questionnaire (ratio/sc)	---	---	---	(02)	(02)
	Altruism, Instilling hope, and Existential domains of Yalom's scale	Yalom Curative Factors (Redcap, by participant, facilitator & RATER) (ratio/scal	---	---	(03)	(03)	(03)
	Group presence sheet	Group composition tracking (Facilitator) (ratio/scale)	---	---	---	---	---
Client satisfaction	End of Treatment Questionnaire (developed by us)	End of treatment questionnaire (ratio/scale)	---	---	---	---	(05)
Group Tracking and monitoring	Developed by us based on Community Wise	Therapist checklist (facilitator) Fidelity measure (raters) (ratio/scale)	---	---	---	---	---

RedCap (Computer software); RATER = External rater

Baseline Survey

Please complete the survey below.

Thank you!

Number of sessions participant missed before completing data collection _____

What day and time would you be free to attend Community Wise groups? Please check all that apply.

	10:00 AM	11:00 PM	12:00 PM	1:00 PM	2:00 PM	3:00 PM	4:00 PM	5:00 PM	6:00PM
Sunday	☐	☐	☐	☐	☐	☐	☐	☐	☐
Monday	☐	☐	☐	☐	☐	☐	☐	☐	☐
Tuesday	☐	☐	☐	☐	☐	☐	☐	☐	☐
Wednesday	☐	☐	☐	☐	☐	☐	☐	☐	☐
Thursday	☐	☐	☐	☐	☐	☐	☐	☐	☐
Friday	☐	☐	☐	☐	☐	☐	☐	☐	☐
Saturday	☐	☐	☐	☐	☐	☐	☐	☐	☐

Demographics

Race

- ◯ Black/Caribbean
- ◯ African American
- ◯ White
- ◯ Asian
- ◯ Alaskan/Native American
- ◯ Other (if you are Latino(a), mark here your race and in the next question, mark yes for Latino (a)).

Please specify _____

Are you Latino(a) or Hispanic?

- ◯ Yes
- ◯ No

What is the best estimate of your household's yearly income before taxes (use only use numbers, no commas or any other signs)? _____

Religion

- ◯ Christian
- ◯ Jewish
- ◯ Muslim/Islam
- ◯ None
- ◯ Other

Please specify your religion _____

How often do you attend religious services?

- ◯ Seldom
- ◯ Sometimes
- ◯ Often

What is your current marital status? (Select One)

- ◯ Never married
- ◯ Separated
- ◯ Divorced
- ◯ Married
- ◯ Widowed

What is your sexual preference?

- ◯ Heterosexual or straight
- ◯ Gay or lesbian
- ◯ Bisexual
- ◯ Asexual
- ◯ Other

How many days were you paid for working in the past 30 days? (Include paid sick and vacation days and days of "under the table" work) _____

Are you currently looking for employment?

- ◯ Yes
- ◯ No

Do you have a valid driver's license (not suspended or revoked)?

- ◯ Yes
- ◯ No

Do you have an automobile available on a regular basis?

- ◯ Yes
- ◯ No

Are you currently in school or a job training program?

- ◯ Not enrolled
- ◯ Enrolled (Part Time)
- ◯ Enrolled (Full Time)
- ◯ Other

Please specify your current situation in terms of school or a job training program _____

Are you currently employed?

- ◯ Employed (Full Time: 35+ hours per week, or would have been)
- ◯ Employed (Part Time)
- ◯ Unemployed (Looking for work)
- ◯ Unemployed (Disabled)
- ◯ Unemployed (Volunteer work)
- ◯ Unemployed (Retired)
- ◯ Unemployed (Not looking for work)
- ◯ Other

Specify your choice "other" _____

Have you every held a full-time job?

- ◯ Yes
- ◯ No

How long did you hold your longest full-time job? (Please indicate the length in number of months) _____

Approximately, how much money did YOU receive (pre-tax individual income) in the past 30 days from ...

a. Wages (2 decimal places) _____

b. Public assistance (TANF, GA, WIC) _____

c. Retirement (Pension, Soc Sec) _____

d. Disability (SSI) _____

e. Non-legal income (hustles) _____

f. Family, and/or friends _____

g. Other _____

Specify other income _____

In the past 30 days, how many days have you experienced employment problems? (Problems include trouble finding work, worry about being fired or laid off, or not liking the work you do.) _____

In the past 30 days, how troubled or bothered have you been by these employment problems?

- ◯ Not at all
- ◯ Slightly
- ◯ Moderately
- ◯ Considerably
- ◯ Extremely

Have you been mandated to treatment?

- ◯ Yes
- ◯ No

Who is mandating you to get the treatment?

	Yes	No
An employer?	○	○
Your lawyer?	○	○
A court, parole or probation officer, or other part of the criminal justice system?	○	○
A housing or other community agency?	○	○
Your church or close friend?	○	○
Your spouse, partner or family?	○	○
Department of Children and Family Services?	○	○
Any other source?	○	○

Please describe the source. _____

Critical Consciousness Scale (CCS)

Please select the choices that best represents your level of agreement that each statement describes who you are today. There is no right or wrong answer.

	Agree	Somewhat Agree	Slightly Agree	Slightly Disagree	Somewhat Disagree	Disagree
I challenge the oppressive culture under which we live (messages, images, and language) by learning about the issues that affect my community	○	○	○	○	○	○
Oppressed individuals can overcome barriers that keep us from getting ahead by working together	○	○	○	○	○	○
People of color can combat oppression by re-defining family values to reflect their own history and standards	○	○	○	○	○	○
Individuals who adopt distorted cultural messages about themselves without realizing it, become participants in their own oppression	○	○	○	○	○	○
Working as a community on civic engagement can change our perceptions of ourselves and of others	○	○	○	○	○	○
In my community, I can find resources (e.g. knowledge, support, partners) to help me work against the biases and "isms" that try to hold us back	○	○	○	○	○	○
My own experiences are valuable resources that I can share with members of my community so that together we can work against oppression	○	○	○	○	○	○
I feel disconnected from others	○	○	○	○	○	○
I am able to listen to what other people have to say	○	○	○	○	○	○

I attend meetings where we discuss issues about my community	○	○	○	○	○	○
I work with my community to hold my government representatives accountable	○	○	○	○	○	○

TLFB

Use the Calendar Handout to answer the following questions (note these questions refer to last month).

Instructions: Please look at the calendar over the past month and note all of the special occasion days you can recall (e.g. someone's birthday, important event occurred, etc). Then go back to the calendar and try to rebuild how much alcohol/drug you used every day during the past 3 months. You will write everyday how many drinks/hits you took each day. Refer to the alcohol handout to make sure you are recording the amounts properly. Then answer the following questions:

In the past month HOW MANY days did you drink alcohol last month? _____

On the days you drank, how many standard drinks (6 ounces) did you have per day? _____

In the past month HOW MANY days did you use Heroine last month? _____

On the days you used Heroine, how much did you use per day? _____

In the past month HOW MANY days did you use Cocaine last month? _____

On the days you used Cocaine, how much did you use per day? _____

In the past month HOW MANY days did you use Canabis last month? _____

On the days you used Canabis, how much did you use per day? _____

In the past month HOW MANY days did you use Opiates last month? _____

On the days you used Opiates, how much did you use per day? _____

In the past month HOW MANY days did you use Downers last month? _____

On the days you used downers, how much did you use per day? _____

In the past month HOW MANY days did you use Hallucinogens last month? _____

On the days you used Hallucinogens, how much did you use per day? _____

In the past month HOW MANY days did you use Synthetic Marijuana last month? _____

On the days you used Synthetic Marijuana, how much did you use per day? _____

In the past month HOW MANY days did you use other drugs last month? _____

On the days you used other drugs, what are the drugs you used and how much did you use per day? _____

GAIN

In the past 30 days did you...

		Yes	No
c	try to hide that you were using alcohol or other drugs?	○	○
d	your parents, family, partner, co-workers, classmates or friends complained about your alcohol or other drug use?	○	○
e	used alcohol or other drugs weekly or more often?	○	○
f	your alcohol or other drug use caused you to feel depressed, nervous, suspicious, uninterested in things, reduced your sexual desire or caused other psychological problem?	○	○
g	your alcohol or other drug use caused you to have numbness, tingling, shakes, blackouts, hepatitis, TB, sexually transmitted disease, or any other health problems?	○	○
h	keep using alcohol or other drugs even though you knew it was keeping you from meeting your responsibilities at work, school, or home?	○	○
j	repeatedly used alcohol or other drugs when it made the situation unsafe or dangerous for you, such as when you were driving a car, using a machine, or when you might have been forced into sex or hurt?	○	○
k	your alcohol or other drug use caused you to have repeated problems with the law?	○	○
m			

	keep using alcohol or other drugs even though it was causing social problems, leading to fights, or getting you into trouble with other people?	○	○
n	need more alcohol or other drugs to get the same high or found that same amount did not get you as high as it used to?	○	○
p	have withdrawal problems from alcohol or other drugs like shaky hands, throwing up, having trouble sitting still or sleeping, or you used any alcohol or other drugs to stop being sick or avoid withdrawal problems?	○	○
q	use alcohol or other drugs in larger amounts, more often or for a longer time than you meant to?	○	○
r	were you unable to cut down on or stop using alcohol or other drugs?	○	○
s	spend a lot of time either getting alcohol or other drugs, using alcohol or other drugs, or feeling the effects of alcohol or other drugs (high, sick)?	○	○
t	your use of alcohol or other drugs caused you to give up, reduce or have problems at important activities at work, school, home or social events?	○	○
u	keep using alcohol or other drugs even after you knew it was causing or adding to medical, psychological or emotional problems you were having?	○	○
ua	have such strong urges to use alcohol or other drugs you could not think of anything else?	○	○

When was the last time you...

	Never	1+years ago	4 to 12 months ago	2 to 3 months ago	Past month
a. had a disagreement in which you pushed, grabbed, or shoved someone?	○	○	○	○	○
b. took something from a store without paying for it?	○	○	○	○	○
c. sold, distributed, or helped to make illegal drugs?	○	○	○	○	○
d. drove a vehicle while under the influence of alcohol or illegal drugs?	○	○	○	○	○
e. purposely damaged or destroyed property that did not belong to you?	○	○	○	○	○

How ready are you now to remain abstinent from (not use) alcohol, marijuana, cocaine, heroin and other drugs?

0% (Not ready to remain abstinent) — 50% — 100% (Ready to remain abstinent)

(Place a mark on the scale above)

When was the last time you smoked or used any kind of tobacco? Please include cigarettes, cigars, chewing tobacco and pipes.

- ○ Never
- ○ More than 12 months ago
- ○ 4 to 12 months ago
- ○ 1 to 3 months ago
- ○ 1 to 4 weeks ago
- ○ 3 7 days ago

During the past 30 days, on how many days have you smoked or used any kind of tobacco?

_____

On those days, how many times per day did you usually smoke or use any kind of tobacco? (NOTE: A pack of cigarettes would be about 20 times)

_____

Do you have any physical problems with your vision, hearing, limbs or any other problems communicating or getting around?

	Yes	No
Deaf	○	○
Limited hearing or other hearing problems	○	○
Legally blind	○	○
Limited vision or other vision problems	○	○
Lost limbs	○	○
Other difficulties moving hands, feet or body	○	○
Other physical impairments	○	○

What problems do you have? _____

When was the last time, if ever, you were told by a doctor or nurse that you have...

	Never	1+ years	2-12 Months	Past Month
Hepatitis, yellow jaundice, or cirrhosis of the liver?	○	○	○	○
Tuberculosis or TB?	○	○	○	○
The Human Immunodeficiency Virus, HIV or AIDS?	○	○	○	○
Other sexually transmitted diseases or infections, such as syphilis, gonorrhea, or chlamydia?	○	○	○	○
Been tested for these or other infectious diseases or illnesses?	○	○	○	○

Please describe the infectious diseases or illnesses you were tested for. _____

Next, we would like to ask a few personal questions about behaviors that may have affected your risk of getting or spreading infectious diseases. Please remember that all of your answers are strictly confidential.

The first questions are about the use of a needle to inject you with drugs or medication. Do NOT include shots given by a doctor or nurse, but do include if you were injected by someone besides a doctor or nurse or if you injected prescribed medication.

When was the last time, if ever, that you used a needle to inject drugs or medication? Please include medication prescribed by a doctor. (Select One)

- ◯ Never
- ◯ More than 12 months ago
- ◯ 4 to 12 months ago
- ◯ 1 to 3 months ago
- ◯ 1 to 4 weeks ago
- ◯ 3 to 7 days ago

Please answer the next questions using yes or no.

During the past month, did you...

