

**REDUCING OFFENDERS' HIV RISK: MI ENHANCED CASE
MANAGEMENT WITH DRUG-FREE HOUSING**

Protocol

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A. Study Aims, Background and Design

At the conclusion of 2005 one in every one hundred thirty-six adults in the U.S. was incarcerated in criminal justice institutions (Pew Charitable Trusts, 2009). When individuals on probation and parole are added, the proportion is a striking one in every thirty-two. The risk for HIV infection among criminal justice offenders is significant. Rates of infection are 4 to 10 times higher than that found in the general population (Golembeski & Fullilove, 2008). Leukefeld et al. (2009) noted that 25% of all HIV infected persons have had contact with the criminal justice system and women offenders are 15 times more likely to be HIV infected than their non-offending peers. However, offenders are under tested and under treated for HIV, which puts them and their partners at risk (Maruschak, 2004). Offenders who are currently HIV negative are at high risk for infection due to high rates of injection drug use and unprotected sex (Belenko, 2006).

This application is based on the premise that probationers and parolees must have access to stable, drug free housing to reduce HIV risk, access needed services and avoid rearrests and reincarceration. Drug free housing at the Sober Living Network (SLN) in California will be studied as a way to provide a positive living environment for probationers and parolees. The houses use a sober living house (SLH) model of recovery that includes a communal recovery environment, abstinence from drugs and alcohol, peer support, and encouragement to attend self-help groups such as Alcoholics Anonymous. Preliminary data based on a sample of 300 individuals entering 20 SLHs in California showed resident improvement in a variety of areas, including drug and alcohol use, employment, psychiatric symptoms, and arrests (Polcin et al., 2010). Although residents referred from parole and probation systems had substance use reductions that were comparable to voluntary residents, they had had far more problems maintaining employment, higher rates of arrest and incarceration, and lower attendance at self-help groups (Polcin, et al., 2010). Thirty seven percent had been rearrested at 6 month follow-up and one reason may be that probationers and parolees received only 35% of the services that they felt they needed to succeed. Although over half met DSM IV criteria for methamphetamine dependence during the last year, a very high risk group for HIV, we did not assess HIV outcomes.

The proposed study will improve SLHs for offenders by adding a Motivational Interviewing Case Management (MICM) intervention specifically targeted to the problems presented by each offender. The list of potential problems that MICM can address is extensive: 1) adapting to the SLH environment, 2) complying with parole and probation, 3) finding and maintain work, 4) successfully accessing and maintaining retention in services, 5) addressing HIV risk, testing and treatment, 6) mobilizing personal and informal resources, and 7) managing setbacks (e.g., relapse, loss of housing, loss of work).

Men and women offenders (N=330) entering SLHs will be assigned to a condition consisting of drug free housing and provision of a resources manual where residents can seek help for a variety of problems (a control group) or drug free housing plus the MICM (intervention).

Aim 1: To assess HIV testing rates, HIV risk behaviors, and utilization for HIV services at baseline, 6, and 12 months.

H1.1 Residents receiving MICM in addition to drug free housing will have higher rates

of HIV testing, higher utilization of HIV services, and fewer HIV risk behaviors than the drug free housing and resources condition.

Aim 2: To compare baseline substance use within each study condition with 6- and 12-month substance use.

H2.1 Residents in each study condition will show significant reductions in drug and alcohol use between baseline and follow-up time points as measured by the Time Line Follow Back (TLFB).

H2.2 Residents in each study condition will show significant reductions in drug and alcohol problems between baseline and follow-up time points on the Addiction Severity Index alcohol and drug scales.

Aim 3: To compare outcomes between the two study conditions at baseline, 6, and 12 months.

H3.1 Residents receiving MICM in addition to drug free housing will have less substance use (TLFB) and lower ASI alcohol and drug severity than the drug free housing and resources condition.

H3.2 Residents receiving MICM in addition to drug free housing will have fewer arrests, fewer days incarcerated and lower ASI legal severity than the drug free housing and resources condition.

