1. **Background:** The overall aims of this project are to reduce risk behaviors and increase health and behavioral health service utilization among disadvantaged, drug-using rural women at high-risk for HIV and HCV. This application is timely and significant as drug abuse is rampant in certain rural areas of the country, particularly the Appalachian region. In fact, misuse of prescription opiates is at an all-time high in this impoverished area. Nearly a decade ago, estimates for Kentucky drug users indicated that about 16% of drug users had injected drugs (Leukefeld et al., 2002). In more recent years, the injection prevalence rate is higher among KY samples of opiate users from Appalachia (44.3%) than reported in other national studies (Havens, Walker, & Leukefeld, 2007). The emergence of injection drug use in this impoverished area of Appalachia creates an impending and significant public health concern among an understudied and vulnerable group of high-risk women in the target region given the risks associated with HIV and HCV due to limited resources for drug treatment and health care (Staton-Tindall et al., 2007). Thus, this application addresses a critical and unmet need by proposing to advance knowledge and research on the delivery of risk reduction evidence-based interventions in real-world settings to an understudied, disadvantaged group of high-risk rural women drug users.

   This project is significant because it addresses the important issue of risk reduction among a disadvantaged group of high-risk rural women drug users. This project has potential to make a significant contribution to science by advancing knowledge about the health disparities, high-risk behaviors (injection drug use, sex risk), and service utilization of this high-risk, vulnerable, and understudied group of women during a time of emerging and significant public health risk in an Appalachian rural setting. This project is innovative because it 1) targets a high-risk and understudied group of women, 2) uses brief intervention to not only reduce risk behavior but also to enhance motivation for using community health and behavioral health resources, and 3) utilizes a real-world setting to identify high-risk women drug users. The long-term goal of this study is to increase access to health and behavioral health services in order to improve the quality of health of high-risk rural women.

2. **Objectives:** The following aims guide the study:

   Specific Aim 1: Compare the effectiveness of an evidence-based HIV risk reduction intervention (MI-HIV) to HIV Education (NIDA Standard) in reducing sex risk behaviors, injection practices, and drug use among a culturally unique sample of disadvantaged, drug-using rural women at high-risk for HIV and HCV. This aim will be accomplished through the random selection of high-risk rural women drug users from rural jails, screening and assessment for high-risk behavior, and random assignment to the HIV-Ed or MI-HIV intervention conditions. Follow-up interviews at 3, 6, and 12 months in the community post-release will examine changes in high-risk behavior. It is expected that MI-HIV participants will report significantly greater reductions in risky injection drug use practices, other drug use, and sex risk behaviors than women who participate in the HIV-Ed condition.

   Specific Aim 2: Examine MI-HIV Intervention engagement as a predictor of community health and behavioral health service utilization (including drug treatment and mental health) at follow-up among disadvantaged, drug-using rural women at high risk for HIV and HCV. This aim will focus on community service utilization during the follow-up period by the intervention and education comparison group, and how health and behavioral health service utilization relates to patterns of HIV/HCV risk behavior. It is expected that MI-HIV participants will utilize more services due to increased motivation for treatment and treatment planning following the brief intervention.

3. **Study Design:** Disadvantaged, drug-using rural women at high-risk for HIV/HCV (N=350) will be randomly selected from jails. Consenting women will be asked to participate in a baseline interview, and will be randomly assigned to one of two conditions: *(1) HIV Education (HIV-Ed n=175).* Participants in this condition will be given HIV education using the NIDA standard pre and post-test counseling, HIV and HCV rapid testing, and an information packet on community drug abuse and HIV/HCV resources; or *(2) Motivational Interviewing-based HIV Risk Reduction (MI-HIV, n=175).* In addition to the HIV-Ed condition, participants will also receive four brief intervention sessions (two prior to release, two by phone in the community) focused on developing an individualized plan for enhancing motivation to reduce risk behavior and engage in community health and behavioral health services. Follow-ups will be conducted at 3, 6, *and 12* months post-release to examine changes in injection drug use practices, other drug use, sex risk behavior, and service utilization.

