SWNA MICRA Project

Southwest Native American Adaptation of Motivational Interviewing and the Community Reinforcement Approach

Manual of Operations (MOO)

Version 5.0

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Manual Development.

This manual was developed based on the COMBINE manual of operations. Brenna Greenfield, Yvette Yamutewa, and Donna Lupee were instrumental in drafting the first draft of the MOO, and Roberta Chavez, Everett Homer, Robert Currier, and Farrah Lesansee assisted with subsequent revisions.

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Chapter 1: Overview of Study Design

1.1 Study Objectives

This study will combine, adapt and test motivational interviewing (MI) and the Community Reinforcement Approach (CRA) as a culturally congruent treatment approach for Native Americans. The proposed developmental research will be conducted in collaboration with the Southwest Native American Tribe. The specific aims of this project are:

Aim 1. To develop, in collaboration with the Southwest Native American community, a combination of MI and CRA (MICRA) that is culturally adapted to the social/cultural context of reservation-dwelling tribal members and includes a secondary focus on HIV/STD prevention

Aim 2. To develop and field test culturally-congruent research materials and procedures (MICRA counselor manual, adapted assessment instruments, manual of operations) that would be needed for a larger clinical trial of MICRA with Southwest Native American or other tribal populations

Aim 3. To train Southwest Native American behavioral health professionals in delivery of MICRA, and pilot test procedures for MICRA certification, supervision, and fidelity assurance

Aim 4. To conduct a pilot study (N=80) to estimate effect sizes for MICRA on key outcome variables with Southwest Native American clients

Aim 5. To estimate the types and prevalence of emotional distress and psychological and health problems likely to be encountered when treating substance use disorders in Native American populations.

1.2 Study Design

MICRA will be conducted in two phases: Phase 1 is a feasibility ($N = 9$) non-randomized one-group design wherein all participants will receive MICRA. The purpose of Phase 1 is to (a) implement and test the draft version of the MICRA counselor manual, (b) test counselor fidelity monitoring procedures, (c) certify counselors in MI and CRA, (d) test the assessment procedures and basic aspects of the MOO, (e) certify the research assistant in assessment administration procedures, and (e) pilot the 4- and 8-month follow-ups.

Phase 2 is a pilot ($N = 80$) 2-group design. Following the screening and baseline interview, participants will be randomized to receive MICRA or treatment as usual (TAU; see Chapter 5 for randomization process). Participants randomized to MICRA will receive from 16 to 20 therapy sessions with one of the MICRA counselors over the course of 16 weeks. In TAU, participants will receive standard outpatient services at Southwest Native American Recovery Center.

1.3 Participant Eligibility

The inclusion criteria will be: (1) Southwest Native American tribal member, (2) resident within the Southwest Native American reservation or neighboring small settlements, (3) aged 18 or older, (4) seeking treatment for a substance use disorder, (5) meets current DSM-IV diagnostic criteria for substance abuse or dependence for at least one of the following: alcohol, amphetamine, cannabis, cocaine, or inhalants (including ocean), and (6) willing and able to understand and voluntarily participate (in English) in assessment and treatment procedures of the study. Exclusion criteria are: (1) any planned absences from Southwest Native American tribe greater than 14 days during the 16 week treatment period, (2) cannot identify at least one "locator" person for follow-up tracking, (3) actively psychotic or chronic mental illness that is not well treated, or (4) major cognitive impairment.

1.4 Behavioral Interventions

1.4.1 Motivational Interviewing

Motivational interviewing (MI) is a clinical style originally developed and tested in the treatment of substance use disorders (Miller & Rollnick, 1991, 2002). It draws particularly upon the client-centered counseling methods described by Carl Rogers and his students, to evoke personal motivation for change. It is collaborative rather than authoritarian, emphasizing listening rather than telling, with empathic interest in the other's values and perspective. The MI style is usually well-accepted by Native American groups, resembling normative communication styles within tribal populations.