	Yes	No
use a needle to shoot up drugs?	◯	◯
reuse a needle that you had used before?	◯	◯
reuse a needle without cleaning it with bleach or boiling water first?	◯	◯
use a needle that you knew or suspected someone else had used before?	◯	◯
use someone else's rinse water, cooker or cotton after they did?	◯	◯
ever skip cleaning your needle with bleach or boiling water after you were done?	◯	◯
let someone else use a needle after you used it?	◯	◯
let someone else use the rinse water, cooker or cotton after you did?	◯	◯
allow someone else to inject you with drugs?	◯	◯

CHAT C10-2

	Disagree strongly	Disagree	Neutral	Agree	Agree strongly	Not applicable
We injection drug users need to provide each other with sterile syringes to prevent the spread of disease among us	○	○	○	○	○	○
I would rather share my drugs than see other injection drug users being dope sick	○	○	○	○	○	○
We injection drug users need to use condoms to prevent the spread of any diseases to others	○	○	○	○	○	○

The next questions are about having sex. When we refer to sex it includes vaginal, oral and anal sex with anyone. (Vaginal sex is when a man puts his penis into a woman's vagina. Oral sex is when one person puts his or her mouth onto the other person's penis or vagina. Anal sex is when a man puts his penis into another person's anus or butt.)

When was the last time, if ever, that you had any kind of vaginal, oral or anal sex with another person?

- ○ Never
- ○ More than 12 months ago
- ○ 4 to 12 months ago
- ○ 1 to 3 months ago
- ○ 1 to 4 weeks ago
- ○ 3 to 7 days ago
- ○ Within the past two days

Please answer the next questions using yes or no.

During the past month, did you ...

	Yes	No
have sex while you or your partner was high on alcohol or other drugs?	○	○
have sex with someone who was an injection drug user?	○	○
have sex involving anal intercourse (penis to butt)?	○	○
have sex with a man who might have had sex with other men?	○	○
trade sex to get drugs, gifts or money?	○	○
use drugs, gifts or money to purchase or get sex?	○	○
have sex with someone who you thought might have HIV or AIDS?	○	○
have two or more different sex partners (not necessarily at the same time)?	○	○
have sex with a male partner?	○	○
have sex with a female partner?	○	○
have sex without using any kind of condom, dental dam or other barrier to protect you and your partner from diseases or pregnancy?	○	○
have a lot of pain during sex or after having had sex?	○	○

use alcohol or other drugs to make sex last longer or hurt less?	○	○

Please answer the next questions using the number of partners or times.

In the past month, how many times did you have any kind of vaginal, oral, or anal sex with another person?	_____
During the past month, how many sex partners did you have who were male?	_____
In the past month, how many sex partners did you have who were female?	_____

GSES

Please answer the following questions by selecting the answer that best matches your beliefs.

	Not at all	Rarely	Sometimes	Nearly Everyday
I can always manage to solve difficult problems if I try hard enough	○	○	○	○
If someone opposes me, I can find means and ways to get what I want	○	○	○	○
It is easy for me to stick to my aims and accomplish my goals	○	○	○	○
I am confident that I could deal efficiently with unexpected events	○	○	○	○
Thanks to my resourcefulness, I know how to handle unforeseen situations	○	○	○	○
I can solve most problems if I invest the necessary effort	○	○	○	○
I can remain calm when facing difficulties because I can rely on my coping abilities	○	○	○	○
When I am confronted with a problem, I can usually find several solutions	○	○	○	○
If I am in trouble, I can usually think of something to do	○	○	○	○
No matter what comes my way, I'm usually able to handle it	○	○	○	○

CHAT C3

When people attack your dignity, how often do you react in each of these ways?

	Never	Rarely	Sometimes	Often	Very Often
I tell them off	○	○	○	○	○
I cry inside	○	○	○	○	○
I cry openly	○	○	○	○	○
I tried to hurt them physically	○	○	○	○	○
I tried to hurt myself physically	○	○	○	○	○
I use more drugs	○	○	○	○	○
I use more alcohol	○	○	○	○	○
I have more sex	○	○	○	○	○
I think about changing what I do, or what I look like to prove them wrong	○	○	○	○	○

CHAT C10-1

Please indicate to what extent you agree with each statement.

	Disagree Strongly	Disagree	Agree	Strongly Agree
I share the resources I have with other people in my community	○	○	○	○
I give to those in need	○	○	○	○
When my community members need help, they know they can count on me	○	○	○	○
In an emergency, I would baby-sit my community member's kid	○	○	○	○
I would bring food to my community member' home if they go through hard time	○	○	○	○
In times like these, we should make sure no one goes hungry	○	○	○	○
People in my community can only survive by helping each other	○	○	○	○
People in my community need to use condoms to prevent the spread of any diseases to others	○	○	○	○
The community needs to accept drug users	○	○	○	○
I should always use sterile syringes to prevent the spread of disease to others	○	○	○	○

CHAT C11

	Disagree strongly	Disagree	Neutral	Agree	Agree strongly
If violence against people of my race is done by police or other people in Essex County, I should speak up	○	○	○	○	○
If violence against people of my race is done by police or other people in Essex County, I should offer support to the victim or his/her family	○	○	○	○	○
I would rather lie or not tell the truth than tell on a fellow co-worker to my boss	○	○	○	○	○
We should organize to prevent the eviction of families from their homes	○	○	○	○	○
I would never tell on someone to the police	○	○	○	○	○
Drug users like me need to support each other	○	○	○	○	○
When my people in my neighborhood are in trouble they can count on me	○	○	○	○	○
In our society, we [your race] have to organize to keep jobs	○	○	○	○	○
When my fellow injection drug users are in trouble they can count on me	○	○	○	○	○

CHAT_C12

	Disagree strongly	Disagree	Neutral	Agree	Agree strongly
People like me should attend political demonstrations to seek social justice	○	○	○	○	○
In times like these, members of my community need to fight against gentrification	○	○	○	○	○
I would organize my co-workers to demand a fair pay	○	○	○	○	○
I would help drive drug dealers out of the neighborhood even if it meant having to beat them up	○	○	○	○	○
[Your race] people need to organize to prevent police abuse	○	○	○	○	○
[Your race] people need to fight just to preserve our rights	○	○	○	○	○
For [Your race] people things will only get better if we organize politically	○	○	○	○	○
Formerly incarcerated people need to organize to prevent police abuse	○	○	○	○	○
Formerly incarcerated people need to fight just to preserve our rights	○	○	○	○	○
For formerly incarcerated people, things will only get better if we organize politically	○	○	○	○	○

CHAT_C13

	Disagree strongly	Disagree	Neutral	Agree	Agree strongly
People should not use drugs	○	○	○	○	○
People should respect the police	○	○	○	○	○
Most drug users are criminals	○	○	○	○	○
It is ok to reject drugs users	○	○	○	○	○
Seeking sex for pleasure is a sin	○	○	○	○	○
Women with many sex partners are sinners	○	○	○	○	○
Marriage should be a union between a man and a women	○	○	○	○	○
Couples should wait and have sex only after marriage	○	○	○	○	○
Those who work hard make the most money	○	○	○	○	○
Men should be head of household	○	○	○	○	○
The rich deserve to be admired	○	○	○	○	○
God wants the poor to work harder	○	○	○	○	○
Those who are in jail deserve it	○	○	○	○	○
Our society provides the same fair chance to everyone	○	○	○	○	○
Men having sex with men is immoral	○	○	○	○	○
It is perfectly natural for a woman to have sex with another woman	○	○	○	○	○

CHAT_C14

	Disagree strongly	Disagree	Neutral	Agree	Agree strongly
In times like these, I have to fight for the few jobs available	○	○	○	○	○
Life is about getting to the top no matter who gets stepped on	○	○	○	○	○
Sex work is about beating other to the best clients	○	○	○	○	○
You have to race with fellow workers just to keep your job nowadays	○	○	○	○	○
I do whatever it takes to get ahead	○	○	○	○	○
Competition makes us better	○	○	○	○	○
To survive you need to defeat others just to get what you need	○	○	○	○	○
Helping others often backfires	○	○	○	○	○
People like me have to compete with others to get the few sex partners who have money	○	○	○	○	○
[Your race] people have to struggle with other people from my race for the little money available	○	○	○	○	○
[Your race] have to battle with other race/ethnicities for the little money available	○	○	○	○	○

CHAT_C15

	Disagree strongly	Disagree	Neutral	Agree	Agree strongly
People on government assistance should be kicked off welfare and forced to get honest jobs	○	○	○	○	○
People who sell their bodies don't care if they pass their diseases on to the rest of the community	○	○	○	○	○
Drug users should be kicked out of my neighborhood	○	○	○	○	○
I dislike most of my neighbors	○	○	○	○	○
Drug users get too many treatment chances	○	○	○	○	○
Helping others is a waste of time	○	○	○	○	○
Prostitutes should all be tossed in jail	○	○	○	○	○
[Your race] are hostile to other race/ethnicities because we need to survive	○	○	○	○	○
I dislike most people who are not from my race	○	○	○	○	○
Other IDUs are not thoughtful about clean needles	○	○	○	○	○

CHAT_C16

	Disagree strongly	Disagree	Neutral	Agree	Agree strongly
At times, one needs to steal to survive	○	○	○	○	○
Survival sometimes means I have to beat up others to protect what belongs to me	○	○	○	○	○
The city is like the jungle where you survive by being selfish	○	○	○	○	○
In times like these, it is ok to get paid to have sex to feed the children	○	○	○	○	○
In times like these, it is ok to beg to survive	○	○	○	○	○
In times like these, it is ok to exchange sex for food, or shelter	○	○	○	○	○
In times like these, it is best to get a gun to protect the little I have	○	○	○	○	○
"If I help you, you help me" this is how I survive	○	○	○	○	○
I only have sexual relationships with people who can support me	○	○	○	○	○
In times like these, some people like me need to sell drugs in order to survive financially	○	○	○	○	○
I struggle every day to make good choices but sometimes I have to do things that I hate in order to survive	○	○	○	○	○

	1 Never	2 Every now and then	3 Sometimes	4 Frequently	5 Most of the time	6 All the time
I exercise	○	○	○	○	○	○
I take my prescription medications as prescribed	○	○	○	○	○	○
I choose carefully what I put in my body because I want to stay healthy	○	○	○	○	○	○
While at the doctors, I make sure I get the health treatment I need by speaking up for my rights	○	○	○	○	○	○
I am a member of at least one group in my community that engages in political (e.g. writing letters, rallying) and/or social action (e.g. demonstrations, community awareness)	○	○	○	○	○	○
Through leading by example, I encourage family and friends to make healthy choices	○	○	○	○	○	○
My friends and I can depend on one another	○	○	○	○	○	○
Loving and respecting all people is important to me	○	○	○	○	○	○
I help keep my neighborhood clean	○	○	○	○	○	○
I speak up for making my community healthier (e.g. healthy food options in my grocery store, reducing the number of liquor stores)	○	○	○	○	○	○
I educate people about the impact of stigma in marginalizing people	○	○	○	○	○	○
I follow politics and take action to hold politicians accountable (e.g. I vote, write letters, join political campaigns such as Black Lives Matter)	○	○	○	○	○	○
I feel too overwhelmed to do anything about my health	○	○	○	○	○	○
I don't have time to meet other members of my community	○	○	○	○	○	○

I try to help others as much as I can	○	○	○	○	○	○
I am involved in activities that address issues with my community's educational system	○	○	○	○	○	○
I don't say anything when I hear people make fun of people or put them down	○	○	○	○	○	○
I get involved with community activities because I believe I can improve our circumstances	○	○	○	○	○	○
I feel disconnected from politics	○	○	○	○	○	○
I feel disconnected from my community	○	○	○	○	○	○
I vote	○	○	○	○	○	○
I engage in unsafe sex	○	○	○	○	○	○
I have unhealthy eating habits	○	○	○	○	○	○
I engage in criminal behavior	○	○	○	○	○	○
I use physical or verbal confrontation (e.g. kicking, punching, cursing) when I get frustrated or upset	○	○	○	○	○	○
I support organizations that advocate for the rights of Whites in the United States	○	○	○	○	○	○
I encourage risky activities that I think are fun in my community (e.g. drug parties)	○	○	○	○	○	○
I support organizations that speak out against global warming	○	○	○	○	○	○
I disrupt peaceful political action	○	○	○	○	○	○
I engage in activities that can trash or damage property in my community (target practice, breaking this for fun, urinating in public)	○	○	○	○	○	○
I play the political system to get more benefits (e.g. lie to pay less taxes, lay on a welfare application)	○	○	○	○	○	○