H3.3 Residents receiving MICM in addition to drug free housing will have fewer work problems (ASI Employment scale) and more days worked than the drug free housing and resources condition.

Aim 4: To assess mediators and moderators of the MICM.

H4.1 Service utilization (Hser et al., 1999) will mediate the relationship between drug free housing plus MICM and outcome (TLFB, ASI Alcohol and Drug scales and criminal justice recidivism).

Exploratory Aims: 1) To explore additional outcomes (e.g., ASI Family, Medical, and Psychiatric scales, long-term housing status) and covariates (e.g., social support, supportive confrontation, motivation). (2) To conduct 30 qualitative interviews (15 per condition) to identify general and intervention specific factors affecting outcome.

B. Subject Population

Study Sites

All of the SLHs taking part in the study have distinct similarities. All of the houses are associated with the Sober Living Network (SLN) in California and have common standards that address health, safety and organization of the SLHs. Thus, we should have a reasonably homogenous group of houses to study and we do not expect large clustering effects that could confound results. The costs of residency in SLHs in the Los Angeles area range from \$300 to \$750 per month depending on size and location. In general, the primary criteria for admission to SLHs include a willingness to 1) abstain from substance use, 2) comply with financial obligations such as rent, and 3) comply with basic house rules such as curfew, chores and attendance at house meetings.

Because there are over 500 houses in southern California, we will have ready access to more than a sufficient number of houses from which to collect our target sample (N=330). Houses taking part in the study will be asked to sign a Letter Agreement outlining expectations of the house and the project staff. Expectations of the house will include the designation of primary contact person to serve as a representative of the house in resident recruitment matters (ensuring weekly communication about new

residents coming into the house and allowing voluntary and confidential recruitment by project staff), allowing project staff to post a flyer about the study in a prominent place in the house, and allowing project staff to screen and recruit residents at the house or over the phone. Expectations of the project staff will include the development and posting the study flyer, screening and recruitment of participants, provision of support to participants in accordance to the houses random assignment to study condition, provision of an annual stipend to the house for costs associated with assisting project staff in recruitment matters based on the number of participants enrolled in the study, availability to attend house meetings to introduce the study to and update residents on study progress, and assurance that no house or residents names will be used outside the research study.

Sample Characteristics

Three hundred and thirty SLH residents who are on probation or parole and are HIV+ or at high risk for HIV will be recruited into the study within their first month of entering the SLH. The director of the Sober Living Network in Southern California, Jeff Christensen, states over 60 houses in Los Angeles County accept large numbers of male and female offenders and the vast majority will be willing to participate in the study. This is consistent with our previous study of SLHs, where less than 5% of potential participants declined to participate. Belenko (2006) has documented that criminal justice offenders have very high rates of HIV infection and high risk behaviors. This supports the feasibility of meeting our recruitment goal to enroll HIV+ or high risk individuals. To be parsimonious in our efforts, we will select the 70 houses with the largest number of offenders admitted. Half of the houses (N=35) will be gender specific for men and half (N=35) will be gender specific for women. Stratified random sampling procedures will be used to ensure an equal number of male and female houses within each study condition. Thus, individuals enrolled in houses assigned to the MICM condition will receive that intervention and individuals assigned to the comparison condition will receive SLH services as usual along with a list of referral resources for a wide variety of problems. Risks for contamination of intervention effects on non-intervention offenders are eliminated because of our randomization of houses. These procedures will enable us to reach our target recruitment with an average of only 10.3 residents per house over 3 years of recruitment. We will randomize more houses if we need them to meet our recruitment goals.

We chose to target a broad group of criminal justice offenders (i.e. those on probation or parole) because both groups have been problematic in terms of having high rates of HIV risk, HIV infection, and re-arrest rates that contribute to serious overcrowding in criminal justice institutions that in turn fuel the spread of HIV (Belenko, 2006). Studies have also shown that both probationers and parolees have difficulty accessing services they need and that these unmet needs play a role in recidivism (e.g., Freudenberg et al, 2005; Urban Institute, 2006). In our preliminary study, we found no reason to suspect that there were differences in how these two groups responded to SLH residency. However, we will conduct comparisons between those residents on parole and those on probation to assess whether there are differences in outcome. Based on enrollment in our preliminary studies we expect about 60% of the sample will consist of parolees and 40% probationers.