As a free-standing intervention, MI is relatively brief, usually 1-4 sessions. It can also be conceived, however, as a general clinical style within which other interventions can be delivered. The NIAAA-funded COMBINE study, for example, tested a Combined Behavioral Intervention that used MI both as an initial induction and as the overall clinical style while drawing upon a menu of cognitive-behavioral treatment methods related to the community reinforcement approach (Anton et al., 2006).

1.4.2 The Community Reinforcement Approach

The community reinforcement approach (CRA) to addiction treatment, introduced by Nathan Azrin three decades ago (Hunt & Azrin, 1973) reasoned that to compete with a potent reinforcer like substance use there must be similarly potent, enduring, and reliable sources of reinforcement for non-use. Azrin made some use of extinction and punishment (e.g., via disulfiram, family withdrawal when drinking, refusal to shield from negative consequences), but relied primarily on establishing competing community-engaged sources of positive reinforcement.

Drawing on a flexible menu of procedures, CRA particularly focuses on engaging clients in their own community, in activities and groups that compete with substance use and provide positive reinforcement and/or social support for abstinence. Concerned significant others (CSOs) play an important role in CRA, being important sources of positive reinforcement and social support. By working with existing family and community structures to support and reinforce personal change, CRA would seem to

interface well with existing Native American social structures that engender personal behavioral change. While the family is often the first line of intervention, the additional Clan and Society social structures in the Southwest Native American tribe provide CRA with unique intervention possibilities that are not widely available outside of Native American communities.

1.4.3 MICRA

The MICRA intervention will average 16 to 20 sessions and include elements of both MI and CRA. Sessions will be individual, in the sense of one identified client rather than group therapy, but we anticipate high involvement of significant others in these sessions. MICRA will be manual-guided, but specific content will not be prescribed session by session. MI will be used as a front-end induction (1-2 sessions) to engage participants in treatment. It will also be used as a guiding style throughout treatment. The CRA portion of treatment will consist of a menu of procedures that the counselors and clients can choose from to meet the client's needs. CRA will seek to increase sources of positive reinforcement for non-use and engage the client in positive social activities. A primary goal in MICRA will be to re-engage clients in extended family, clan, community, and (if applicable) society activities and responsibilities.

The HIV/STD component of MICRA will be integrated throughout treatment and will be consistent with MI and CRA. This component will not be the main focus of treatment sessions, but will be woven throughout so that participants understand the relationship between substance use and risky sexual behavior. For example, using an MI style, counselors might discuss with participants how sexual behavior and substance use are related. In line with CRA, counselors might complete a functional analysis of situations that lead to risky sex. The MICRA team will decide on the specific components of the HIV/STD prevention piece so that it is congruent with Southwest Native American values.

1.4.4 Treatment as Usual

Southwest Native American Recovery Center (SWNARC), the sole outpatient substance abuse treatment program in the Southwest Native American tribe, will serve as the treatment as usual (TAU) comparison for this study. Treatment provided by the Southwest Native American Recovery Center is fairly consistent in its approach. The intake staff assess all clients. Detailed histories are gathered, individual cases are staffed, and clinical assignments are made. Clients are assigned to counselors who have openings; there is no attempt to match client to counselor, other than with an eye towards gender. Treatment starts with individual sessions. Soon thereafter the client joins ongoing group sessions. The clinical staff usually runs group sessions (90 minutes on average), and they engage clients with a reflective style, encouraging them to share their stories regarding substances. Newer group members are generally quiet. From time to time, elder Southwest Native Americans will come to the group meeting and discuss either their personal struggle with substance abuse, or share Southwest Native American perspectives on treating all things - including the self- with respect. Examples of ongoing groups

include a men's group, women's group, arts and crafts group, and Triple A dance group. Individual counseling sessions (60 minutes on average) consist of listening and implementing a generally didactic style that compares current behavior with desired behavior, current situation with optimal situation. Individual sessions occur once weekly, but may happen more frequently if an individual is in crisis. 12 step principles are presented at SWNARC, but more in spirit than in substance. Family members are usually not included in counseling sessions. Individual sessions also review Southwest Native American traditional teachings, showing the client his or her place within the framework of Southwest Native American life. Three cultural educators are part of the SWNARC staff. Release from substance abuse treatment is based on clinical judgment. While clients can spend up to a year at SWNARC, the average length of treatment is two months.