SEAHI

	1 Disagree Completely	2 Somewhat Disagree	3 Slightly Disagree	4 Slightly Agree	5 Somewhat Agree	6 Agree Completely
Affordable and quality housing can help improve the well-being of communities and community members	○	○	○	○	○	○
Having access to an affordable doctor, who I trust, in my neighborhood can improve my health	○	○	○	○	○	○
Building trusting relationships can improve my health	○	○	○	○	○	○
Putting myself in someone else's shoes improves my awareness of issues within the community	○	○	○	○	○	○
The food selection in the neighborhood grocery store contributes to my community's health	○	○	○	○	○	○
The quality of air and water in my neighborhood can affect my health	○	○	○	○	○	○
Good education can have a positive impact on the community's health	○	○	○	○	○	○
Having affordable public transportation in communities improves access to necessary resources for quality living (for example, doctor offices, grocery stores)	○	○	○	○	○	○
A clean neighborhood is a healthier neighborhood	○	○	○	○	○	○
I believe people must take care of our planet	○	○	○	○	○	○
I think it is important to keep my neighborhood clean	○	○	○	○	○	○
I feel healthier when I am getting along with others	○	○	○	○	○	○

TSR

Where did you live in the past month? (Select as many as apply)

- ☐ Alone (in private house, apartment, hotel, etc.)
- ☐ With others (in private house, apartment, hotel, etc.)
- ☐ Institution, e.g., hospital, jail, prison (controlled environment)
- ☐ Structured living situation, e.g., recovery house, group home, halfway house
- ☐ Homeless shelter
- ☐ Homeless, i.e., on the street, in an abandoned building, in a car

Specify the institution

_____

Select all that apply

- ☐ For alcohol or drug problems (incl. dual dx)
- ☐ For psychological or emotional problems
- ☐ For medical problems
- ☐ For criminal behavior or legal problems
- ☐ For domestic violence

Did you receive any services for drug and/or alcohol in the past month? Select the types of substance abuse treatment you received. (Check as many as apply)

- ☐ Outpatient group therapy
- ☐ Individual group therapy
- ☐ Residential program
- ☐ Detox
- ☐ 12 steps meetings/ program
- ☐ Prescriptions (e.g. methadone, naltrexone, Antabuse, Vivitrol, Suboxone)
- ☐ Needle exchange program
- ☐ Drop-in center
- ☐ Smoking cesation

List the medications you took over the past month and what you used it for.

_____

In the past month, how many days did you attend treatment for emotional or psychological problems?

_____

How many times were you hospitalized in the past moth?

_____

How many times did you visit the emergency room in the past month?

_____

How many times did you see a medical doctor in the past month?

_____

Did you receive any HIV treatment in the past month?

- ○ Yes
- ○ No

In the past month, how many counseling sessions did you attend specifically for prevention of or education about communicable/infectious diseases (e.g. HIV, Hepatitis, STD)?

_____

Did you receive any family related services such as Dyfs, parenting classes, family therapy?

- ○ Yes
- ○ No

How many sessions did you attend where job/education counseling, placement was the main focus in the past month?

_____

How many sessions did you attend where specific housing services were main focus in the past month? _____

How many sessions did you attend where financial/benefits issues were main focus in the past month? _____

How many times did you meet/speak with a probation/parole/pre-trial supervision officer in the past month? (exclude reschedules, cancels, etc.) _____

How many times did you meet/speak with a public defender or criminal defense lawyer/legal assistant in the past month? (exclude reschedules, cancels, etc.) _____

Did you receive any other services during past 30 days (e.g. psych testing, food bank, soup kitchen)?

- ○ Yes
- ○ No

Specify the other services you received. _____

TSR

Given all the services and treatments and contacts you've had in the past 30 days, how much of all these services dealt with:

		None	A little bit	Some	Quite a bit	A lot
3a	Your substance use problems and issues?	○	○	○	○	○
3b	Your physical health or medical problems?	○	○	○	○	○
3c	Your mental health or psychological problems and issues?	○	○	○	○	○
3d	Your family problems and issues?	○	○	○	○	○
3e	Your employment, education, finances, or housing?	○	○	○	○	○
3f	Your legal or criminal problems and issues?	○	○	○	○	○

The next set of questions is about any upsetting memories or feelings that keep bothering you from times when you or someone close to you was in danger of being hurt, was actually hurt, or died. This includes memories related to emotional, physical or sexual abuse; neglect; serious illness; accidents or disasters; violence in you community; war; or other traumatic events. These may be things you experienced yourself or that you witnessed.

When was the last time, if ever, your life was disturbed by memories or feelings of something you did, something you saw, something that happened to you, or something you heard about happening to someone else? (Select one)

- ◯ Never
- ◯ More than 12 months ago
- ◯ 4 to 12 months ago
- ◯ 1 to 3 months ago
- ◯ 1 to 4 weeks ago
- ◯ 3 to 7 days ago

During the past month, have the following situations happened to you?

	Yes	No
When something reminded you of the past, you became very distressed and upset?	◯	◯
you had nightmares about things in your past that really happened?	◯	◯
When you thought of things you had done, you wished you were dead?	◯	◯
It seemed as if you had no feelings?	◯	◯
Your dreams at night were so real that you awoke in a cold sweat and forced yourself to stay awake?	◯	◯
You felt like you could not go on?	◯	◯
You were frightened by your urges?	◯	◯
You used alcohol or other drugs to help yourself sleep or forget about things that happened in the past?	◯	◯
You lost your cool and exploded over minor, everyday things?	◯	◯
You were afraid to go to sleep at night?	◯	◯
You had a hard time expressing your feelings, even to the people you cared about?	◯	◯

You felt guilty about things that happened because you felt like you should have done something to prevent them?	○	○

Have you ever had any of the problems just mentioned for three or more months?

○ Yes
○ No

Please answer the next question using the number of days.

During the past month, on how many days have you been disturbed by memories of things from the past that yo did, saw or had happen to you?

_____

The next questions are about common nerve, mental or psychological problems that many people have. These problems are considered significant when you have them for two or more weeks, when they keep coming back, when they keep you from meeting your responsibilities or when they make you feel like you cannot go on.

Please answer the next questions using yes or no.

During the past month, have you had significant problems with...

	Yes	No
headaches, faintness, dizziness, tingling, numbness, sweating, or hot or cold spells?	○	○
sleep trouble, such as bad dreams, sleeping restlessly or falling asleep during the day?	○	○
having dry mouth, loose bowel movements, constipation, trouble controlling your bladder, or related itching?	○	○
pain or heavy feeling in your heart, chest, lower back, arms, legs or other muscles?	○	○

During the past month, on how many days did these problems keep you from meeting your responsibilities at work, school or home, or make you feel like you could not go on? _____

During the past month, on how many days were you bothered by any nerve, mental, or psychological problems? _____

During the past month, have you thought about ending your life or committing suicide?
○ Yes
○ No

During the past month, have you had significant problems with...

	Yes	No
feeling very trapped, lonely, sad, blue, depressed, or hopeless about the future?	○	○
remembering, concentrating, making decisions, or have your mind go blank?	○	○
feeling very shy, self-conscious or uneasy about what people thought or were saying about you?	○	○
thoughts that other people did not understand you or appreciate your situation?	○	○
feeling easily annoyed, irritated, or having trouble controlling your temper?	○	○
feeling tired, having no energy, or feeling like you could not get things done?	○	○
losing interest or pleasure in work, school, friends, sex or other things you cared about?	○	○
losing or gaining 10 or more funds when you were not trying to?	○	○
moving and talking much slower than usual?	○	○
feeling worthless or that the bad things that have happened in your life are your fault?	○	○

Incarceration

In you lifetime, how many times have you been arrested and charged with a crime? Please include all the times this happened, even if you were then released or the charges were dropped. _____

How many times were you found guilty and sentenced, including being adjudicated as an adolescent or convicted as an adult? _____

How old were you the first time you were adjudicated or convicted? _____

During the past month, how many days have you been on probation? _____

During the past month, how many days have you been on parole? _____

During the past month, how many days have you been in jail or prison? _____

During the past month, how many days have you been on house arrest? _____

During the past month, how many days have you been on electronic monitoring? _____

How may of these days did you get into trouble with your probation officer or parole officer? _____

TOSCA

You make plans to meet a friend for lunch. At five o'clock, you realize you have stood your friend up.

	Not likely	Slightly likely	Somewhat likely	Likely	Very likely
You would think: "I'm inconsiderate."	○	○	○	○	○
You'd think you should make it up to your friend as soon as possible.	○	○	○	○	○
You would think: "My boss distracted me just before lunch."	○	○	○	○	○

You break something at work and then hid it.

	Not likely	Slightly likely	Somewhat likely	Likely	Very likely
You would think: "This is making me anxious. I need to either fix it or get someone else to."	○	○	○	○	○
You would think about quitting.	○	○	○	○	○
You could think: "A lot of things aren't made very well these days."	○	○	○	○	○

At work, you wait until the last minute to plan a project, and it turns out badly.

	Not likely	Slightly likely	Somewhat likely	Likely	Very likely
Yo would feel incompetent.	○	○	○	○	○
You would think: "There are never enough hours in the day."	○	○	○	○	○
You would fee: " I deserve to be reprimanded for mismanaging the project."	○	○	○	○	○

You make a mistake at work and find out a co-worker is blamed for the error.

	Not likely	Slightly likely	Somewhat likely	Likely	Ver likely
You would think the company did not like the co-worker.	○	○	○	○	○
You would keep quiet and avoid the co-worker.	○	○	○	○	○
You would feel unhappy and eager to correct the situation.	○	○	○	○	○

While playing around, you throw a ball, and it hits your friend in the face.

	Not likely	Slightly likely	Somewhat likely	Likely	Ver likely
You would feel inadequate that you can't even throw a ball.	○	○	○	○	○
You would think maybe your friend needs more practice at catching.	○	○	○	○	○
You would apologize and make sure your friend feels better.	○	○	○	○	○

You are driving around the road, and you hit a small animal.

	Not likely	Slightly likely	Somewhat likely	Likely	Ver likely
You would think the animal shouldn't have been on the road.	○	○	○	○	○
You would think: "I'm terrible."	○	○	○	○	○
You'd fee bad you hadn't been more alert driving down the road.	○	○	○	○	○

You walk out of an exam thinking you did extremely well, then you find out you did poorly.

	Not likely	Slightly likely	Somewhat likely	Likely	Ver likely
You would think: "The instructor doesn't like me."	○	○	○	○	○
You would think: :I should have studied harder."	○	○	○	○	○
You would feel stupid.	○	○	○	○	○

While out with a group of friends, you make fun of a friend who's not there.

	Not likely	Slightly likely	Somewhat likely	Likely	Ver likely
You would feel small...like a rat.	○	○	○	○	○
Yo would think that perhaps that friend should have been there to defend himself/herself.	○	○	○	○	○
You would apologize and talk about that person's good points.	○	○	○	○	○

You make a big mistake on an important project at work. People were depending on you, and your boss criticizes you.

	Not likely	Slightly likely	Somewhat likely	Likely	Ver likely
You would think your boss should have been more clear about what was expected of you.	○	○	○	○	○
You would feel as if you wanted to hide.	○	○	○	○	○
You would think: "I should have recognized the problem and done a better job."	○	○	○	○	○

You are taking care of your friend's dog while they are on vacation, and the dog runs away.

	Not likely	Slightly likely	Somewhat likely	Likely	Ver likely
You would think, "I'm irresponsible and incompetent."	○	○	○	○	○
You would think your friend must not take very good care of her dog or it wouldn't have run away.	○	○	○	○	○
You would vow to be more careful next time.	○	○	○	○	○

You attend your co-worker's housewarming party, and you spill red wide on a new cream-colored carpet, but you think no one notices.

	Not likely	Slightly likely	Somewhat likely	Likely	Ver likely
You would stay late to help clean up the stain after the party.	○	○	○	○	○
You would wish you were anywhere but at the party.	○	○	○	○	○
You would wonder why your co-worker chose to serve red wide with the new light carpet.	○	○	○	○	○

Community Wise Optimization

FOCUS GROUP PROTOCOL

[moderator name] [date]

Thank you all for coming today. You have participated in x weekly Community Wise sessions during the past 5 months and you have filled out surveys to give us feedback on some of the questionnaires you took at the beginning and end of the intervention program. Today we would like to hear from you in your own words about what you think of the experience you had – what you liked and didn't like about the sessions, and any suggestions you have for changes. We will take the information you give us today and use it to help improve sessions in the future. Please feel free to be honest, you will not be hurting or offending the facilitators and researchers if you have complaints. We need to hear your honest opinion so that we can make the intervention better. Let's be mindful of time and give everyone an opportunity to share. I will be facilitating this to make sure we can hear each person. So please raise your hands, one at a time, and avoid talking at the same time. I want to ask you to avoid going into personal issues during this session and I may need to cut you off here and there, I apologize in advance, but I need to make sure we get the information we need. If you have personal issues you need to discuss with a therapist, let me know and we can make a referral at the end of the focus group. Any questions before we start?