4. **Study Population:** The study population will include high-risk women substance users who are incarcerated in rural jails. Inclusion criteria for the study will include 1) NIDA-modified ASSIST score of 4+, 2) engagement in at least one sex risk behavior in the past 3 months; 3) willingness to participate in brief intervention sessions, and 4) incarceration period of at least 2 weeksin order to complete intervention sessions but not longer than 3 months. Potential participants will be excluded from the study if they are suffering from mental illness or other cognitive impairments for which participation in the intervention is not intended to address. Based on findings from a recent study of jail women (Staton-Tindall et al., 2011), it is expected that participants who meet eligibility criteria and enter the study will be about 32 years old, mostly white (95%), about a quarter will be single (24%), and 27% will have a high school diploma or GED. The majority will report a history of alcohol, marijuana, cocaine, and prescription drug abuse including opiates and sedatives, and most will be using at moderate to high-risk levels. It is also expected that about one-third will have ever injected drugs – primarily prescription opiates. Consistent with the target population for the Weir et al. (2009) MI-HIV CDC evidence-based trial, the target population for this study is likely to have engaged in sex risk behavior with multiple partners including having unprotected sex and exchanging sex for drugs or money (Havens et al., 2010). Most of their current charges include drug-related offenses (possession and trafficking). Despite the rates of substance use and the association between drug use and crime, the target group for the current study is not expected to have a history of formal treatment (Staton-Tindall et al., 2007).

5. **Subject Recruitment Methods and Privacy**: UK staff will recruit participants from each of the rural jails once a month based on a randomized schedule. A stratified sampling design is used to target numbers of jail inmates selected proportionate to the number of inmates housed in each proposed jail recruitment site. For example, more women are projected to be enrolled from the Pike County Detention Center over the recruitment period compared to the Laurel County Detention Center based on jail population sizes. On each recruitment day, UK research staff will randomly select women offenders serving time in the jail from the daily census sheet to participate in the screening sessions. The total number selected will depend on daily census counts by jail and study enrollment numbers. Jail personnel are not involved in the random selection of cases, and they will only providing access to the daily census sheet. UK research staff will randomly select participants from all women residing in the jail on the day of screening who meet the time frame criteria of at least two weeks– three months incarcerated, and all women inmates will have an equal opportunity of being selected for inclusion in the screening process by the UK research team, including minorities, as long as they are at least 18 years of age and not previously screened for the study. It is anticipated that approximately 12 women will be recruited into the study each month in order to maintain a manageable number of participants in the intervention sessions.

6. **Informed Consent Process**: Potential participants who are interested in the study will be asked to participate in the screening session at the jail with the UK research coordinator. Potential participants will be provided with informed consent prior to the collection of screener data. As part of the informed consent process, potential participants will be assured that: (a) Neither participation nor refusal to participate in a protocol will affect their legal parole status (if applicable); (b) No individual or identifiable data collected as part of a study protocol will be made available to any criminal justice authority including jail, parole, or community mandated treatment; and (c) If potential participants do NOT wish to participate, their parole or other legal status will not be affected. Potential participants who choose NOT to participate in the study protocol will not be identified in their records, and non-participation will NOT become a matter of official record in any file. Informed consent procedures will cover participation in the screener, baseline interview, HIV/HCV testing, and follow-up interviews so that participants are fully aware of all possible study procedures before making a decision about entering the study.

   Due to the sensitive nature of some of the questions asked in the interviews, confidentiality issues will be stressed during informed consent which will include a description of a federal Certificate of Confidentiality which provides an additional layer of human subject protection. Participants will also be assured that their screening results, study participation, and study data will not be made available to any representative of the criminal justice system. The research coordinator will keep detailed records on the number of interested participants who participate in the screening session and the number of refusals. Screening data will be examined as part of the implementation phase to examine characteristics of participants who enter the study compared to those who are not eligible.