The application targets equal proportions of men and women. All participants will be adults age 18 and older. Based on information obtained from the Sober Living Network on residents entering SLHs in Los Angeles County we expect the racial breakdown to be approximately 40% African American, 25% White, 20% Hispanic/Latino, and 15% Other.

Summary of Inclusion/Exclusion Criteria

We plan to recruit only offenders who are HIV+ or at high risk for HIV. Inclusion criteria will require at least one of the following: HIV+, MSM, history of injection drug use, history of sex work, and past month unprotected anal or vaginal sex with more than one partner. All potential participants will be recruited from a pool of individuals who have a history of substance dependence and criminal justice involvement, factors known to be associated with HIV infection and risk (Belenko, 2006). Over half of our potential sample will have a history of methamphetamine dependence, another high risk factor (Center for Disease Control, 2007). Offenders must be able to speak English and those who show evidence of a serious mental health disorder that would hinder their ability to provide informed consent will be excluded. Study therapists will conduct these assessments when necessary and make a determination. In addition, to be included in the study residents must agree to be randomly assigned to one of the 2 study conditions and provide some contact information that can be used to locate them for follow-up interviews.

C. Recruitment Process

All participants will be recruited into the study within their first month of entering the SLHs. We will monitor resident entry into houses by contacting house managers on a weekly basis. When a new resident enters the house the house manager will hand them a flyer describing the study and a phone number and e-mail where the research assistant can be reached. In addition, research assistants will routinely attend house meetings to address general questions about the research and to be available to meet with new residents who may have specific questions or be interested in participating. Efforts will be made to attend house meetings particularly when new residents are entering the facility. Residents will be able to enroll in the study by approaching the research assistant when they are on site, calling the research assistant or sending them an e-mail. Interviews can take place at the research assistant's office, the SLH residence (provided there is adequate privacy), or a mutually agreed upon public space (e.g., public park, coffee shop) provided there is adequate privacy. The initial baseline interview will take approximately 2 hours and can be divided into two sessions if necessary. The adequacy of confidentiality will be protected through certification of the study from the Office of Human Research Protection (OHRP) and an NIH "Federal Certificate of Confidentiality."

Recruitment for the qualitative component will include a minimum of 28 participants, 13-15 in each of the two study conditions. These interviews will take place after the 6-month follow up time point. Because our goal is to learn what is most helpful as well as counterproductive in the intervention we will use "maximum variation sampling" (Kuzel, 1992). This strategy employs a purposive sampling strategy that seeks to interview individuals with different points of view and different experiences. Within each condition, five will be interviewed in each group (1-3) that is determined by

their responses on the 6-month data that reflects either low, medium or high HIV risk. Participants were consecutively selected to fill slots based on data provided in their 6-month interviews. Selection will stop once all slots have been filled. Replacements for participants whose interviews were not completed within 6 weeks after their 6-month follow-up will be marked as missed and another participant will be selected for that slot.

D. Procedures

Design Summary

This study will use a stratified randomization design to assess male (N=165) and female (N=165) offenders on probation or parole who are either HIV+ or at high risk for HIV. Study participants will be recruited from individuals entering selected SLHs in Los Angeles County. Seventy SLHs (35 gender-specific for men and 35 gender-specific for women) that are members of the Sober Living Network will be randomly stratified between MICM (the intervention) and referral resources (the control). Using an “intent to treat model,” we will interview all participants at three time points over a 1-year period: baseline (within one month of entering the house) and 6- and 12-month follow up. The two study conditions will be compared on the primary and secondary outcome measures. Qualitative interviews will be conducted with 13-15 residents in each study condition (N=28) to explore strengths, weaknesses, and potential mechanisms of action of SLHs and MICM.