1. Overall, how do you feel about your experience in the intervention? (Prompts: Was it helpful? Why or why not? What did you like/dislike and why?)

2. What do you think of the capacity building project/ quality of life wheel/ critical dialogue? (Prompts: Was it helpful? Why or why not? What did you like/dislike and why?)

3. Why did you decide to participate in the intervention?

4. What do you think were the most important parts of the intervention? Why? (prompts: the images, the group discussions, the goal setting, the homework, the handbook, the facilitators, the capacity building projects, discussing oppression and critical consciousness)

5. How did you feel about your group facilitator?

6. Do you have any suggestions for improving Community Wise?

7. Is there anything I haven't asked that you would like to mention about the intervention?

INTEGRITY, INC.

Policy and Procedures Form

Facility/Department: All Programs	**Integrity Policy #: I-1.22**
Subject: Acts of Aggression and Physical Confrontation	**Administrative_____** **Clinical___X___** **Human Resources_____**

Purpose: To establish written guidelines for Integrity staff to manage situations which involve a response to inappropriate behavior that has the potential to result in violence or the threat of violence.

Procedures

Agitated Client

If a staff member is faced with an agitated client the following measures should be taken:

1. Separate the client from others to prevent the situation from getting out of control and from an attempt to solicit others to be sympathetic to the individual's situation. Separation may be through the exiting of the agitated client or the exiting of all other clients.
2. Take the client to a private area and explain that the client is now being given time to calm down and to think about the incident and the member's response.
3. The client's case aide/counselor should be notified. The client should then receive an immediate individual counseling session (IC). The counselor must document the incident through the IC in the client's clinical record.

Severely Agitated/Assaultive Client

In the event a client shows signs of imminent physical threat to the Integrity community, or becomes assaultive, the following procedures should be followed:

1. Attending staff should clear the room of all clients not directly involved in the situation. Senior staff on duty should be notified to report to the situation.
2. The attending staff should attempt to reason with the client in an effort to calm him or her down. The staff should act open minded to what the client has to say but should not make any promises that cannot be kept.
3. Involved clients and staff should be separated from one another and the community.
4. If clients engage in a physical confrontation with one another or staff, the police should immediately be called to remove the offending individual.
5. If someone is injured, call 911 immediately per Policy I-1.28: Medical Emergencies.
6. The Program Director must be contacted immediately. Staff in charge should document the incident in an incident report as per **Policy I-1.14: Incident Reports.**
7. If a client escalates the act by possessing a weapon, the police should be called immediately. All individuals must evacuate the area and the client with the weapon should be confined to one room. Staff members should not attempt to take the weapon, but if they come into possession of

it, each individual in possession of the weapon must be documented. The weapon is to be turned over to the police immediately on their arrival.

Staff/Client Confrontation

Staff is strictly prohibited from physically restraining a client. Staff is to remain "hands off" during any physical confrontation.

Senior Management Approval _____ Date 7-12-12

President's Signature _____ Date 7-19-12

Initial Policy Date: 9/30/1998
Revised: 7/6/2012
PRC: N/A

INTEGRITY, INC.

Policy and Procedures Form

Facility/Department: All Programs	Integrity Policy #: I-1.28
Subject: Medical Emergencies	**Administrative__X__** **Clinical__X__** **Human Resources____**

Purpose: To ensure the immediate treatment of clients in the event of a medical emergency.

Definition

Medical Emergency is an injury or illness that is acute and poses an immediate risk to a person's life or long-term health.

Policy

All clients that experience medical emergencies receive prompt attention to and treatment of the injury or illness.

Procedure

The following steps are to be followed in the event of a medical emergency:

1. The responding staff member must call 911 immediately. Staff must disclose to the operator the specific Integrity House location.
2. Integrity House medical staff must be contacted immediately and notified of the situation.
3. Staff trained in and/or certified in first aid may begin attending to the client with appropriate first aid procedures.
4. Attending staff are to provide all relevant information to emergency personnel upon arrival.
5. Clients and staff experiencing medical emergencies are to be transported to the nearest medical facility by ambulance or other medical emergency vehicles.
6. The Program Director must be notified of the medical emergency within two (2) hours.
7. An incident report must be filed as per ***Policy I-1.14: Incident Reports***.
8. If the medical emergency results in death, ***Policy I-1.31: Death on the Premises*** *or* ***Policy I-1.87: Death off of the Premises*** is to be followed.
9. A client's emergency contact must be notified of the medical emergency (provided that a signed release allowing disclosure is present in the client's file).
10. A client's referral source must be notified of the medical emergency (provided that a signed release allowing disclosure is present in the client's file).
11. If the medical emergency has the potential to cause an outbreak of a contagious disease the Medical Director, The Director of Nursing, the Chief Executive Officer, and the Chief of Operations must be notified within two (2) hours. If necessary the Medical Director the will report to the New Jersey Department of Health any necessary information regarding any diseases listed in *NJAC 8:57 -1.3 Reportable Diseases*.

Medical Director's Signature _____ Date 6/22/15

Senior Management Approval _____ Date 6-30-15

President's Signature _____ Date 6-30-15

Initial Policy Date: 4/6/1999
Revised: 6/19/2015
PRC: N/A

INTEGRITY, INC.

Policy and Procedures Form

Facility/Department: Secaucus	Integrity Policy #: I-1.64
Subject: Emergency Room Referral for Clients	Administrative__X__ Clinical__X__ Human Resources__X__

Purpose: To provide guidelines for the referral of clients to the emergency room.

Procedures

1. If a staff member believes that a client needs to go to the emergency room due to illness or injury, medical staff should be contacted immediately.
2. If the medical staff determines that the client needs to be seen in the emergency room the staff in charge must arrange transportation of the client to the emergency room. If the incident is a medical emergency refer to ***Policy I-1.28: Medical Emergencies. Note: in the case of a medical emergency the client can only be transported to the Emergency Room by emergency personnel.***
3. The client's emergency contact must be notified by the staff (provided that a signed release is present in the client's file).
4. The client's referral source must be notified by staff (provided that a signed release allowing disclosure is in the client's file).
5. The staff in charge must file an incident report as per ***Policy I-1.14 Incident Reports***.

Martin's Place and 30-32 Central Ave

1. If a staff member believes that a client needs to go to the emergency room due to illness or injury the staff in charge must arrange transportation of the client to the emergency room. If the incident is a medical emergency refer to ***Policy I-1.28: Medical Emergencies. Note: in the case of a medical emergency the client can only be transported to the Emergency Room by emergency personnel.***
2. The client's emergency contact must be notified by the staff (provided that a signed release is present in the client's file).
3. The client's referral source must be notified by staff (provided that a signed release allowing disclosure is in the client's file).
4. The staff in charge must file an incident report as per ***Policy I-1.14 Incident Reports***.

Medical Director's Signature _____ Date 6/22/15

Senior Management Approval _____ Date 6-30-15

President's Signature _____ Date 6-30-15

Initial Policy Date: 11/19/1999
Revised: 6/19/2015
PRC: 6/27/2011

Community Wise Referral List

Type of Service	Organization	Address	Address 2	Telephone	Description of Services
AIDS/HIV	AIDS Resource Foundation for Children, Inc.	77 Academy Street	Newark, NJ 07102	973-643-0400 (X737 for Vashonna)	Housing, medical support, etc for children and families with AIDs & other serious medical conditions.
AIDS/HIV	Hyacinth AIDS Foundation	155 Washington St, Suite 206	Newark, NJ 07102	973-565-0300, hotline: 800-433-0254	Variety of support services including Project Connect, a group for people released from prison w/ HIV/AIDs
AIDS/HIV	North Jersey Community Research Initiative (NJCRI)	393 Central Ave, Suite 301	Newark, NJ 07103	(973) 483-3444	HIV testing, counseling, gay and lesbian support, many other support groups available as well.
AIDS/HIV	St. Bridget's Residence- Catholic Community Services	404 University Ave	Newark, NJ 07102	(973) 799-0484 or -0485	Counseling, support, meals, family support, etc for people living with or affected by HIV/AIDs.
Community Assistance	Newark Now Family Success Centers	Newark Now 89 James St	Newark, NJ 07102	973-733-3460	3 centers offering a variety of support services to families
Community Assistance	Renaissance Community Development Corporation Center (RCDCC)	400 7th Avenue West	Newark, NJ 07107	973-481-3431	Offers counseling, job training and support, GED & literacy assistance, addiction services & more,
Crisis	University Behavioral Healthcare - Access Center	The crisis center they refer ppl to is	at 183 South Orange Ave	1-800-969-5300.	Patient service requests for any level of mental health care- (inpatient, outpatient, partial, psychiatric medication, etc)
Crisis	National Suicide/Emotional Crisis Hotline			1800-784-2433	Provides emotional/psychiatric support and assistance.
Crisis	UMDNJ Hotline and Psychiatric Emergency Room		Newark, NJ 07103	Crisis Hotline: 973-623-2323	Provides emotional/psychiatric support and assistance. Sliding scale fees for individual and family counseling.
Crisis	Newark Beth Israel Medical Center	201 Lyons Avenue	Newark, NJ	Crisis Hotline: 973-926-7444	Provides emotional/psychiatric support and assistance
Crisis	Crisis Intervention Unit- East Orange General Hospital	300 Central Ave	East Orange, NJ 07018	Crisis Hotline: 973-266-4478	24/7 Emergency Mental Health Treatment, including counseling and medication.
Domestic Violence	Purple Reign			973-93-PURPL	Support groups, advocacy, safety planning, workshops, etc.
Domestic Violence	Irvington Counseling Center	21-29 Wagner Place	Irvington, NJ 07111	(973) 399-3132	DV counseling & support groups, batterer group counseling, support for the formerly incarcerated and their children
Domestic Violence	Babyland Family Services, Inc	755 South Orange Ave	Newark, NJ 07106	973-399-3400	24/7 Family Violence Hotline, DV shelter and support

Community Wise Referral List

Education	Alternative Programs- East Orange School District (former Edmonson Center)	199 Fourth Ave	East Orange, NJ 07017	(973)-266-2957	GED Programs, ESL classes, Basic Adult Education classes.
Education	Catholic Community Services Workforce Development	321 Central Ave.	Newark, NJ 07102	(973)268-3162 or (973)268-3160	GED Programs and ESL Classes.
Education	Essex County College- Continuing Education Adult Learning Center	303 University Avenue, Level 3 –Yellow Area	Newark, NJ 07102	(973)877-1894	Basic Adult Education, GED Programs, ESL Classes. For more info contact the community and continuing education Department.
Education	Workforce Advantage	390 Broad Street, 2nd Floor	Newark, NJ 07104	973-412-7814	ESL/Computer Services Classes
Education	Newark Tech - Essex County Vocational and Technical School	91 West Market Street	Newark, NJ 07103	(973)412-2291	Adult Education Programs. Also offers a variety of full and part-time training programs. For ex: Automotive Technology; Electricity; Plumbing; Welding Technology; and Cable/TV Installation and Network Cable Training, Nursing, etc.
Employment	FOCUS- Hispanic Center for Community Development	441-443 Broad St.	Newark, NJ 07102	(973)624-2528	Educational programs, employment & training programs (Project AWAKE), Welfare-to-Work Programs
Employment	Essex County Department of Economic Development, Division of Training and Employment	50 South Clinton Street	Newark, NJ 07018	(973)395-8400	Assessment and training referrals, job search/job readiness program, job placement, basic adult education,GED testing, child drop-off center, assistance with transportation.
Employment	Urban League of Essex County	508 Central Ave	Newark, NJ 07107	973-624-9535	Variety of support services, referrals, seminars, study groups, job networking, remedial skills training, and technology training.
Employment	North Ward Center Newark Business and Training Institute (NBTI)	346 Mount Prospect Avenue	Newark, NJ 07104	(973) 481-0415	Variety of training and educational supports including the Newark Business Training Institute
Employment	Newark One-Stop Career Counseling	990 Broad Street	Newark, NJ 07102	973-733-8500	Multiple Locations. Career counseling, planning, training, etc
Employment	The First Occupational Center of NJ	120 Arlington Ave	Bloomfield, NJ 07003	973-429-5500	The Center provides jobs through its seven wholly-owned and operated companies, including Recycling, Building Services Grounds keeping, etc.
Employment	New Community Corporation (Workforce Dev Center)	201 Bergen Street	Newark, NJ 07103	973-639-5600	Provides job training in a variety of specialized areas. Must have a diploma/GED