The Center's Director, Dr. Robert Currier, approximates that 65% of their patient referrals come from the Southwest Native American Tribal Court Systems, 25% from the local IHS (Indian Health Services) Hospital in the Southwest Native American tribe, and the remainder are self-referred. Client flow per month ranges from 70-90, with 30% (lower bound estimate of 21) of those referred under the age of 18 years and approximately 70% (lower bound estimate of 49) over the age of 18 years. Of the 70% over the age of 18, approximately 80% (lower bound estimate of 56) of referrals are men and 20% (lower bound estimate of 14) are women.

1.5 Assessments

Assessment and data collection for MICRA has been designed to consider the temporal needs of measuring changes that may result from behavioral interventions. Initial screening will focus on participant eligibility and reasons for participation or nonparticipation. Baseline and follow-up assessment domains include substance use and related consequences, psychosocial functioning, sexual behavior, psychiatric symptoms, condom use self-efficacy, cultural identity, microaggressions, and future orientation.

Follow-up assessments will take place at 4, 8, and 12 months after the intake assessment (Phase 1 has follow-ups only at 4 and 8 months). Please refer to Chapters 4 and 6 for a more detailed description of the assessments.

1.6 Study Size and Duration

The research assistant will consent nine participants referred from Southwest Native American Recovery Center to participate in MICRA during Phase 1. The research assistant will consent and complete a baseline interview with 80 participants referred from Southwest Native American Recovery Center during Phase 2. These 80 participants will be randomized to MICRA or TAU.

Phase 1 participants and Phase 2 participants randomized to MICRA will receive 16 to 20 therapy sessions over the course of 16 weeks. Phase 2 participants randomized to TAU will receive outpatient treatment at SWNARC. Phase 1 participants will have follow-up assessments at 4 and 8 months; Phase 2 participants will have follow-up assessments at 4, 8, and 12 months.

Chapter 2: Eligibility

Inclusion and exclusion criteria are summarized below.

2.1 Inclusion Criteria

Individuals will be eligible to enroll if they meet all of the following criteria. If even one of the inclusion criteria is not met, then the prospective participant is not eligible.

2.1.1 Male or Female Southwest Native American individual

Potential participants must self-identify as primarily Southwest Native American. They are still eligible for the study if they are part Southwest Native American (e.g., half Southwest Native American, half Navajo).

2.1.2 Resident within the Southwest Native American reservation or neighboring small settlements

Potential participants must live in the Southwest Native American tribe, Ramah, or Vanderwagon.

2.1.3 Aged 18 or older

Potential participants must be at least 18 years of age for inclusion. However, there is no upper limit on age. Practical barriers may exist for participants of advanced age with regards to mobility and/or cognitive functioning.

2.1.4 Seeking treatment for a Substance Use Disorder

Potential participants must present to Southwest Native American Recovery Center, the single point of study entrance, for substance abuse treatment services.

2.1.5 Meets DSM-IV criteria for Substance Abuse or Dependence

Based on responses to the SCID, potential participants must meet current (i.e., past-month) DSM-IV criteria for substance dependence or abuse for at least one of the following: alcohol, amphetamines, cannabis, cocaine, or inhalants (including ocean).

2.1.6 Willing and able to understand and voluntarily participate (in English) in assessment and treatment procedures in the study

Potential participants must be fluent in conversational English.

2.2 Exclusion Criteria

People will be ineligible if they meet any of the following criteria. If even one of the exclusion criteria is met, then the prospective participant is not eligible for the study.