Focus Groups

Two focus groups consisting of sober living house managers who will be conducted during the first year. The purpose will be to inform final modification of the intervention and the procedures used to assess outcome. Two groups of 12 will be interviewed, one consisting of managers of houses for women and one consisting of managers of houses for men. We will recruit participating managers through the Sober Living Network, our collaborating partner on this project. The Executive director, Jeff Christensen, will send an e-mail to Los Angeles area house managers who are members of SLN inviting them to participate. If they are interested they will contact the PI (Doug Polcin) by e-mail. Once an adequate number agree to take part meetings will be scheduled. Groups will take place after regularly scheduled coalition meetings in Los Angeles. Groups will be audiotapes and transcribed to identify important themes. All audio and transcribed data will be stored in a locked file.

The procedures for collection of focus group data do not include collection of individual data. Data collected from these procedures will not be on the focus group participants themselves. Rather, it will be on their views about the needs of offenders entering sober living houses and reactions to our study intervention and data collection procedures. We therefore do not think they need to be consented as research participants. Participants will be told that all content of the groups is confidential. No participants will be identified.

Content of the groups will focus on the following themes: 1) What do offenders need as they transition from prison or jail into the community? 2) Relative to other residents, what are the unique needs of residents on probation or parole and how do their outcomes compare? Do they receive the types of help they need? Why or why not. What types of services are needed more? 3) How successful are offenders at finding and keeping employment? 4) How do the needs and outcomes of male and female offenders

differ? 5) Does your facility offer any information to residents about HIV testing, treatment, or prevention? How much does that help?

We will also ask questions about our proposed Motivational Interviewing Case Management intervention. After a brief explanation of the intervention we will ask about strengths, weaknesses, and suggested changes.

Research Interviews

Residents who are interested in participating will attend a research interview that will begin with an assessment of inclusion/exclusion criteria. Those who meet the criteria will be administered the baseline interview after they are consented. Randomization will occur at the house level, so individuals in houses randomized to the MICM condition will receive that intervention and individuals in houses assigned to the comparison condition will receive SLH services as usual along with a list of referral resources for a variety of problems. Using an “Intent to Treat” design, all participants will be followed up at all of the time points even if they leave the SLH immediately after completion of the baseline interview. Follow-up interview procedures will include updating contact information at each interview as well as at 3 and 9 months. During these interim 3- and 9-month contacts, we will first reach out to participants by phone and, if we were unsuccessful, we would send a letter encouraging them to call us. Those who we were able to speak with would receive a \$5 gift card at the 3-month contact and a \$10 gift card at the 9-month contact. For participants who are difficult to reach we will use tracking methods described by Anglin et al (1996). They include procedures to utilize contact information from respondents’ families and friends and locating participants in jails, prisons, and other institutions. Participants will receive \$30 for the baseline interview and \$50 for interviews at 6- and 12-month follow up. We expect baseline sessions to last 2 hours and follow up sessions to last about 90 minutes. We are using Survey Gizmo as the platform for the interviews, which will require an internet connection for us to access the survey. The connection being used while transferring data between ARG equipment and Survey Gizmo will be protected by a 128-bit encrypted SSL tunnel so as to prevent confidential data from being sniffed. Interviewers will conduct interviews only on ARG laptops, which will be password protected and configured on the ARG secure network.

Qualitative Interviews

13-15 study participants in each of the study conditions (Total N=28) will be asked a series of questions about the houses where they live. Based up on their 6-month follow-up data, we will retrospectively approach participants who have relatively successful, mixed, and unsuccessful outcomes. Questions for all 28 participants will elicit their views about the physical characteristics of houses, rules and requirements for residency, supportiveness of the household, level of structure, amount of resident involvement in management of the house and decision making, and ways the SLH environment impacted HIV and substance use outcomes. The overriding goal will be to identify characteristics of the physical and social environment that are perceived to be supportive and detrimental to HIV and recovery from substance use disorders.