Community Wise Referral List

Employment	Catholic Community Services Workforce Development	321 Central Ave.	Newark, NJ 07102	(973)268-3162 or (973)268-3160	Provides job training in a variety of specialized areas. Ex: Certified Nurses Assistant, Commercial Driver's License Training, Displaced Homemakers Program, Food Services, Janitorial Maintenance Program, Retail Sales Training, etc.
Employment/ Domestic Violence/Etc	La Casa de Don Pedro	39 Broadway	Newark, NJ 07104	973-481-4713	Variety of services, including a prisoner reentry program, welfare to work program.
Family Counseling	New Community Corporation (Family Service Bureau of	274 South Orange Ave	Newark, NJ 07103	973-412-2056	2 locations- one in Newark & one in Kearny, variety of family and individual counseling and support services
Family Counseling	Family Connections	395 South Center St	Orange, NJ 07050	(973) 675-3817	Counseling for youth and families.
Fatherhood	Newark Comprehensive Center for Fathers (NCCF)	Newark Now 89 James St	Newark, NJ 07102	973-732-0713	NCCF offers fathers mentoring, parenting and life skills, legal assistance, help to improve math and reading skills, individual counseling, support groups, Father/Child activities, employment search and interview preparation services.
Food	Bethany Baptist Church	275 West Market	Newark, NJ	973-623-8161	Hours: Mon. - Thurs. 11:00 am - 1:00 pm, referral letter needed
Food/Job	Community Food Bank of New Jersey	31 Evans Terminal	Hillside, NJ 07205	(908) 355-FOOD	Food bank, hires former prisoners.
Healthcare	Newark Community Health Center- Dayton St Health Center	101 Ludlow Street	Newark, NJ 07114	973-565-0355	Call for additional locations in Newark, East Orange, Orange & Irvington. Provides health care services at a sliding scale cost or for free, even if client does not [illegible]
Healthcare	Newark Homeless Healthcare Project	110 William Street	Newark, NJ 07102	973-733-5706	Call first as there are multiple locations. Basic medical care for homeless people or those at risk of
Healthcare- related to Sleep problems	Sleep Disorders Clinic @ Newark Beth Israel	201 Lyons Ave at Osborne	Newark, NJ 07112	(973) 926-2973	The center evaluates for a large range of disorders including sleep apnea, snoring, insomnia, narcolepsy, sleep-wake schedule disorders, male impotency, etc.
Healthcare	Planned Parenthood of Metropolitan New Jersey	151 Washington Street	Newark, NJ 07102	973-622-3900	General health care, sexual health, gynecological exams, STD screening & counseling, abortion, contraceptives, etc. Walk-in or by appointment.
Housing/Food	The Apostle's House	24 Grant Street	Newark, NJ 07104	973-482-8865	Shelter provided for women and their children. Food pantry for everyone.
Housing/Food	Salvation Army	45 Central Ave	Newark, NJ	(973)623-5959	Food, clothing, information and referral services.
Housing/Food	Goodwill Rescue Mission (Newark Location)	79 University Avenue	Newark, NJ 07102	973-621-9560	Drop-in center, shelter, feeding program, men's discipleship program

Community Wise Referral List

Housing/Food	The Open Door Drop-In Center-Liberation in Truth Unity Fellowship Church	47-49 New Street	Newark, NJ 07102	(973)424-9555	Open 10am-2pm Monday-Friday. Offers a variety of services including showering, laundry machines, food, and temporary resting or respite opportunities.
Housing/Food	YMCA of Newark & Vicinity	600 Broad Street	Newark, NJ 07102	973-624-8900	Emergency Residence Program, including case management services
Legal Services	Seton Hall University School of Law Center for Social Justice	1 Newark Ctr # 1-5	Newark, NJ 07102	973-642-8700	Variety of legal services/representation provided. They do not take clients in May, June or July.
Legal Services	Community Health Law Project	650 Bloomfield Ave, Suite #210	Bloomfield, NJ 07003	973-680-5599	Provides health/medical legal services.
Legal Services	Essex-Newark Legal Services (Legal Services of NJ)	5 Commerce St, 2nd Floor	Newark, NJ	(973) 624-4500	Variety of legal services for low income people in Essex County.
Legal Services	Newark Reentry Legal Services-ReLeSe (partnered with Volunteer Lawyers for Justice)	no walk-ins & by referral only	Newark, NJ	(973)-645-0022	Must be referred by another agency. Assists formerly incarcerated people with a variety of legal services, including expungement.
Mental Health	Mental Health Association of Essex County	33 South Fullerton Ave	Montclair, NJ 07042	973-509-9777	Services include collaborative justice programs designed to assist people reentering the community.
Mental Health	New Hope Behavioral Health Center	277 Coit Street	Irvington, NJ 07111	(973) 373-5100	Mental health and substance abuse TX for individuals.
Mental Health	Renaissance Challenge Conquerers	400 7th Ave	Newark, NJ 07108	973-551-9564	Provides mental health services, substance abuse treatment services as well.
Mental Health	Newark Beth Israel Medical Center-Community Mental Health Center	210 Lehigh Avenue	Newark, NJ 07112	(973) 926-7026	24/7 Emergency Mental Health Treatment, including counseling and medication.
Mental Health	Mount Carmel Guild Behavioral Health System- Catholic Community Services	56 Freeman Street	Newark, NJ 07105	(973) 596-4190 or (973) 596-3925	Outpatient psychotherapy, inpatient psychiatric and substance abuse services.
Reentry (general)	United Community Corporation-Training and Resource Center	31 Fulton St.	Newark, NJ 07102	(973) 642-0181	Variety of services, resources and training. Computer labs for individuals who need internet or computer access. Hands-on training for programs on automotive services, medical billing, computer software repair, etc.

Community Wise Referral List

Reentry (general)	FORGE (Female Offender Reentry Group Effort)	Essex County College- 303 University Ave, Level 3, Yellow Area	Newark, NJ 07102	973-353-9083	"Single" Entry resource center for female offenders under criminal justice supervision. Variety of services offered.
Reentry (general)	Wise Women's Center	Essex County College- 303 University Ave, Level 3, Yellow Area	Newark, NJ 07102	973-877-3395	Career & educational assistance for women, reentry support for women, parenting classes for men & women.
Reentry (general)	Offender Aid & Restoration (OAR)	303 Washington St (3rd Floor)	Newark, NJ 07102	973-373-0100	Variety of support services for people in reentry, such as counseling, employment assistance, etc.
Shelters/Emergency Housing	Lighthouse Community Services	487 Washington St	Newark, NJ	973-802-1802	Mostly for men. Provides shelter, should call first. Also soup kitchen, clothes rack & food pantry.
Shelters/Emergency Housing	Isaiah House	238 North Munn Ave	East Orange, NJ 07017	973-678-5882	Shelter, various programs. Mostly for women, teens & children.
Shelters/Emergency Housing	Project Solution	712 Springfield Ave	Newark, NJ	973-353-0005	Mostly for men. Provides shelter & two meals a day.
Shelters/Emergency Housing	Missionaries of Charity	60 Jay Street	Newark, NJ 07103	973-481-9056	Shelter for non-pregnant women. Can stay up to 3 weeks.
Shelter/Free Professional Clothing	Newark Emergency Services for Families (NESF)	982 Broad St.	Newark, NJ 07102	800-696-7063 (24 Hour Hotline), Phone: 973-639-2100	Provides emergency services, food, clothing,drop in laundry & showers, 24 hr shelter referrals, etc.
Substance Abuse	Narcotics Anonymous of New Jersey			Meeting info: 732-933-0462, Helpline: 800-992-0462	Fellowship of addicts committed to achieving & maintaining sobriety.
Substance Abuse	Northern New Jersey Alcoholics Anonymous			Meeting info: 908-687-8566, Helpline: 800-245-1377	Fellowship of alcoholics committed to achieving & maintaining sobriety.
Substance Abuse	Integrity House	97-99 Lincoln Park	Newark, NJ 07102	973-623-0600	Outpatient and residential substance abuse treatment and support.
Substance Abuse	Newark Renaissance House	62-80 Norfolk St	Newark, NJ 07107	(973) 623-3386	Outpatient substance abuse services for women, including women with children and pregnant women.
Substance Abuse	The Bridge, Inc	1065 Clinton Ave	Irvington, NJ 07111	973-372-2624	Intensive outpatient counseling for people struggling with alcohol and drug addiction.
Substance Abuse (Spanish Speaking)	CURA, Inc	35 Lincoln Park	Newark, NJ 07102	(973) 645-4396	Tx & rehabilitation for Spanish speaking individuals with drug & alcohol abuse problems, HIV, etc.

Community Wise Referral List

Support	Bethel Worldwide Outreach Ministries	Greater Friendship Baptist Church, 63-65 Pierce St,	Newark, NJ	973-744-8952	Interfaith program for recovering addicts, support groups for people out of prison.

Newark Community Collaborative Board (NCCB)

Bylaws

Vision

The vision of the NCCB is to build a community where vulnerable individuals are empowered to freely exercise their civil rights and advocate for equitable opportunities for all.

Mission

The mission of the NCCB is to empower individuals with a history of substance use issues who are transitioning from incarceration into distressed communities through research, community engagement, critical thinking, and civic participation.

The NCCB will accomplish this mission through the following actions:

1. Research:
    a. To investigate community problems and develop empowering solutions using scientific methods
    b. To disseminate research findings to the community, government, and potential funding agencies.

2. Community engagement
    a. To meet regularly and collaboratively to develop, test, and implement the Community Wise manual.
    b. Provide mentorship to community members

3. Critical thinking
    a. Using Community Wise to develop critical thinking among community members
    b. Disseminate critical consciousness theory in the community
    c. Challenge one another to continuously engage in critical dialogue

4. Civic participation

    a. To engage and collaborate with community agencies serving individuals with histories of substance use issues and incarceration

Board Description

The NCCB is a community collaborative board of community members (e.g., residents, consumers, researchers, service providers, and government representatives) working together to build safer and healthier communities through engagement in participatory action reseach and advocacy.

Structure

NCCB members share the responsibility of governing the board. Members shall develop and approve the bylaws which can be updated and revised at any time by the NCCB. Members will share the responsibility of developing NCCB activities including the development of Community Wise, its implementation, evaluation, and dissemination of the results. With the exception of the project's principal investigator (PI) and co-investigators, NCCB participation in meetings is remunerated. Community members, consumers, and practitioners receive a $30 stipend for attendance at NCCB meetings. NCCB is managed by the staff under the supervision of Liliane Windsor, PhD, MSW, who also serves as PI and Chair of the NCCB.

Membership

The NCCB will consist of no less than 10 and no more than 20 members. Membership is open to researchers; local community residents; and employees of local community-based organizations, public health agencies, and other academic and governmental institutions. Membership is represented by individuals. Individuals interested in joining the NCCB as members must submit a membership application to the NCCB. The chair will forward the information to the NCCB and invite the aspiring member to attend the public portion of the meeting as a guest. If after the meeting the person is still interested in membership, a membership subcommittee will interview the person and make a membership recommendation at the next NCCB meeting. The NCCB will then vote. Membership is approved by a majority vote.

New NCCB members will receive training on critical consciousness theory and the work that the NCCB does. New members will be expected to read articles that report the work of the NCCB and during the their third NCCB meeting attendance, they will engage in dialogue with the NCCB about their understanding of critical consicousness and the NCCB work. New members will also be assigned an NCCB member mentor to help answer questions and ensure the new member is well integrated into the NCCB.

For procedural purposes, members may miss up to 3 consecutive meetings provided they notify the chair or up to 2 meetings per year without notification. Members who miss a meeting are responsible for reviewing the minutes and staying in touch with the NCCB chair. Members who are unable to attend a meeting in person, may request to attend online. Meeting videos will be recorded and stored indefinitely by the staff. Any member who wishes to review a particular meeting video can submit an e-mail request to the NCCB chair who will respond within 48 hours. Any NCCB member may request that any of the NCCB videos be destroyed for any reason. Attendance will be measured through the meeting minutes. Members who miss more than 3 excused consecutive meetings or more than 2 unexcused meetings annually will be automatically terminated. If the member wishes to be reinstated, he or she can write a letter to the NCCB explaining their absences and their interest in remaining on the board. The member will have the option to attend the first 15 minutes of the meeting when the NCCB will review the letter so that the member can answer any questions the NCCB may have about the content in the letter. After the member leaves, the NCCB will vote on whether membership should be reinstated. Members who are terminated must wait at least 3 months before applying to join the NCCB again.