Because of the short time frame between baseline and follow-up interviews (3 months), consent procedures will not be repeated at each follow-up interview since no new procedures will be introduced. However, a follow-up script will be reviewed with the participant to remind her of the key elements of informed consent.

7. **Research Procedures:** The research procedures for this study can be described as screening, baseline interview, intervention, and follow-up.

Screening: Following random selection, the purpose of the screening session is to initially identify rural women engaging in moderate to high-risk drug use. The screening session (estimated 20 minutes) will be conducted between a trained study interviewer and the potential participants either in a face-to-face format or in a group setting, depending on the jail accomodations. The session will include informed consent and an emphasis on the voluntary nature of study participation (see *Human Subjects Protections* section). Following consent, participants will be administered the NIDA-modified ASSIST to screen for moderate to high-risk drug use (NIDA, 2009). If the screener is administered in a group format, ASSIST questions will be read aloud to participants and responses will be recorded confidentially on paper copies of the screener. The ASSIST was developed and validated by the WHO for both men and women (Humeniuk & Ali, 2006) to detect substance abuse risk in health care settings. The NIDA-modified ASSIST was selected for use in this study because it can be administered by an interviewer, and scores can be used to interpret participant risk levels that map to indicators for brief intervention (defined in this study as either the HIV-Education or MI-HIV conditions). An ASSIST score of 4+ (identified as being at moderate risk with potential benefit from receiving a brief intervention) will be considered the cutoff score for entry into the study as the goal is to include as many rural women as possible rather than limiting enrollment to only those who are likely to meet criteria for abuse or dependence.

Baseline data collection: Participants meeting study eligibility criteria will complete a face-to-face baseline interview with the study interviewer the same day of the initial screening session, which as expected to last about 2 hours. The interviewer will be trained in the study protocol, as well as in jail policies and procedures. Interviews will be conducted in the jail visiting rooms which are large enough to provide a confidential face-to-face interview, and have been used to conduct interviews for other studies with female offenders (Staton-Tindall et al., 2007; Havens et al., 2009). While jail staff may monitor participant entry and exit into the visitation room, no jail staff will be present for the confidential interviews. Prior to the baseline interview, participants will be provided with a reminder of the key elements of informed consent since the informed consent form was collected prior to the screening session.

Randomization and study conditions: Following the baseline interview, participants will be randomized using www.randomizer.org into one of two study conditions:

(1) HIV Education **(HIV Ed n=175):** In this condition, women will participate in the NIDA Standard HIV intervention as the HIV/HCV pre-test counseling session. The NIDA Standard Intervention was developed as part of the AIDS Cooperative Agreement which began in 1990. The intervention is manualized and includes important HIV education information to be delivered before testing including transmission routes, risky behaviors, indirect sharing, risks associated with crack use and cocaine use, male and female condom use, communication with sexual partners, stopping unsafe sexual practices, cleaning and bleach disinfection of injection equipment, disposal of hazardous waste material, stopping unsafe drug use, and the benefits of drug treatment. In addition, correct condom use will be demonstrated and rehearsed by the individual until properly performed. Women will also be given a resource packet of addresses and phone numbers of local health and behavioral health service clinics and treatment centers in the area.

HIV/HCV Testing: After the NIDA Standard pre-test counseling session, HIV and HCV testing will be conducted using OraQUICK *ADVANCE®* Rapid HIV-1/2 and OraQUICK *ADVANCE®* Rapid HCV Antibody Test kits, a relatively new test with demonstrated sensitivity and specificity in clinical performance equivalent to current laboratory-based EIA (Lee et al., 2010; Lee et al., 2011), following procedures used in other NIDA-funded studies (Havens et al., R01 DA024598; Oser et al., R01 DA022967). Pre-and post-test counseling, following CDC protocols, will be conducted at the baseline, 6-month, and 12-month interviews. Pre-test counseling will occur following the testing procedures with respondents told about the purposes and procedures of testing, test results meaning, and confidentiality. Post-test counseling will be conducted by the research staff, who will be certified HIV/HCV counselors. At post-test counseling, respondents are told the results of their tests and are assured that the results will remain confidential. Regardless of test results, all respondents will remain in the research study. Moreover,