2.2.1 Extended absences from Southwest Native American tribal lands

The potential participant plans to be absent for more than 14 consecutive days during the 16-week treatment period.

2.2.2 No available locators

The individual cannot identify at least one "locator" person for research tracking purposes.

The following 2 exclusion criteria will mainly be assessed at SWNARC prior to study referral:

2.2.3 Actively psychotic or chronic mental illness that is not well treated

The individual needs inpatient mental health or substance abuse treatment.

2.2.4 Major Cognitive Impairment

This includes major head trauma or mental retardation.

2.3 Other Eligibility Guidelines

- Some participants may request that staff report about their progress to an outside agency (i.e., parole officer, court, etc.). If this situation presents itself, staff may report on attendance but not progress, and value statements should be avoided (i.e., participant completed the study successfully). A sample Referral Form is located in Appendix A and should be used to communicate this information. MICRA counselors will complete the Referral Form, place it in a sealed enveloped, and staff at SWNARC will pick up the envelopes from the MICRA offices and deliver them to SWNARC Intake Technician. SWNARC Intake Technician will send a copy to the Southwest Native American Courts.
- Phase 1 participants are not eligible for participation in Phase 2.
- Individuals can only be screened once.
- If someone who is interested in participating in the study lives with a current or former participant (e.g., sexual partner, friend, or family), the interested individual is not eligible to participate in the study.

Chapter 3: Recruitment and Screening

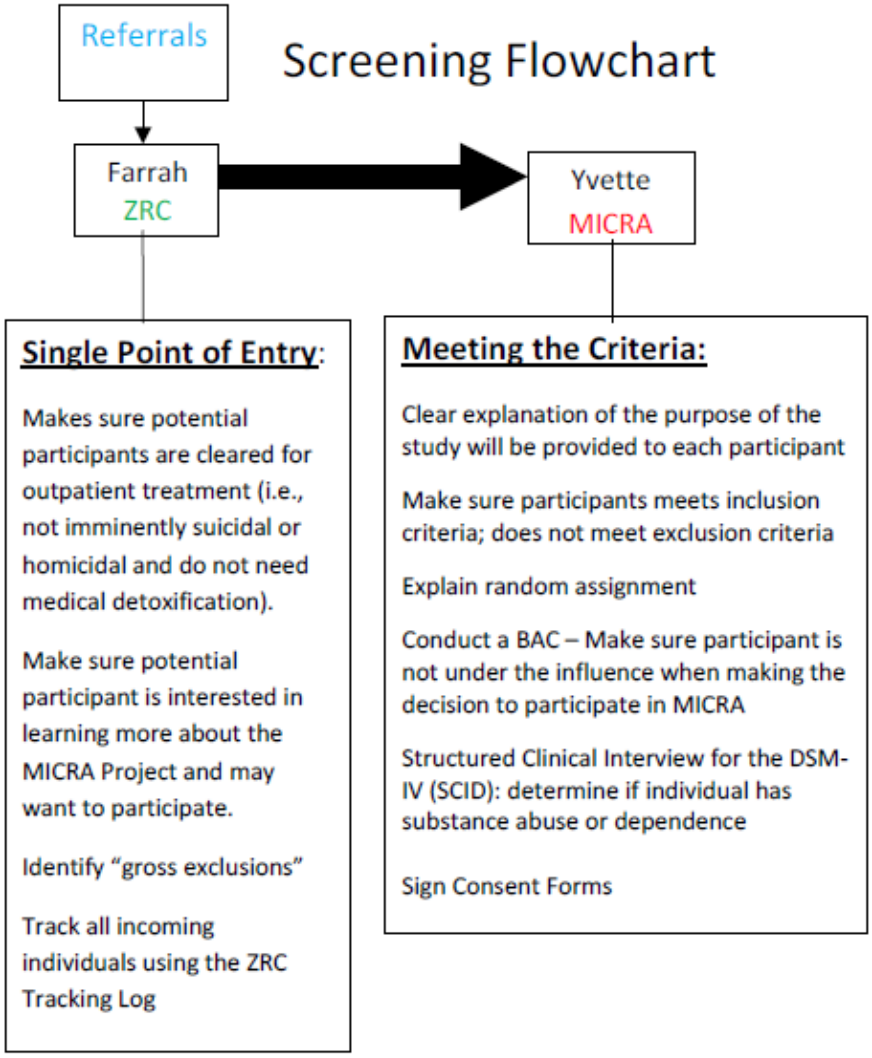
3.1 Overview of Recruitment and Screening