Additional content of the qualitative interviews for MICM condition will assess: 1) what was helpful about the intervention, 2) what was unhelpful, 3) what might be improved in terms of the process, structure or dose of the intervention, 4) how the

intervention did and did not help with adjustment to the SLH environment, and 5) how might the intervention be improved to respond to issues gender, race, culture or class? A final list of items will be developed based on pilot interviews with participants. Qualitative findings will be used to inform the development of mediator and moderator analyses as well as to improve the content and process of the interventions. Qualitative interviews will take place after the 6-month follow up period. This ensures enough time for residents to experience significant success as well as problems that can be discussed in the interviews.

Motivational Interviewing Case Management

MICM intervention combines aspects of motivational interviewing along with case management to influence HIV risk and recovery from alcohol and drug problems. The theoretical rationale for increasing motivation draws upon the Stages of Change Theory developed by Prochaska et al. (1992) and adapted to Motivational Interviewing by Miller and Rollnick (2001). The model posits that clients proceed from little or no motivation (pre-contemplation) to stages that incrementally involve increased motivation: contemplation –increasing recognition of substance related problems, preparation – consideration of options for making changes, action – enactment of a change plan, and maintenance – maintaining improvements.

MICM differs from standard MI in that it targets a much broader range of problems as they apply to each client. The therapist uses MI techniques to enhance case management procedures that connect clients with services they need and then helps them succeed in using those services. Thus, standard MI techniques (e.g., reflections, open questions, feedback, developing discrepancies, engaging ambivalence, etc.) are used to 1) help offenders address obstacles and challenges encountered as they use services, begin employment, and adapt to a drug-free living environment, 2) help offenders examine options if they discontinue services, residence in the SLH, or employment, 3) mobilize informal sources of support (e.g., social networks, self-help groups, and religious institutions) that might help them manage problems when services are not available or when they decline services, and 4) reduce the harm associated with problem behaviors such as HIV risk and substance use. The therapist is given maximum flexibility to address the most pressing issues as clinically indicated for each offender. See Appendix A for details of how MI techniques are used to increase motivation and then help offenders succeed in adapting to a drug-free living environment, access and succeed in use of services, and find and maintaining employment. The broad range of problems addressed is based on syndemic theory (Koblin, et al., 2006; Kurtz, 2008; Singer, 2008), which posits a broad range of problems (e.g., substance use, mental health problems, housing instability and unemployment) exacerbate HIV disease. We do not know of any other studies that use MI as a way of helping clients succeed in service utilization, employment, drug free housing and mobilization of informal supports.

Structure of MICM Sessions

Participants assigned to the MICM condition will receive 3 individual sessions within the first month of entering the SLH. Thereafter they will have contact with the MICM therapist monthly throughout the duration of their enrollment in the study (12 months). However, therapists will also be available to address crises that occur, such as

psychiatric emergencies, arrests, and sudden loss of job or housing. For participants who have left the geographical area the session will be conducted by phone.

Comparison Condition

The comparison condition will consist of offenders receiving SLH services as usual along with a list of resources that can be used to address a variety of problems. This will help ensure that intervention effects for MICM are not simply the result of receiving information about various services that are available in the community.

Pilot Testing

We plan to test the survey measures and MICM with pilot subjects before we begin recruitment. The purpose of testing the survey is to see how respondents react to the questions, evaluate whether the questions need to be adjusted, test out the skip patterns and reliability of the online technology, and see how long the survey will take to administer. We do not plan to use the data in any of our analyses.

Some of the pilot subjects will be asked to participate in testing the MICM sessions. These subjects will meet with the therapists 1-3 times, depending on how the sessions go. The purpose of testing out the MICM is to gain a better understanding of how the intervention is received and for our therapist supervisors to ensure that the therapists are following the intervention manual appropriately and consistently. As names and contact information will be collected for some of these pilot subjects, a separate consent form will be administered.