they will be told what a positive test result means, and, if the respondent wishes, referrals will be made to appropriate agencies for continuing treatment and other health assistance, crisis intervention, and support. Participants will also be given information about the services provided by each local health department regarding HIV/HCV resources. Women testing positive in the jail will be referred to the medical staff at the jail for additional services, but it is their option to follow through on services during their incarceration. Women testing positive who do not wish to engage in health care services within the correctional setting will be offered referrals to community-based services once released, including a referral to the Bluegrass Care Clinic, the clinic of the University of Kentucky Medical Center specializing in HIV primary care.

(2) Motivational Interviewing-based HIV Risk Reduction **(MI-HIV, n=175)**: In this condition, women will also participate in the NIDA Standard HIV intervention during the pre-test counseling session and complete their HIV/HCV testing session. In addition, they will participate in brief intervention sessions which target motivation to change their injection drug use practices, other drug use, and risky sex behaviors. A minimum of four brief intervention sessions (maximum of 12 sessions) will be conducted over a 12 week (3 month) study period between baseline and the first 3 month follow-up (two sessions within 1 week prior to release from jail and two sessions by phone during the first 30 days and 60 days in the community) which is consistent with the overall approach (Weir, 2009). The summary of intervention sessions is found in Table 1. Participants will be randomized to MI-HIV with at least 2 weeks left to serve in jail so that enough time is allotted to complete the jail-based sessions. The study interventionist (hired from the local area and familiar with local resources) will meet face-to-face with participants for two brief intervention sessions prior to their release. As noted in the support letters, each jailer has agreed to provide confidential space within the jail for private therapy sessions.

Table 1. Summary of MI-HIV Sessions

Study Session	*Location*	*Time Frame*	*MI-HIV Core Component*	*Content*
Session 1	Jail	Within 2 week of randomization	MI-HIV Component 1	to identify risky sexual behavior and risky drug use (including needle use) using an assessment tool (NIDA RBA/Woman)
Session 1 – 2	Jail	Within 2 week of randomization	MI-HIV Component 2	to discuss with the woman her perception of the risks associated with those behaviors
Session 1 – 12	Jail	Within 2 week of randomization	MI-HIV Component 3	to determine her readiness to address those risks
Follow-up	Community/Phone	30 days post-release	MI-HIV Component 4	to engage in stage-base discussion about behavior change
Follow-up	Community/Phone	60 days post-release	MI-HIV Component 4	to engage in stage-base discussion about behavior change

Consistent with the best-practices model, sessions 1-12 in the jail will focus on the first three components of the MI-HIV intervention. The follow-up sessions will be conducted by phone in the community and will focus on component four (stage-based discussion for change) and be grounded in the participant's experiences and desire for personal changes. Use of the phone has been shown to be an effective way to deliver motivational interventions (Cosio et al., 2010; Lovejoy et al., 2011; Picciano et al., 2007; Walker et al., 2007), and it provides the participant with an on-going contact with the study interventionist during community re-entry.

Focus Groups: In order to gain a better understanding of drug use and risky sexual activity in the community, focus groups will also be conducted with consenting participants. Participation in focus groups is voluntary and participants will be informed about potential focus group participation at the time of informed consent. When focus groups are scheduled, they will still have the opportunity to withdraw from participation if they choose. Only enrolled participants who complete a baseline will be asked to participate in focus groups. Focus groups will be conducted in a private group room at the jail, and participations will be compensated for participation.