The final number of participants will be 89 men and women (9 for Phase I, 80 for Phase II).

If an individual decides not to participate at any point during the recruitment and/or screening process, the reason(s) for non-interest should be documented in the appropriate tracking log.

[PHASE II ONLY] Participants will be randomized after the baseline interview or within one week of the baseline interview if the randomization criteria are unclear. Participants who are randomized but who fail to begin treatment at SWNARC or through MICRA will not be replaced. Participants must begin treatment at SWNARC or MICRA within two weeks after randomization.

A flow chart of the screening process appears below:



3.2 Recruitment and Screening Principles

Here are some principles to follow in screening and recruitment as a general approach to the study:

- The primary goal is to eliminate non-eligible participants while minimizing loss of potential participants by:
  -assuming eligibility until ruled-out, &
  -excluding the obviously ineligible before face-to-face encounter
- Screening levels include:
  -"Basic exclusions" at initial contact with SWNARC intake staff
  e.g., age; tribal non-affiliation
  -"More specific" issues: e.g., does not meet criteria for current substance abuse or dependence
- Data collection, compliance and retention begins with initial contact

3.3 Identifying Potential Participants

Participants primarily will be recruited through Southwest Native American Recovery Center (SWNARC). The SWNARC intake technician, Farrah Lesansee will approach all individuals who come to SWNARC for treatment and briefly discuss the study with them to assess their level of interest. If a SWNARC staff member other than the intake technician completes the intake, they will also tell the individual about the study. This discussion will take place in a private room, after the potential participant has completed the intake papers and the SASSI. Individuals with multiple questions about the study will be encouraged to contact the MICRA research assistant. Occasionally individuals may enter the MICRA offices and inquire about the study without first going to SWNARC. When this happens, they will be given a pamphlet, a brief explanation of the MICRA Project, and referred to the intake technician at SWNARC to begin the intake and recruitment process. MICRA counselors will also give presentations at the Southwest Native American Detention Center explaining the MICRA study to detainees, but individuals must still go through SWNARC as the single point of entry to become enrolled in the study. Many individuals from the Southwest Native American detention center are subsequently referred to SWNARC, so these presentations will help to raise awareness about the study.

All interactions with potential participants will be recorded in the SWNARC Screening Log. The Screening log reports gender, whether individuals were approached for and/or interested in the study, action taken post-study discussion. Tracking updates will be e-mailed to Brenna Greenfield, the CASAA RA, on the 1st and 15th of the month. There are some cases where individuals who come into SWNARC will not be approached for the study (although these individuals must be included in the SWNARC tracking log):

- Major cognitive impairment, actively psychotic, or chronic mental illness not well-treated, as assessed by SWNARC staff/the Co-I Dr. Currier.
- The individual requires more intensive detoxification services and is referred out of SWNARC (they can be approached for the study post-detox).

- Basic exclusion criteria are evident: The individual is under 18, not Southwest Native American, does not speak English, is not willing to be randomized (for Phase II), or does not live within the required area.