Measures

Baseline Only

1) DSM-IV Checklist for Lifetime and 12-Month Alcohol and Drug Abuse and Dependence. Items are based on DSM-IV diagnostic criteria (American Psychiatric Association, 2000) and have been used in NIDA Clinical Trial Network studies (Forman et al., 2004). 2) Demographic and Descriptive Characteristics. In addition to standard demographics (e.g., sex, age, race/ethnicity, and education), we ask about criminal justice history.

Table 1. Administration of Instruments at Each Time Point

Instrument	Baseline	6 Months	1 Year
<u>Baseline Only</u>			
Lifetime DSM Checklist for Alcohol/Drug Disorders	X		
Demographics	X		
<u>Primary Outcome</u>			
HIV Measures:	X	X	X
RAB			
HIV Status			
HIV Testing			
HIV Treatment			
Probation/Parole Violations	X	X	X
Arrests	X	X	X
Days Incarcerated	X	X	X
TLFB for Drugs and Alcohol	X	X	X
ASI Alcohol and Drug	X	X	X
<u>Secondary Outcomes</u>			
ASI Scales	X	X	X
Work/Income History	X		X
Housing Stability	X	X	X
<u>Moderators/Mediators</u>			
General Social Support	X	X	X
Social Network	X	X	X
AA/NA Involvement	X	X	X
Services Received	X	X	X
Retention	X	X	X
Confrontation (ADCS)	X	X	X
Trauma, PTSD, Abuse	X		
ADCQ	X	X	X
<u>Biological Measures</u>			
Urine Screen	X	X	X
<u>Qualitative Interview</u>			
<u>House Environment</u>			
SMPS		N/A	

Primary Outcomes

1) Criminal Justice Outcomes are taken from Petersilia (2003) and Petteruti and Walsh (2008) and include: a) Parole/Probation Violations, b) Arrests and c) Days Incarcerated. Arrests will be specified by type of offense and whether the respondent was convicted. Incarceration will be specified as due to arrest for a new offense and due to a technical violation of probation or parole. Data will be self-report but also will be confirmed using publicly available criminal justice records. 2) Timeline Follow-Back (TLFB) will be used to record the subject's self-report of alcohol and drug use during each interview period assessed. To maximize recall of alcohol and drug use we will assess 90-day time periods. This instrument has been used extensively in a variety of drug and alcohol studies (Sobel et al., 1996). 3) Four scales from the Addiction Severity Index Lite (ASI) (McLellan et al., 1992) will be used as primary outcomes. Alcohol and drug scales will be used to assess alcohol and drug severity, the legal scale will be

used to assess legal severity and the employment scale will be used to assess employment problems. 3) The Risk Assessment Battery (RAB) (Metzger, et al, 2001) will be used to assess injection and sexual risk behaviors. An additional measure of HIV will include a count of HIV testing overall and the number who are tested for their first time. We will also record self-report of HIV status and current engagement in HIV treatment services (coded yes/no) for those who are positive.

Secondary Outcomes

1) Other scales on the ASI constitute some of our secondary outcomes, including medical, family/social and psychological. 2) Days worked over the assessment time period is a measure is taken from Gerstein et al. (1994) and is a simple count of number of days worked over the follow-up time point. We will also assess days involved in vocational training, GED or other schooling. 3) Housing stability is taken from our previous study of SLHs depicting the usual housing situation over the past 6 months as well as the number of day homeless or residence in a shelter. We will have additional questions that assess whether there are any requirements to live in the home, such as abstinence from alcohol and drug use, compliance with a curfew, attendance at 12-step meetings, or involvement in counseling.

Mediators and Moderators of Outcome

1) A short form measuring social support will ask about support from people close to the respondent. 2) We will ask three questions to assess the extent to which individuals in their social network are heavy alcohol and drug users. 3) The Alcoholics Anonymous

Affiliation Scale (AAS) is a nine-item scale that measures the strength of an individual's affiliation with AA and other 12-step groups (Humphreys, Kaskutas & Weisner, 1998).