8. **Resources:** Kentucky has 93 jails across 120 counties that house nearly 15,000 inmates, an incarceration rate that is 8% higher than the national average (NIC, n.d.). Approximately one-quarter (26% or 4000) inmates are housed in 27 jails in rural Appalachian counties, and all 27 Appalachian jails house women. Due to the geographic challenges in the Appalachian area, recruiting women from all facilities is simply not feasible. The proposed study will use the approach established by the National Institute of Justice for arrestee data collection in the US (ADAM, 2003). Of the 27 jails, 25 have a daily census count above 50, and 10% of the remaining jails (2.5, or n=3) will be purposely selected for inclusion in the study based on geographic location, the proportion of women in custody, and having no substance abuse treatment program for county women inmates. Based on these criteria, the following jails in Appalachian counties were identified for inclusion: Laurel County (206 West 4th Street London, KY 40741, Jailer Jamie Mosley), Kentucky River Regional Jail in Perry County (200 Justice Dr., Hazard, KY 41701, Jail Administrator Tim Kilburn) and the Leslie County Detention Center (493 Detention Road, Hyden, KY 41749, Jailer Billy Bowling). Across the jails, there is an average daily census of 165 women, and based on average length of incarceration, an average yearly population of 370 women. With the estimated prevalence of drug use, it is expected that the target number of 350 women with follow-ups in five years is quite feasible. Each of the jails provides medical services and will be available to respond to referrals for HIV/HCV testing procedures if needed. However, because many of the women in the study are expected to be re-entering the community, HIV/HCV referrals will also be made to local health departments and community based services as well.

9. **Potential Risks:** The procedures to be used by this study will involve conventional clinical and social science research methods that are routine in studies of this type. The potential psychological risks will be discussed with participants during recruitment contacts to assist them in making an informed decision as to whether they wish to participate in a study protocol. These potential psychological risks are primarily related to being asked questions in the interview that they do not feel comfortable asking. There is also a risk that for participants assigned to the MI-HIV condition, there may be a breach of confidentiality of their study files or counseling information. Every effort will be taken to ensure that this does not happen. Therapist records for client sessions will be completed and stored in the research office at UK. No files – hard copy or electronic – will be stored in the jail. For participants who are not randomized in to the MI-HIV condition that they may have to wait to get in to treatment services in the community. These risks will be discussed with each potential study participant during the informed consent process.

   Screening for substance use with a criminal justice involved sample can be biased by a participant's willingness to self-report behavior (Maggia, et al., 2004; Reinert & Allen, 2007), particularly when there may be perceived consequences. Therefore, confidentiality issues will be stressed during informed consent which will include the description of a federal Certificate of Confidentiality which provides an additional layer of human subject protection. Participants will also be assured that their screening results, HIV test results, study participation, and study data will not be made available to any representative of the jail or criminal justice system. Jail officials and administrators will not be informed of participants who participate in the screening, eligibility data, or refusals in order to protect participant confidentiality.

   It is possible, that a study participant may experience anxiety, emotional distress, or other negative reactions due to the content of the interview questions, HIV testing, and/or intervention. Based on our experiences working with this population, such occurrences are rare. However, with the participant's permission, they will be referred to the medical staff at the jail for additional help and support related to psychological distress. Participants will also be given a referral sheet for additional mental health and substance abuse services in the community.

10. **Safety Precautions:** All interviews and intervention sessions will take place in private, confidential office setting. All data collected will be kept in password protected files on a secure server and under lock/key. Clients will also be reminded that their legal status will not be altered based on their participation in the study. As an additional safeguard to ensure protection of client confidentiality, a Certificate of Confidentiality will be obtained from DHHS following IRB approval.

11. **Benefit vs. Risk:** The potential benefits of the proposed study are significant. First, all respondents will have equal opportunity to be screened as assessed for substance abuse risk. Second, for participants randomized into

the MI-HIV condition, there will be additional jail-based intervention for dealing with substance abuse, HIV risk, and other potential barriers that might increase the risk to a participant's recovery. Third, there will be significant potential benefits to science because the study will provide important information about the feasibility of delivering services to women in rural areas who otherwise face enormous challenges to service utilization. The proposed study may also provide information which can be used to improve substance abuse programs and services for rural women as well as reduce drug use, related risk behavior, and drug-related crime. Fourth, the project will generate important information related to rural female drug users' treatment needs, access to services, and barriers to care, providing the foundation for a future real-world interventions.