For those individuals who are interested in the study and do not meet any of the basic exclusion criteria, the intake technician or other staff person doing the intake will call the MICRA research assistant (RA) to connect the potential participants with more information about the study. Depending on the RA's availability and the individual's availability, one of the following will happen:

- RA will immediately drive to SWNARC and continue screening and recruitment process
- Interested individual will immediately go to MICRA offices to continue screening and recruitment process.
- RA and interested individual will schedule a meeting at SWNARC or the MICRA offices to discuss the study within the next five business days
- If the RA and individual are not able to meet within five business days, the individual will continue with the SWNARC intake process, if desired, and ineligible for the study. The RA will record this information in the MICRA Screening Log. The RA will inform the intake technician that the recruitment meeting did not occur, and the intake technician will contact the individual to continue the SWNARC intake process, if the individual so desires.

3.4 Screening Visit (pre-baseline)

Screening visits will occur in an office at SWNARC or in the MICRA offices – wherever is most convenient for the potential participant. The RA will introduce herself, thank the individual for his or her interest, and briefly describe the study [see Appendices B and C for sample screening scripts]. The RA will also explain that the role of the Research Assistant is to: *collect research data before, during and after treatment in order to see how well the treatment is working*, and explain that research staff are separate from the treatment staff. Information obtained from the individual during follow-up assessments will not be shared with the counselors. After the study description, if the individual *is not* interested in determining his or her eligibility for the study, then the RA will call or inform Farrah to reconnect the individual with the SWNARC admission process. Reasons for non-interest will be documented in the MICRA Screening log. If the individual *is* interested in determining his or her eligibility, continue with the following:

3.4.1 Initiate a Discussion about Adherence

Participants should be made aware of how missing data and study dropout affect the quality of the study. Ask the participant his or her reasons or motivation for applying for participation in the study. As part of the informed consent process, ask each participant about the following issues:

1) "Is there anything that may interfere with your ability to participate in the study?"
2) "In the event that you cannot be located, research staff must go to great lengths to relocate you and obtain an interview. This will include calling locators that you

provide, visiting your last known address, text messaging you, and calling you at work. Is that a problem for you?"

3.4.2 Breath Alcohol Content

After the study introduction, the RA will ask the individual for verbal permission to continue with the BAC and eligibility screening. If the individual does not wish to continue, they will be rescheduled for a screen within the next 2 weeks, or referred back to SWNARC for further treatment. Reasons for non-participation will be documented in the MICRA Screening Log. If the individual agrees to the BAC and SCID, the RA will collect the individual's breath alcohol content level and record the information on the MICRA Screening & Consent Form. All individuals should be informed that their BAC must be .05 or less for research interviews, or they will be rescheduled for another day.

If the person's BAC level is > 0.05, the RA will inform the individual of his or her BAC level and that it is not safe to drive. The RA will inquire about the individual's transportation to and from the screening. The RA may call someone to pick the person up, or let him or her stay in the office until the BAC is less than or equal to .02. If the person insists on driving away, the RA will inform him or her that they have to call the police but will not try to keep him or her from leaving the building. If BAC > .05, the individual must reschedule the screening for another day. Even if an individual has a BAC of .05 or lower, the RA has the right to not continue with the consent and screening if the individual smells like alcohol or seems intoxicated or impaired by other drugs. It is important to be safe. In such cases, the RA will ask the person to reschedule for another day.

If the BAC reading is less than or equal to .05, continue with the screening. The BAC must be less than or equal to .05 mg/dl in order for the person to sign the consent form. At this point, potentially eligible participants will be given a Screening Identification Code and evaluated for study admission. The Screening Identification Code will also serve as the study ID number if the individual becomes a part of the study. Screening Identification Codes will only be used once, thus there may be gaps between Study ID numbers reflecting screened individuals who did not meet eligibility criteria for the study. Study ID numbers will start with 1 for Phase 1 (e.g., 1001, 1002) and start with the number 2 for Phase 2 (e.g., 2001, 2002).