Membership appointments last 2 years. At that time, anyone interested in continuing to serve must reapply to the NCCB by submitting the renewal form. The NCCB will take a closed vote. In order to be renewed, a member must have *a majority* vote. Members will be due for renewal after 2 years of membership start date. Members will be notified by staff when their membership renewal is due and they will have 30 days to submit the renewal form. Failure to do so will result in the member's dismissal. NCCB members can take one leave of absence of no more than 6 months per appointment cycle.

The NCCB's grant PI's membership cannot be terminated. The NCCB members will have an opportunity to evaluate the PI's performance after each year via an annonymous evaluation form.

Voting

All NCCB members will have one vote during the consensus voting process. Fifty (50) percent plus one (1) of NCCB members present at the meeting are necessary to approve a motion. Each voting NCCB member has one vote. Voting members will make a reasonable effort to reach consensus agreement on all issues. Members absent at the time of voting who feel strongly against the

NCCB voting decision may request that time be included in the agenda to present their argument and the NCCB may reconsider the vote.

Individual Responsibilities

NCCB members agree to:

- Monitor the NCCB documents regularly (e.g.: meeting agenda, minutes, videos) and engage in e-mail discussions between meetings.
- Submit items of interest for inclusion to the meetings agenda and be responsible for facilitating that agenda item during the meeting.
- Present ideas to the NCCB members; the NCCB shall then decide on which ideas to implement.
- Participate in sub-committees. Sub-committes are formed around each emerging NCCB need. The subcommittees shall be overseen by its own facilitator, who will report to the NCCB during board meetings.

Chair and Staff Responsibilities

- The PI and staff are responsible for the orderly conduct of NCCB meetings, designating a person to record meeting minutes (by electronic recording and manual), to set the agenda, disburse payments, manage project budget, and ensure active participation of NCCB members in all aspects of the NCCB activity.
- Meeting minutes will be available and distributed via the website at least one week after each meeting and approved by the NCCB during the next meeting.
- The first half of each NCCB meeting will be open to the guests and the second half will be reserved for members only. The chair will organize the agenda so that confidential business is handled during the second half of the meeting.

Addition/Resignation/Removal

Any NCCB member can make a motion to terminate another member. Such motion must be discussed in a NCCB meeting. Membership termination will require a 2/3 majority vote.

Code of Conduct

The NCCB will adopt the Robert's Rule of Conduct Revised. In addition, NCCB members agree to be courteous and follow the following code:

- Respect each other's opinions
- Disagree without being disagreeable

- Speak with respect, even when feeling strongly about a topic
- Listen to what others have to say
- Silence phones and avoid texting.

Guests

Guests include any individual interested in taking part on the NCCB meetings and manual development. The NCCB must extend an invitation to those interested in attending meetings as guests and the invitation can be withdrawn by the NCCB at any time. Guests will not have voting power or receive reimbursement for their participation. They may have access to the compass 2g website if a request is formally made and such request approved by a majority vote of the NCCB. Guests will be able to take part in the discussion and express their views.

Dissemination

Any dissemination material resulting from the work conducted by any members of the NCCB will be submitted to all members for feedback prior to dissemination. Members will have up to two weeks to review the materials and provide feedback. Authorship will be granted only to the individuals who directly and significantly contribute to the actual dissemination materials. The work of all NCCB members will be acknowleged by the authors under acknowledgement. Members interested in using any data derived from the NCCB work will submit a request to the Chair specifying what data is needed, by when, and for what purpose. The Chair may deny the request if the data is already being used.

Informed Consent to Participate
Community Wise

NAME OF LEAD RESEARCHERS: Dr. Liliane Windsor, MSW and Dr. Ellen Benoit

RESEARCH STUDY: We invite you to participate in a research study that seeks to evaluate Community Wise, a new program seeking to reduce substance use. We want to develop the best program we can by identifying and keeping only the activities that work to reduce substance use. 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 may relate to mental health issues, substance use or experiences you've had in Essex County since your release. 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 three different components of Community Wise reduce substance use.

DURATION: If you agree to participate in this study you will complete up to 9 research interviews (each lasting between 30 minutes and 90 minutes) and attending up to 15 weekly group meetings (2 hours each). It will take approximately 5 months to complete the meetings and all of the interviews.

PROCEDURES: If you agree to participate, we will ask you to take part in **up to 15** weekly group sessions (approximately 2 hours each) led either by a peer or a licensed facilitator where you will meet with other people in Essex County who have had similar experiences as you. The number of sessions you will be asked to attend will depend upon which version of the program you are randomly selected to join. Thus you will not be able to choose which group you will be joining. This means you could be randomized (picked by chance or luck) to join the "Core" group that includes 3 sessions. You also may be randomized to attend a group that is only offered at a time that is inconvenient for you. If this is the case, you will have to wait 5 months before you will be able to participate in Community Wise. However, if this is the case, you will have the opportunity to receive the full version of Community Wise after you complete the study. The shortest version of the program consists of 3 weeks of meetings. But your participation in the study will take approximately 5 months, regardless of which group you were randomly selected for.

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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, incarceration, and your relationship with your community. You may also learn tools that you can use to improve your health.

The group conversations will be voice recorded. You will use your codename and no identifying information about you will be included in the recording. You must consent to be audio recorded in order to participate in this study. ***We will ask you to make a pledge to respect the privacy of the session, we hope everybody will abide by this pledge but please understand that we can't guarantee that some group members won't reveal information about you to others after the session is over.***

In addition to attending these group sessions, your participation in this study will involve the following interviews: a brief phone talk, an individual interview, up to 6 monthly computer interviews, and possibly a focus group (for a total of 9 research interviews). Each interview will include a urine drug screen, meaning we will ask you for a sample of urine and will test it for certain substances. In the baseline interview we will ask your permission to take a digital photo of you. You may refuse to take the photo without penalty. The information you give us, including results from saliva screens and photo, will be kept private. There are no consequences to having positive or negative urine drug screens and no one outside of this study, including parole officers or the providers at NJCRI, will be informed of the results. Your answers to any questions that will be asked throughout this study will be completely confidential. If, at any time, you do not want to answer a question or participate in a certain part of the study, you may refuse without penalty. You should know that some of the interviews include questions about suicide. If we find that you are thinking about killing yourself, your group facilitator will be notified and asked to offer you assistance.

PARTICIPANTS: 592 men will be recruited from Essex County, NJ. All participants will be adults with a history of substance use disorder transitioning from incarceration into Essex County.

RISKS/DISCOMFORTS: Discussing issues related to mental health, substance use, incarceration 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 an interview, you may stop participating. At that time we can let you speak with our project manager or a trained counselor at NJCRI. 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 while the researcher transports your consent form to the office. We will take every precaution to prevent this from happening, including the use of a locked file and password protected secured server to safeguard your information. **The only instance where the**

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researcher will reveal information you provide is if during the interview 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 the interview, the researcher will remind you that such information cannot be kept confidential or secret.

BENEFITS: We hope that the group sessions in this study will help you with issues you may be having with substance use and returning to the community from incarceration. 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.

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 parole, parole decisions, or your relationship with providers in the community, the University of Illinois at Urbana-Champaign or NDRI. It will not have any effect on the services provided to you at NJCRI.

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 locked file cabinet in the project manager's office. There will be a code number placed on all of the documents related to your interviews and the urine screens and you will use a code name during the interviews and group sessions. Only the project manager and Dr. Benoit will have access to the only document that links your name to your code number. Your comments 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.

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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 not receive payments for the weekly group discussions. However, you will receive compensation for each interview activity you participate in, ranging from $10 for 30 minutes and $20 for 90 minutes depending on the interview and the group you will be in. You have the opportunity to receive a minimum of $157.50 to a maximum of $187.50 if you are eligible and choose to participate in all possible research interviews over the period of 5 months.

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. We will keep group session voice recordings indefinitely and that is the only part of the data you may not request to be destroyed because it has data from other participants included in the sessions.

CONTACTS: If you have questions or suggestions about the study or the procedures, you may contact Dr. Benoit at (212) 845-4425 (benoit@ndri.org) or Dr. Liliane Windsor at (217) 300-1782 (lwindsor@illinois.edu). If you feel you have not been treated according to the

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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, or contact NDRI's Research Integrity Officer, Lisa Bernhard at (212) 845-4567.

I have read this entire form, or it has been read to me, 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.

Participant Name: _____

Participant Signature: _____ Date: _____

Researcher Signature: _____ Date: _____

CONSENT TO AUDIO RECORD PARTICIPANT: We are asking your permission to make audio recordings of the weekly group sessions that you will be participating in as part of this study. The recording(s) will be used for data analysis by the research team and will not be disseminated.

The recording(s) will include the voices of you, your fellow participants and the group facilitator. We will ask you not to use real names for anyone you talk about or talk to during the group session. The group facilitator will remind you of this rule during the group sessions. If you accidentally use your real name, or someone else's real name, the interviewer will edit the name out of the audio file before submitting it for analysis. The recording(s) will be stored in a password protected server with no link to your real identity. We will keep the audio recordings indefinitely for possible further data analysis.

If you do not consent to allowing yourself to be audio recorded during the group sessions, you will **not** be able to participate in this study. Please check your corresponding choice:

☐ I consent to having myself audio recorded during this study

☐ I refuse to consent to having myself audio recorded during this study

Signature: _____ Date: _____

CONSENT TO BE CONTACTED IN JAIL OR PRISON TO COMPLETE THE FOLLOW-UP IN CASE OF RE-INCARCERATION

In the event you are re-incarcerated, we would like your permission to attempt to find you and obtain permission from the appropriate authorities to complete the follow-up interview while you

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are incarcerated. Note that this means we will need to disclose to the relevant authorities that you are a participant in the current study. We will only give them a general description of the study (e.g., "a health study") and no personal information about you will be disclosed other than that you are a study participant. Note we will only conduct the data collection during incarceration if the relevant authority agrees to grant us complete privacy and confidentiality of the data that we will collect from you.

Please check your corresponding choice:

☐ I consent to study staff attempting to contact me in the event I am re-incarcerated so that I can complete the study follow-ups while incarcerated.

☐ I refuse to consent to study staff attempting to contact me in the event I am re-incarcerated so that I can complete the study follow-ups while incarcerated.

Signature: _____ Date: _____

CONSENT TO BE PHOTOGRAPHED AT BASELINE:

We are asking your permission to take a digital photograph of you today. Your photo will assist us with finding you in case we lose touch during follow-ups. The photo will be in a master key file along with your name and contact information. The outreach worker, project coordinator, and principal investigators will be the only people with access to your photo. These information will be used to help outreach workers to recognize you on the streets. You may refuse to take your photo without penalty. You may also ask us to destroy your photo at anytime by asking any member of the research team to do it.

Please check your corresponding choice:

☐ I consent to study staff to take my photo.

☐ I refuse to consent to study staff to take my photo.

Signature: _____ Date: _____

CONSENT TO ADD YOUR CONTACT INFORMATION TO THE COMMUNITY WISE COURTESEY GROUP CONTACT LIST

If you are randomized to the short version of the intervention or if you are unable to attend your group meetings for any reason, you can have the opportunity to participate in the full intervention after you complete the study, 5 months from now. You will not be paid to

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participate in these groups and there is not transportation reimbursement. Please check your corresponding choice:

☐ I consent to study staff to add my contact information to the Community Wise courtesy group list. They will contact me 5 months from now to offer me the opportunity to complete the full intervention.

☐ I am not interested in the courtesy group.

CONSENT TO ADD YOUR CONTACT INFORMATION TO THE COMMUNITY WISE ALUMNI GROUP

Please check your corresponding choice:

☐ I consent to study staff to add my contact information to the Community Wise.alumni group so that I can have the opportunity to stay involved in community projects with my peers.

☐ I am not interested in the Community Wise alumni group.

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.

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This questionnaire will be entered into REDCap The clinical screen will be completed by the RA directly in REDCap.

Clinical Screen Consent

Total administration time: 32 minutes

Screening Script and Documentation of Consent

I would like to tell you about a research study taking place at NJCRI. This research study is being conducted by the University of Illinois at Urbana-Champaign and by the National Development and Research Institutes, Inc. It was funded by the National Institute on Minority Health and Health Disparities. We are evaluating a new program called Community Wise, which is expected to prevent substance use among people returning from incarceration to communities in Essex County. We are testing several forms of Community Wise, ranging from 6 to 15 weekly group meetings that will take place at NJCRI. We will also ask you to complete a few research interviews, for which you will be paid, over a period of about 5 months.