12. **Available Alternative Treatment(s):** There are no alternatives to participation in this evaluation project except not participating.

13. **Research Materials, Records, and Privacy:** Self-reported behavioral data will be collected at the baseline and at 3, 6, and 12 months post-release from jail for follow-up interviews, along with HIV/HCV Orasure tests. The study interviewer will attend an intensive week-long training that covers topics including human subjects protection and issues that could arise during jail-based data collection. For example, training will be conducted on the importance of ensuring that all materials brought in to the jail are also taken out of the jail by the interviewers (e.g., pens, study materials, etc). A variety of behavioral data including demographic characteristics, past drug use, injection drug use, health and mental health problems, and service utilization will be collected through self-reports using Computer Assisted Personal Interviewing. administration with a portable computer (DELL notebook). During the CAPI portion of the interview, the trained interviewer will read the instructions, questions, and response categories from a laptop and directly enter the participant's response. The CAPI formatting will be programmed using Questionnaire Development System (QDS™) from Nova Research (http://www.novaresearch.com). Data with the participant ID and all other identifying information (consent form, locator sheet, payment forms) will be stored separately. Consent forms, locator sheets, and payment forms will be managed on site. Security of the data will be maintained through regular computer server backups and CD Rom back-ups secured in fire-safe locked boxes. In addition, data will be collected in brief intervention sessions with the study therapist on engagement, participation, number of services attended, session content, and needed service referrals. Measures of adherence to the MI-HIV intervention will also be collected. No clinical data (including missed sessions) will be provided to jail officials or any other criminal justice official. Participation in this study will not be considered in probation or parole decisions.

14. **Confidentiality:** Every effort will be made in the protection of human participants and issues relating to participant confidentiality. Because this study will involve individuals who are incarcerated, this study's human participants' protocol will comply fully with the special protections pertaining to behavioral research involving prisoners as participants.

    A Certificate of Confidentiality will be obtained from the National Institute on Drug Abuse which, under federal statute PL 94-255, prohibits all data collected during the course of a study protocol from being used in any legal or criminal proceedings. Participants will receive a copy of the Certificate of Confidentiality. In addition, participants will be verbally informed and given a copy of the signed informed consent, which describes the study purpose and the confidentiality safeguards. As such, no self-reported data will be shared with anyone outside of approved key personnel. No criminal justice authorities will have access to the self-reported data collected in the interviews or to the clinical data collected during individual sessions.

    All research data will be kept in locked file cabinets in the office of the Principal Investigator at the University Of Kentucky College Of Social Work. Each participant will receive a unique identifying number. All research data collection instruments will be identified by this number only. The master list matching identifiers to specific participants will be maintained in a locked file in the PI's office. Research data will be reported in aggregate form only. Computer files will be retained and all electronic data will be password protected, stored on secure UK-maintained servers, and accessible only be the researchers on this study., CIn addition, no DOC personnel (including jail staff or personnel, probation/parole officers, etc) will be asked about participants information for locating and tracking for follow-up. The consent form includes a statement about access to state-maintained records including the KOMS system (Kentucky Offender Management System) which is

standard for offender protocols at UK CDAR. Information on participants in the study should be available from those systems and through self-reported locator information.

15. **Payment**: All participants will receive $25 to complete the baseline interview and each follow-up interview. At the conclusion of the 12-month follow-up, all study participants will receive a $25 completion bonus. Therefore, participants in the study have the opportunity to earn up to $125 during their time in the study. Participants will also receive $10 if they are selected to participate in the focus groups.

16. **Costs to Subjects**: There are no costs to research participants for this study data collection interviews or for the clinical intervention sessions.