3.4.3 Screen for basic eligibility criteria

Prior to beginning the formal screening process, the RA will determine if the individual meets the following eligibility criteria (use Eligibility Checklist), and does not meet any exclusion criteria:

- 18 years or older
- Seeking treatment for substance use disorder
- Willing to be randomized
- Southwest Native American tribal member
- Lives in Southwest Native American tribe, Ramah, or Vanderwagon
- Willing and able to participate in English

- Can provide a phone number or address for at least 1 locator at the baseline interview (RA will follow-up with participant for more locator information)
- Will not be gone more than 14 days during the 16 week treatment period
- Is not actively psychotic; does not have a chronic mental illness
- No major cognitive impairments

The intake technician will evaluate some of these criteria, but the RA will double-check the criteria to avoid protocol violations. Some of these can be done indirectly: for example, inquiring about where the participant lives in casual conversation. If the participant becomes ineligible at any time during the screening process, staff should use their discretion when informing the person of the reason(s) for their ineligibility. The eligibility criteria should be kept somewhat private so individuals do not misrepresent the criteria they meet, or hear about the criteria from other individuals and assume they do not meet them. If the participant is not eligible for the study because of any of the reasons above, the Research Assistant will inform the Intake Technician and re-connect them with the SWNARC referral process. Reasons for ineligibility will be documented in the MICRA Screening Log.

3.4.4 Structured Clinical Interview for the DSM-IV, Module E: Substance Use (SCID)

This SCID-IV module focuses on the assessment of alcohol and drug use to determine the number of DSM-IV diagnostic symptoms endorsed and whether current or lifetime alcohol and/or drug dependence is present. The full module is administered during the screening, focusing specifically on the three substances (including alcohol) that were most frequently used (or caused the most problems) in the past year. If three substances were not used in the past year, the time period can be extended beyond the past year. If the individual has used less than three substances in their life, the SCID will focus on the number of substances they have used. Current abuse or dependence on alcohol, amphetamines, cannabis, cocaine, or inhalants (including ocean) is required for an individual to be eligible for the study. The SCID Module E is also administered at the final follow-up (8 months for Phase I; 12 months for Phase II), at which point the assessment time frame is since the baseline interview. At the final assessment, the RA will only ask about the three substances identified during the Screening as most commonly used or most problematic. In preparation for the release of DSM-V, the SCID includes a supplemental question regarding craving for alcohol or drugs.

Information from the SCID Module E should be recorded on the SCID summary score sheet and YES or NO should be circled on the Eligibility Criteria list (#5). If the individual meets criteria for current substance abuse or dependence, the RA will continue with the consent process. If he or she does not meet criteria, the RA will inform the person using language similar to that found in the following section (3.4.5).

3.4.5 Screening Failures

A screening failure is defined as someone who completed the screen but does not meet eligibility criteria. This information will be captured in the MICRA Screening Logs. Research staff can inform the participant as to why they are ineligible but should use

good judgment when doing so (e.g., if the person did not drink enough to qualify for study participation and they are informed of this, they might drink more to be included).

(If EXCLUDE) Those are all the questions that I have for you. I would like to thank you for your time and cooperation. Unfortunately, you do not meet the criteria for inclusion in our study. We will refer you back to Southwest Native American Recovery Center so that you can continue the intake process there, if you would like. *(Document the referral in the MICRA Screening Log, or indicate if the referral is declined.)*

(If CAUTION) Those are all the questions that I have for you. I would like to thank you for your time and cooperation. It looks as though you may meet the basic criteria for inclusion into our study, but I will need to discuss this with my supervisor before I will know. Also, we may need to ask you some more detailed questions to help us decide if we can include you. *(Ask for a phone number where they can be reached. Inform them that all information is confidential, and that we will not disclose in our call that we are a research study – we will leave our first name and phone number only. If they refuse to give a phone number, then ask them if there is a time when they could call back after you have had a chance to discuss things with your supervisor).*
(Document, in the MICRA Screening Log, the name and phone number (if provided), whether the person said they would call back, or whether the person declined to follow through)