If you are interested, the first step is to answer a few questions to see if you might be eligible to participate. We call this a clinical screen and will ask you about your demographic background and mental health. This will take up to 32 minutes. Your name will not appear with any of these answers and your answers will not be available to staff of NJCRI. The researchers will be the only ones to have access to the information, however in the event that other faculty, students, and staff see your information, they will maintain confidentiality to the extent of laws and university policies. Identifying information will not be published or presented. You can refuse to answer any of the questions or stop participating at any time. If you agree to complete the screening, we will include the information you give us in our database and use it in the study's analysis whether you are found to be eligible or not. Your identifying information (e.g., name, address) will not be included with the data and it will be destroyed once data collection is completed. You may request that we destroy all of your information at any time during the study by notifying the project director or the principal investigators. After the study is completed we will destroy all identifying information and we will no longer be able to tell what information belongs to whom.

To help us protect your privacy, 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.

Discussing issues related to mental health, substance use, incarceration and other personal experiences can at times be painful and uncomfortable. You always have the right to stop participating in the research study and intervention at any time without penalty. If you feel upset during any part of the study - for example, during the group sessions or during an interview - you may stop participating. At that time we can let you speak with our project manager, Mr. Steve Morris, or a trained counselor at NJCRI. 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.

This screening interview asks about sensitive information such as mental health status and substance use. While we will take several steps to protect your identity and the confidentiality of your responses, there is a small chance that confidentiality may be lost. For instance, the data could be stolen while the researcher transports your consent form to the office. We will take every precaution to prevent this from happening, including the use of a locked file and password protected secured server at the University of Illinois at Urbana-Champaign to safeguard your information. **The only instance where the researcher will reveal information you provide is if during the interview 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 the interview, the researcher will remind you that such information cannot be kept confidential or secret.

If it appears you might be eligible for the study, I can set up an appointment for you to meet with study staff. You will hear more about the research study at that time and can decide if it is something you would like to participate in. We will pay you $10 to complete the clinical screen.

Do you give consent to participate in the clinical screen?

_____

Research Participant Signature

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Staff Obtaining Permission Printed Name Signature

Informed Consent to Participate
Newark Community Collaborative Board

Hello, you are being asked to participate as one of 20 members of the Newark Community Collaborative Board (NCCB). The project is being conducted by Dr. Liliane Windsor, at the School of Social Work at the University of Illinois at Urbana-Champaign and Dr. Ellen Benoit at National Development and Research Institutes (NDRI). The purpose of the study is to form a the NCCB with the goal of developing and pilot testing Community Wise, a manualized community-based, multi-level intervention to reduce substance use among individuals with histories of substance use disorder and incarceration being released into Essex County, NJ.

Your participation in this study will require a twelve-month commitment to attend 6 bi-monthly scheduled NCCB meetings for 2 hours each and participate in subcommittees. You will be asked to take an active role in the NCCB by engaging in brainstorming, planning, developing and pilot testing the treatment manual. During each of the meetings, you will be asked open-ended questions about your thoughts on how the manual needs to be changed, how to conduct ethical research with this vulnerable community, best practices in recruitment, implementation, data collection, and research reporting. This data will be compiled in the form of qualitative data in the form of meeting minutes, video tapes, e-mail exchanges, and the manual itself. You will receive $20 per hour of service. You will also receive $5 per eligible participant who enrolls in the Community Wise Optimization study. This will be done as a lump sum at the end or recruitment in each wave and you will not know which people you referred actually enrolled. All meetings are video-taped, thus agreeing to be video-taped is a condition for participation. Meetings will be kept private at a password protected computer at Rutgers. Any NCCB member can request to watch meeting videos at any time. Videos will be used to aid in the development of minutes and to maintain a record of the manual development process. They will be kept indefinitely until the NCCB decides to destroy them through a majority vote.

You may choose to engage in study related tasks such as recruitment and data collection. In order to protect the privacy of potential Community Wise participants, we will ask you not to engage with anyone you may have a personal relationship with in any capacity as part of the Community Wise study. If at any point you unexpectedly encounter someone you know in a study related activity, you will recuse yourself and notify the project director and the principal investigators.

Your participation in this study will be made public through the NCCB website where your name and affiliation will be displayed as a member of the NCCB. No private information will be displayed at the public website (see http://www.cbhs-cjr.rutgers.edu/research_nccb.html). Your name will also be published in the manual as one of the contributors to its development.

Risks: There are minimal risks associated with participation in this project. Discomfort and embarrassment are possible, but not expected. Loss of confidentiality is also a possible risk; however, several procedures will be employed to protect subjects. The meetings do not require you to divulge personal, intimate, or psychological information. You may leave the NCCB at any time by informing Dr. Windsor you no longer wish to participate.

Benefits: You may gain personal and professional development--networking, skill building, leadership and program development, publications, research, and presentations. Since you will represent your employment organizations and/or their communities, involvement with the board may result in capacity building for those they represent. The information learned from the research project will generate empirical data which will be used by you and other participants to guide the development of a community based intervention manual and to foster future community-academic research collaborations.

University of Illinois at Urbana-Champaign
Institutional Review Board

Confidentiality: Your participation in this research is public. However, all data, including meeting videos, will be kept in password-locked computer files at Rutgers, to which only relevant personnel will have access.

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. However, laws and university rules might require us to disclose information about you. For example, if required by laws or University Policy, study information which identifies you and the consent form signed by you may be seen or copied by the following people or groups: a) The university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for Protection of Research Subjects; and b) University and state auditors, and Departments of the university responsible for oversight of research; and c) Federal government regulatory agencies such as the Office of Human Research Protections in the Department of Health and Human Services, and our NIH funding agency.

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.

If you have questions or suggestions about the study or the procedures, you may contact Dr. Benoit at (212) 845-4425 (benoit@ndri.org) or Dr. Liliane Windsor at (973) 353-5729 (lwindsor@ssw.rutgers.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 subject, including questions, concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at 217-333-2670 or e-mail OPRS at irb@illinois.edu or NDRI's Research Integrity Officer, Lisa Bernhard at (212) 845-4567 to answer any questions you may have about your rights as a research subject.

Your participation in this study is voluntary, and you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at any time without penalty.
You will be given a copy of this consent form for your records.

If you choose to participate, please print and sign your name and date on the lines below.

Participant Name (print): _____

Participant Name (signature): _____

Date: _____

University of Illinois at Urbana-Champaign
Institutional Review Board
Approval Date: November 15, 2021
IRB # 16574

Informed Consent to Participate
In Community Wise Focus Group

NAME OF LEAD RESEARCHERS: Dr. Liliane Windsor, Ph.D., MSW and Dr. Ellen Benoit

RESEARCH STUDY: We invite you to participate in a focus group about your experiences in Community Wise. You are one of 160 study participants we randomly selected to participate in the focus groups.

PURPOSE: The purpose of the focus groups is to gather participant feedback about what they liked about Community Wise and what they would change, so that we can improve the intervention.

DURATION: Focus groups will take place at the end of your intervention. It will happen once and last for 2 hours.

PROCEDURES: If you agree to participate, we will ask you to take part in a discussion with other participants and a research assistant about Community Wise. The group conversation will be voice recorded. You will use your codename and no identifying information about you will be included in the voice recording. We will not ask any personal or sensitive information during the focus group. You may refuse to answer any question or stop participating at any time without penalty.

RISKS/DISCOMFORTS: The risks of participating in the focus groups are minimal. We will keep information confidential. The main possible risk is if confidentiality is broken. You must be warned that peers who participate in your focus group will hear information that you choose to share in the group. Focus 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.

BENEFITS: There are no direct benefits to you for participating in the focus groups. However, you will be helping us improve the intervention so that you and others may benefit in the future.

ALTERNATIVES: Participating in this focus group is completely voluntary.

CONFIDENTIALITY: We will keep your information confidential. That means we will not share the group content with others. You will use a codename during the interviews and only Mr. Baxter and Dr. Benoit will know your code name and number. 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." Only researchers working on this study will have access to the information you provide. In the event other faculty, students, and staff see your information, they will maintain confidentiality to the extent of laws and university policies. When this research is discussed or published, no one will know that you were in the study. The only instance where the researcher will reveal information you provide is if

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University of Illinois at Urbana-Champaign
Institutional Review Board
Approval Date: November 16, 2021
IRB #16574

during the interview 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 the interview, the researcher will remind you that such information cannot be kept confidential or secret.

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.

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. All data will be stripped of personal identifiers before we allow it to be used by other researchers.

FINANCIAL COSTS/PAYMENTS TO THE PARTICIPANT: You will receive $20 to participate.

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 to which you are otherwise entitled, or 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 at any time.

CONTACTS: If you have questions or suggestions about the study or the procedures, you may contact Dr. Benoit at (212) 845-4425 (benoit@ndri.org) or 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 participants, including questions, concerns, complaints, or to offer input, you may call the Office for the Protection of Research Subjects (OPRS) at (217)333-2670 or e-mail OPRS at irb@illinois.edu, or contact NDRI's Research Integrity Officer, Lisa Bernhard at (212) 845-4567.

Initials

I have read this entire form, or it has been read to me, 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.

Participant Name: _____

Participant Signature: _____ Date: _____

Researcher Signature: _____ Date: _____

CONSENT TO VOICE RECORD PARTICIPANT: We are asking your permission to allow us to audio record the focus group. The recording(s) will be used for data analysis by the research team and it will not be disseminated.

We will ask you not to use real names for anyone you talk about or talk to during the focus group session. The research assistant will remind you of this rule during the group sessions. If you accidentally use your real name, or someone else's real name, the research assistant will edit the name out of the audio file before submitting it for analysis. The recording(s) will be stored in a password protected server with no link to your real identity outside of your image. We will destroy the files after 3 years from study completion.

If you do not consent to allowing yourself to be audio recorded during the focus group sessions, you will **not** be able to participate in this study. Please check your corresponding choice:

☐ I consent to having myself voice recorded during this study

☐ I refuse to consent to having myself voice recorded during this study

Signature: _____ Date: _____

Informed Consent to Participate
Community Wise

NAME OF LEAD RESEARCHERS: Dr. Liliane Windsor, MSW and Dr. Ellen Benoit

RESEARCH STUDY: We invite you to participate in a research study that seeks to evaluate Community Wise, a new program seeking to reduce substance use. We want to develop the best program we can by identifying and keeping only the activities that work to reduce substance use. 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 may relate to mental health issues, substance use or experiences you've had in Essex County since your release. 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 three different components of Community Wise reduce substance use.

DURATION: If you agree to participate in this study you will complete up to 9 research interviews (each lasting between 30 minutes and 90 minutes) and attending up to 15 weekly group meetings (2 hours each). It will take approximately 5 months to complete the meetings and all of the interviews.

PROCEDURES: If you agree to participate, we will ask you to take part in 15 **weekly group sessions (approximately 2 hours each) led either by a trained facilitator where you will meet with other people in Essex County who have had similar experiences as you. Your participation in the study will take approximately 5 months. 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, incarceration, and your relationship with your community. You may also learn tools that you can use to improve your health. Note that this will be an open group, thus you may see the same people or new people in each group session. The group conversations will be voice recorded. You will use your codename and no identifying information about you will be included in the recording. <u>You must consent to be audio recorded in order to participate in this study.</u> ***We will ask you to make a pledge to respect the privacy of the session, we hope everybody will abide by this pledge but***

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Initials

please understand that we can't guarantee that some group members won't reveal information about you to others after the session is over.

In addition to attending these group sessions, your participation in this study will involve the following interviews: a brief phone talk, an individual interview, up to 6 monthly computer interviews, and possibly a focus group (for a total of 9 research interviews). Each interview will include a urine drug screen, meaning we will ask you for a sample of urine and will test it for certain substances. In the baseline interview we will ask your permission to take a digital photo of you. You may refuse to take the photo without penalty. The information you give us, including results from saliva screens and photo, will be kept private. There are no consequences to having positive or negative urine drug screens and no one outside of this study, including parole officers or the providers at NJCRI, will be informed of the results. Your answers to any questions that will be asked throughout this study will be completely confidential. If, at any time, you do not want to answer a question or participate in a certain part of the study, you may refuse without penalty. You should know that some of the interviews include questions about suicide. If we find that you are thinking about killing yourself, your group facilitator will be notified and asked to offer you assistance.

PARTICIPANTS: 631 men will be recruited from Essex County, NJ. All participants will be adults with a history of substance use disorder transitioning from incarceration into Essex County.

RISKS/DISCOMFORTS: Discussing issues related to mental health, substance use, incarceration 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 an interview, you may stop participating. At that time we can let you speak with our project manager or a trained counselor at NJCRI. 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 while the researcher transports your consent form to the office. We will take every precaution to prevent this from happening, including the use of a locked file and password protected secured server to safeguard your information. **The only instance where the researcher will reveal information you provide is if during the interview 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 the interview, the researcher will remind you that such information cannot be kept confidential or secret.