4) Services Received is a measure from our current study of SLHs that assesses the extent to which participants are involved in a variety of services (e.g., substance abuse, mental health, healthcare, legal and job training) (Hser et al., 1999). 5) Supportive confrontation will be assessed using the Alcohol and Drug Confrontation Scale (ADCS) developed by Polcin et al (2006; Polcin & Greenfield, 2006). Confrontation is defined as warnings individuals receive about potential consequences of alcohol or drug use from family, friends, peers and professionals. 6) Retention will be assessed as number of continuous days of residence after admission. 7) We will ask a set of questions about the effects of traumatic life events using a PTSD checklist. We will ask about their history of physical and sexual abuse using questions adapted from the National Alcohol Study and the WHO women and violence study. 8) The Alcohol and Drug Consequences Questionnaire (Cunningham, et al., 1997) will be used to assess motivation for change. Two scales assess the consequences and benefits of changing substance use. Consistent with previous studies of SLHs (Polcin & Greenfield, 2006) we will also use these items to assess motivation to maintain abstinence.

Biological Measures

1) Urine screens will be administered to corroborate self-report of drug use. Self-reported use will be the default measure unless a report of no use is falsified by a positive urine screen (Leiderman & Bigelow, 1999).

Qualitative Interviews

Qualitative interviews will be conducted with approximately 13-15 participants in each study condition (N=28). See the subheading above entitled "Qualitative Interviews" for a description of the items used.

House Environment

The Social Model Philosophy Scale (SMPS) (Kaskutas et al, 1998) will be used to measure the physical and social environment at each house. The SMPS assesses the physical environment, house manager roles, authority base, governance, view of recovery, and orientation toward the surrounding community. The scale will be assessed at each house that has signed a letter agreement and where we enrolled study participants. The respondent will be compensated with a \$5 gift card for this scale that will take approximately 15 minutes to complete. The SMPS is scored along six domains and has an overall internal reliability of 0.92. Should differences exist across the 30 houses used in the proposed study, we will investigate whether those differences are associated with outcome.

E. Assessment of Benefits

Direct benefits include \$30 for participation in the baseline interview and \$50 for participation in the 6- and 12-month follow up interviews as well as a \$5 gift card for confirming/updating their locator information at the 3-month interim contact and a \$10 gift card for confirming/updating their locator information at the 9-month interim contact. The 28 individuals taking part in the qualitative component will be compensated \$20. Participants in the 2 study conditions may benefit through residing in a sober living residence that supports abstinence from alcohol and drugs. The MICM intervention condition may also benefit through accessing community supports with the assistance of the therapist. The comparison condition might benefit through provision

of alcohol and drug free housing and acquisition of a list of referral resources that might be helpful to them. All individuals in the study may benefit by the self-reflection required of the research questions.

F. Assessment of Risks

This study is a clinical trial. Our sample targets 330 individuals who are on probation or parole and are entering a sober living house in Los Angeles County. Risks that the research participants may undergo are expected to be minimal. They may feel uncomfortable or embarrassed by some questions. For example, they may feel discomfort about providing information about their substance use patterns, illegal behaviors, and psychiatric symptoms. However, the questions asked of them are typical counseling questions that are often asked as part of any treatment or recovery program. Participants may also be embarrassed by a positive urine screen. While extensive efforts are made to ensure confidentiality of all research procedures, there is a possibility that confidentiality could be compromised to the detriment of the study participant. Although the supportive living environment of the SLH and supportive case management are not likely to cause psychiatric crisis such as suicide, homicide, or psychotic regression, these problems are always possible among the population we are investigating.