17. **Data and Safety Monitoring:** While not required by this protocol, data safety and quality is a priority for the Principal Investigator and study team. The PI helped to develop written Data Safety and Monitoring Procedures (2001) which have been used by the University of Kentucky Center on Drug and Alcohol Research. It should be noted that each study protocol and all activities concerning human participants will be approved by the University of Kentucky IRB with the following requirements: (1) All participants must understand, agree to, and sign a consent form before participating. (2) Strict adherence to a participant's right to withdraw or refuse to answer questions is maintained. (3) The interview is completely confidential and no names will be associated with the interview. (4) Data will be secured in a lock box during transport. (5) At no time will a person who is not study staff be permitted to review identifying data. (6) Consent forms and identifying information will be kept separate from the actual participant data. (7) All identifying information (consents, locator data, W-9s) will be kept locked at all times. (8) All documentation of IRB approval, original consents, Certificate of Confidentiality, human participants certification for staff, and other related study information will be filed and easily accessible to the Principal Investigators.

    The established Data Safety and Monitoring Procedures (2001) which will be modified for use by this study's staff include: (1) All staff, including data entry personnel and students, must successfully complete the Protecting Study Volunteers in Research Certification. (2) All staff must attend semi-annual meetings and trainings on human participants. (3) Random audits for data safety are conducted twice each year. This audit will verify that all precautions are taken to secure data as specified by the IRB and to protect confidentiality of research participants. (4) Specific and clear protocols for adverse events and violations of study protocols are established. (5) Intensive data monitoring and quality control of every aspect of each study protocol will be conducted through extensive and ongoing reviews of interviews and locators, observation of recruitment, interviews, and screening participants. (6) Random participant verifications are completed to verify participant satisfaction, questions, and locator information. (7) Extensive data audits and verifications are completed. (8) Intensive data reports including recruitment and interview reports, contact and tracking reports, no show/refusal reports, and returned mail are prepared on a regular basis. Standardized reports record audit results. It should be noted that these quality assurance procedures have been used in other NIDA supported Center on Drug and Alcohol Research projects. All quality assurance procedures will be conducted by key study personnel, will be IRB approved, and will be clearly outlined on the consent form. These procedures will ensure that both the human subjects and the data are protected.

18. **Subject Complaints:** Participants will be encouraged to call the Principal Investigator if any questions arise during the course of the research. Phone numbers for the PI and the ORI are included in the consent form. It is expected that providing the phone number and contact information for the PI may offer a safe, confidential, and reliable channel for participants to express problems, concerns or questions, and obtain study information since the PI will not, on most occasions, be the person originally collecting the data.

19. **Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture:** The target population is almost entirely English-speaking. Due to the commitment of delivering a manualized intervention required in this study, any non-English speaking participants will not be eligible for participation.

20. **HIV/AIDS Research:** HIV/HCV testing procedures are covered under #7 Research Procedures. Testing procedures will be using FDA and CDC approved for ORAQUICK Advance® HIV and HCV Rapid Testing. Testing of subjects will be conducted on a voluntary basis at all interview contacts. As such, none of the subjects will be coerced in any way to submit to testing. As shown on the consent form, consent to test is separate, and participants may be able to participate in the larger study without consenting to the HIV/HCV testing procedures. They will also be asked to consent for release of any positive HIV screen to the state Department for Public Health in Frankfort knowing that a HIV care coordinator may be contacting them for additional follow-up. In addition: (a) subjects who refuse HIV/HCV testing at baseline or follow up interviews will nevertheless be retained in the sample; (b) HIV/HCV test results collected at the initial and follow up assessment points will be used for research purposes only and will not be made available to correctional or treatment program authorities; (c) all HIV/HCV testing will include pre- and post-test counseling following Centers for Disease Control and Prevention (CDC) protocols; (d) subjects testing positive for HIV/HCV infection will be retained in the study; and, (d) subjects testing positive for HIV/HCV infection will be given referral information as to the appropriate community resources for counseling and treatment, and assisted in contacting these agencies if they so desire it.

21. **PI-Sponsored FDA-Regulated Research:** N/A

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