BENEFITS: We hope that the group sessions in this study will help you with issues you may be having with substance use and returning to the community from incarceration. 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

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Initials

empowered by having the opportunity to share your stories, relate to others and gain a voice that can be used to help your community.

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 parole, parole decisions, or your relationship with providers in the community, the University of Illinois at Urbana-Champaign or NDRI. It will not have any effect on the services provided to you at NJCRI.

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 locked file cabinet in the project manager's office. There will be a code number placed on all of the documents related to your interviews and the urine screens and you will use a code name during the interviews and group sessions. Only the project manager and Dr. Benoit will have access to the only document that links your name to your code number. Your comments 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.

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Initials

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 $2.50 for each intervention weekly group discussions. You will receive compensation for each research interview activity you participate in, ranging from $10 for 30 minutes and $20 for 90 minutes. You have the opportunity to receive a maximum of $167.50 if you choose to participate in all possible research interviews over the period of 5 months.

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. We will keep group session voice recordings indefinitely and that is the only part of the data you may not request to be destroyed because it has data from other participants included in the sessions.

CONTACTS: If you have questions or suggestions about the study or the procedures, you may contact Dr. Benoit at (212) 845-4425 (benoit@ndri.org) or 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, or contact NDRI's Research Integrity Officer, Lisa Bernhard at (212) 845-4567.

I have read this entire form, or it has been read to me, 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.

Participant Name: _____

Participant Signature: _____ Date: _____

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Initials

Researcher Signature: _____ Date: _____

CONSENT TO AUDIO RECORD PARTICIPANT: We are asking your permission to make audio recordings of the weekly group sessions that you will be participating in as part of this study. The recording(s) will be used for data analysis by the research team and will not be disseminated.

The recording(s) will include the voices of you, your fellow participants and the group facilitator. We will ask you not to use real names for anyone you talk about or talk to during the group session. The group facilitator will remind you of this rule during the group sessions. If you accidentally use your real name, or someone else's real name, the interviewer will edit the name out of the audio file before submitting it for analysis. The recording(s) will be stored in a password protected server with no link to your real identity. We will keep the audio recordings indefinitely for possible further data analysis.

If you do not consent to allowing yourself to be audio recorded during the group sessions, you will **not** be able to participate in this study. Please check your corresponding choice:

☐ I consent to having myself audio recorded during this study

☐ I refuse to consent to having myself audio recorded during this study

Signature: _____ Date: _____

CONSENT TO BE CONTACTED IN JAIL OR PRISON TO COMPLETE THE FOLLOW-UP IN CASE OF RE-INCARCERATION

In the event you are re-incarcerated, we would like your permission to attempt to find you and obtain permission from the appropriate authorities to complete the follow-up interview while you are incarcerated. Note that this means we will need to disclose to the relevant authorities that you are a participant in the current study. We will only give them a general description of the study (e.g., "a health study") and no personal information about you will be disclosed other than that you are a study participant. Note we will only conduct the data collection during incarceration if the relevant authority agrees to grant us complete privacy and confidentiality of the data that we will collect from you.

Please check your corresponding choice:

☐ I consent to study staff attempting to contact me in the event I am re-incarcerated so that I can complete the study follow-ups while incarcerated.

☐

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Initials

I refuse to consent to study staff attempting to contact me in the event I am re-incarcerated so that I can complete the study follow-ups while incarcerated.

Signature: _____ Date: _____

CONSENT TO BE PHOTOGRAPHED AT BASELINE:

We are asking your permission to take a digital photograph of you today. Your photo will assist us with finding you in case we lose touch during follow-ups. The photo will be in a master key file along with your name and contact information. The outreach worker, project coordinator, and principal investigators will be the only people with access to your photo. These information will be used to help outreach workers to recognize you on the streets.You may refuse to take your photo without penalty. You may also ask us to destroy your photo at anytime by asking any member of the research team to do it.

Please check your corresponding choice:

☐ I consent to study staff to take my photo.

☐ I refuse to consent to study staff to take my photo.

Signature: _____ Date: _____

_____
Initials

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute on Minority
Health and Health Disparities
National Institutes of Health
6707 Democracy Boulevard, Suite
800
Bethesda, MD 20892

September 29, 2016

University of Illinois Urbana-Champaign
Dr. Liliane Windsor
1901 S.First Street Suite A,MC685
Champaign, IL 61801

Dear Dr. Windsor,

Enclosed is the Confidentiality Certificate, protecting the identity of research subjects in your single-site/single-protocol project entitled "Community Wise:An innovativemulti-level intervention to reduce alcohol and illegal drug use".

Please note that the Certificate expires on 12/31/2019.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

If you determine that the research project will not be completed by the expiration date, 12/31/2019, you must submit a written request for an extension of the Certificate three (3) months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to:

Joyce Hunter Ph.D.
National Institute on Minority Health and Health Disparities
National Institutes of Health
6707 Democracy Boulevard, Suite 800
Bethesda, MD 20892

Sincerely,

Approved Date: 09/29/2016

Joyce Hunter Ph.D.
Deputy Director
National Institute on Minority Health and Health Disparities

Enclosure

CONFIDENTIALITY CERTIFICATE

CC-MD-16-023

issued to

University of Illinois Urbana-Champaign

conducting research known as

"Community Wise:An innovativemulti-level intervention to reduce alcohol and illegal drug use"

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, Dr. Liliane Windsor, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Liliane Windsor is primarily responsible for the conduct of this research, which is funded by:

Institution Center: NIMHD, Grant Number:1U01MD01629-01

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with University of Illinois Urbana-Champaign and its contractors or cooperating agencies, and

2. have in the course of their employment or association access to information that would identify individuals, who are the subjects of the research, pertaining to the project known as "Community Wise:An innovativemulti-level intervention to reduce alcohol and illegal drug use".

3. are hereby authorized to protect the privacy of the individuals, who are the subjects of that research, by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

This project will develop a better understanding of the application of critical consciousness theory to the field of health inequalities related to AIDU. Approximately 320 males will be recruited as project participants.

A Certificate of Confidentiality is needed because sensitive information will be collected during the course of the study. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

Project staff are trained to carefully follow detailed procedures designed to assure that no information about any participant will be given to law enforcement, government agencies, or anyone but research staff. Every member of the research team will be required to undergo human subject protection training. Code numbers and code names will be used for participants.

The only place participants' names or other identifying information appears is on informed consent forms and locator forms. These forms will be kept electronically in a password secured computer at the Project Director (PD) which will be kept separate from data. Mr. Baxter, the PD, and Dr. Benoit, a Principal Investigator (PI), are the only people who will have access to the filing cabinet. The electronic files generated through data collection will be identified by code numbers and code names only and kept in password-protected devices/servers, separate from identifying information and available only to project staff.

This research begins on 05/16/2016 , and is expected to end on 12/31/2019.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on 12/31/2019. The protection afforded by this Confidentiality Certificate is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during the time the Certificate is in effect.

Sincerely,

Signed Date:

Joyce A. Hunter

Joyce Hunter Ph.D.
Deputy Director
National Institute on Minority Health and Health Disparities

SCHOOL OF SOCIAL WORK
UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN

September 16, 2016

Att: Joyce A. Hunter, Ph.D.
National Institute on Minority Health and Health Disparities
Phone: (301) 402-1366
Email: NIMHDCertificateofConfidentiality@mail.nih.gov

This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.

The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.

All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.

Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

Liliane C. Windsor, Ph,D., MSW (Principal Investigator)

Peter Schiffer, Ph.D. (Institutional Official)

1010 W. Nevada St. | Urbana, IL 61801
www.socialwork.illinois.edu

SCHOOL OF SOCIAL WORK
UNIVERSITY OF ILLINOIS AT URBANA-CHAMPAIGN

September 16, 2016

Att: Joyce A. Hunter, Ph.D.
National Institute on Minority Health and Health Disparities
Phone: (301) 402-1366
Email: NIMHDCertificateofConfidentiality@mail.nih.gov

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Liliane C. Windsor, Ph,D., MSW (Principal Investigator)

Peter Schiffer 9-20-2016

Peter Schiffer, Ph.D. (Institutional Official)

1010 W. Nevada St. | Urbana, IL 61801
www.socialwork.illinois.edu

Assurances

Please provide a scanned copy, on institutional letterhead, of the assurances referencing this application with signatures, identification of the signatories, and the date of the signing. Both the PI and the Institutional Official named in this application must sign this letter. If you are a lead site applying for a Certificate for a multi-site project, please upload the assurance from your institution. The lead site is also responsible for obtaining similar signed assurances from all of the participating institutions and should develop appropriate agreements with these institutions to implement the assurances.

Sample language can be viewed here

The following assurances are required and should be inserted verbatim into the assurance letter to be signed and uploaded into this application:

This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges.

The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.

This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.

All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate.

Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.

Liliane C. Windsor, Ph.D., MSW
Assistant Professor
University of Illinois at Urbana-Champaign
School of Social Work
1010 W. Nevada St., Room 2113
Urbana, IL 61801
Phone: (217) 300-1782
www.newarkccb.org
http://socialwork.illinois.edu/faculty-staff/liliane-windsor/

University of Illinois
at Urbana-Champaign

Institutional Review Board Office
528 East Green Street, Suite 203 MC-419
Champaign, IL 61820
tel: 217-333-2670 fax: 217-333-0405
E-mail: irb@illinois.edu Web: www.irb.illinois.edu

WAIVER OR ALTERATION OF INFORMED CONSENT * (45CFR46.116(d))

ALL APPLICATIONS MUST BE TYPEWRITTEN, SIGNED, AND SUBMITTED AS SINGLE-SIDED HARD COPY. PLEASE, NO STAPLES!

Responsible Project Investigator (RPI):

Last Name: Windsor	First Name: Liliane	Dept. or Unit: School of Social Work
Phone: 217-3001782	Fax:	E-mail: lwindsor@illinois.edu

Project Title:

Community Wise: An Innovative multi-level intervention to reduce alcohol and illegal drug use

* FDA regulated research is **not eligible** for a waiver or alteration of informed consent. Research supported by the Department of Defense[1] may not be eligible for this waiver.

A consent procedure which does not include, or which alters, some or all of the elements of informed consent may be approved by the IRB under certain conditions. To request IRB approval of a waiver of the requirement to obtain informed consent completely, or of a consent procedure which does not include, or which alters, some or all of the elements of informed consent, please provide a response to **ALL** of the following questions. Please be specific in explaining why each statement is true for this research.

1. The research involves no more than minimal risk to the subjects.

We are seeking waiver of informed consent to conduct a brief, preliminary phone screen to assess eligibility to participate in the study. This part of the procedure involves no more than minimal risks to participants as we will simply ask a few questions to establish preliminary eligibility and if appropriate, schedule the clinical screen. Specifically, potential participants will call the study number in response to the study flier. A trained RA will collect information from the participant and enter it in the phone screening excel sheet to establish eligibility. Specifically and before collecting any identifying information, the RA will ask the participant if they are a men over 21 year of age, live in Essex county, believe they have a substance use problem, and have been released from incarceration in the past 4 years. If the participant meets this preliminary eligibility, the RA will explain the study briefly and invite them to schedule an appointment to complete a clinical screen by agreeing on a time and obtaining their first name, phone number, e-mail adress, and instructions about the best way to contact them in case they need to reschedule, and if it is ok leave a message (see phone screen script and excel file).

2. The waiver or alteration will not adversely affect the rights and welfare of the subjects.

This will be a simple phone call and the participants will still be told that participation is voluntary, they can choose not to answer any questions, and hang up at anytime. Obtaining a signed consent for the phone screen would mean we are collecting identifying information from people who are not eligible just to meet the signed consent requirement.

3. The research could not practicably be carried out without the waiver or alteration.

It is impossible to obtain signed consent over the phone and potential participants would need to come to the office to assess eligibility, posing unnecessary burden to them.

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Those deemed ineligible will be informed about why they are not eligible. Those who are eligible will have an oportunity to ask any questions they want about the study and decide if they want to come in to complete the clinical screen, at which time they will be handed a written informed consent to participate in the clinical screen.

University of Illinois
at Urbana-Champaign

Institutional Review Board Office
528 East Green Street, Suite 203, MC-419
Champaign, IL 61820
tel: 217-333-2670 fax: 217-333-0405
E-mail: irb@illinois.edu Web: www.irb.illinois.edu

☒ This research is not FDA regulated.
☒ This research is not funded by the Department of Defense.[1]

RPI Signature: _____ Date: 3-19-2016

IRB Member Approval: _____ Date: _____

[1] If the research subject meets the definition of "experimental subject," a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research subject does not meet the definition of "experimental subject," the IRB may waive consent.

University of Illinois at Urbana-Champaign
Institutional Review Board
Approved: 4-14-2016
IRB #: 16574

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