To minimize risk, participants will be informed before each research and case management interview that they may decline to answer questions with which they are uncomfortable, and they may terminate the interview at any time without penalty. Case management sessions and qualitative interviews will be audiotaped, but residents will be free to turn off the tape at any point. Audiotapes and case report forms will not contain any identifying information and will be kept in a locked cabinet. Audiotape recordings will be destroyed 5 years after completion of the study. Case management meetings and research interviews will only be conducted when there is sufficient privacy. We have extensive experience conducting interviews within criminal justice institutions and have not had any concerns about privacy. Typically, these meetings take place in “interview rooms” where attorneys meet with their incarcerated clients. We will obtain approval for these procedures from our IRB, the OHRP, and a federal Certificate of Confidentiality. We have used many similar items to those proposed here in other studies and have not experienced reports of excessive discomfort from participants. Risks that the research participants may undergo are expected to be minimal. The questions asked of participants in the study are opinions or typical counseling questions that clients are often asked as part of their treatment. Although the supportive living environment of the SLH and supportive case management are not likely to cause psychiatric crisis such as suicide, homicide, or psychotic regression, these problems are always possible among the population we are investigating. The therapist will be a licensed mental health professional trained in how to manage such issues. Voluntary or involuntary psychiatric hospitalization will be considered if clinically and legally appropriate. The therapist will work with local psychiatric emergency centers to coordinate hospitalization if necessary. Dr. Polcin will supervise the therapists and be available for consultation as needed. Dr. Polcin is a licensed mental health practitioner with many years of experience in psychiatric day treatment settings, and he has addressed psychiatric crises as a regular part of his work.

G. Confidentiality

All participant data will be reported on case report forms without identifying information. Similarly, all audiotape recordings will be coded with a number and no identifying information will be on them. Respondents will be reassured that all data will be kept under lock and key to assure confidentiality of the data. Only research staff will have access to the data. A federal Certificate of Confidentiality will be obtained for this project to add further safeguards to confidentiality.

All research staff will sign pledges of confidentiality and receive training on data security procedures. Because we may interview subjects in state prisons or local jails, we will obtain approval from the Office of Human Research Protection (OHRP). The study will be analyzed statistically in an aggregate manner and will not identify specific respondents. Data for tracking will be kept in a password protected database accessible only to staff.

Case report forms and audiotapes will be kept for 5 years after the study ends. At that point Dr. Polcin will arrange for shredding of case report forms and erasure and destruction of audiotapes. All data will be kept locked during this time.

H. Informed Consent

All participants will be required to sign an IRB approved consent form before beginning interviews. This form will include the following information: 1) participation is voluntary and refusing to participate or deciding to discontinue participation at any time is without penalty, 2) the general research purpose, 3) participation consists of completing questionnaires and interview questions, 4) questions will address issues pertaining to community support, substance use, psychiatric symptoms, and related problem areas (e.g., work, family and medical), 5) participants will be compensated \$30 for their participation in the baseline interview and \$50 for their participation in the 6-, and 12-month interviews as well as a \$5 gift card for confirming/updating their locator information at the 3-month interim contact and a \$10 gift card for confirming/updating their locator information at the 9-month interim contact, 6) all responses will be entirely confidential and no identifying information will appear in any research reports, 7) data will be presented in aggregate form, 8) the study is approved by the Public Health Institute Institutional Review Board (IRB), 9) the study is approved by the Office of Human Research Protection (OHRP), 10) the study has acquired a federal Certificate of Confidentiality, and 11) whom to contact if they wish additional information.

The 28 individuals selected for qualitative interviews at the 6-month interview will sign an additional consent form that describes the purpose and procedures for these interviews. They will be informed that the sessions will be audiotaped but stored in a locked file cabinet without any identifying information

I. Financial Issues

There are no costs to participants taking part in the study. There are no costs associated with receiving MICM in the intervention condition and no cost for receiving a list of referral resources in the comparison condition. Payment to participants for their time completing research interviews is \$30 for participation in the baseline interview and \$50 for participation in the 6- and 12-month follow up interviews as well as a \$5 gift card for confirming/updating their locator information at the 3-month interim contact

and a \$15 gift card for confirming/updating their locator information at the 9-month interim contact. The 28 individuals taking part in the qualitative component will be compensated \$20. Individuals entering SLHs will be required to pay ordinary fees associated with living in the facility.