3.4.6 The Research Timeline Handout

Provide a copy of the handout ***"Your Roles and Responsibilities as a Research Volunteer"*** (Appendices D and E) to individuals who meet study eligibility criteria and review the content of the form. Potential participants should be informed of the study specifics in a manner that increases willingness to participate. For example, benefits of participation should be highlighted, incentives for study participation and retention should be clear and participants should also be alerted to inadvertent non-compliance with assessment procedures**.** Be sure to cover the following points:

- Difference between treatment and research
- Structure of the interviews (listed on the timeline), including a Breathalyzer and oral fluid drug test at each visit, as well as paper and pen self-report forms, and interviews.
- Compensation schedules; explain that the participant will be compensated after completing each follow-up visit.
- The importance of continuing in research follow-up interviews even if the participant decides to discontinue treatment
- The importance of complete and accurate data
- We will be giving reminder letters and calls

Explain that the RA will collect data during the treatment phase of the study, and will also collect data during the follow-up phase. During the latter phase the participant will only be meeting with the RA. This data will be used to determine how helpful this particular treatment is.

Ask the participant if he/she has any concerns regarding the assessments, the time commitment, or any other aspect of the study. Respond to any questions that the participant brings up, focusing primarily on clarifying study procedures and reinforcing the importance of the research participant's role. If the participant identifies any concerns such as childcare, transportation, etc., refer these issues first to the Program Coordinator (Donna Lupee) for resolution, and then to the Principal Investigator (Kamilla Venner) if further clarification is needed.

3.4.7 Informed Consent

It is important for the staff person to acknowledge the full range of potential risks, costs, and discomforts associated with the experimental design, as well as anticipated benefits of participation. Being "fully informed" means that the participant has had an opportunity to discuss concerns about any of the assessment, treatment, or follow-up procedures, and has had an opportunity to consider alternatives to participation in the study. This includes explaining that participants randomized to SWNARC for Phase II will need to go through the SWNARC assessment, and that information collected for the research assessment will not be shared with SWNARC. The participant should be given time to decide whether to participate, which may include taking the consent home and discussing the study with family members. If the individual decides to take the consent home to consider the study, the RA will ask him or her to stop by or call the next day to inform the RA about his or her decision regarding study participation. The RA will sign the translation line on the consent form if any part of the consent was translated into Southwest Native American language. Once participants sign the consent and HIPAA forms, they will be given a carbon copy for their own records, as well as the RA's card with contact information. All consent forms will be kept in the MICRA offices. If the RA is unsure whether the individual meets full eligibility criteria, she may tell the individual that his or her enrollment in the study is pending review by the Principal Investigator (see 3.4.5). The date of the consent will be recorded in the Participant Enrollment Log.

3.5 Transitioning to the Baseline Assessment

If an individual is eligible for and interested in the study and signs the consent form, the next step is to continue with the baseline interview. In some cases, the RA will have time to continue with the baseline interview immediately following the screening and consent. This will depend on the RA and participant's availability and energy levels. If the participant does not continue with the baseline interview, then the RA will schedule another time to complete the baseline interview. The scheduled baseline interview date will be recorded in the Participant Enrollment Log. The baseline interview must be completed within two weeks of the screening, and the RA should call to remind the participant about the baseline interview the day before it is scheduled. The RA will say something along these lines: "Okay [insert name], now we need to schedule your first research appointment. It would be best if we could schedule it for tomorrow, but if that doesn't work for you we need to schedule it within the next week. The next visit will last approximately three to four hours. You will meet with me to fill out some paper questionnaires and complete a short interview." If the participant misses three scheduled baseline interview appointments, they will be referred back to SWNARC for treatment there. Only individuals who complete the baseline interview (and are randomized if in

Phase II) will count towards the total number of study participants. Participants who are randomized but do not begin treatment will still be invited to continue on with the research assessments.

Chapter 4: Baseline Assessment

4.1 Overview of Baseline Assessment

The baseline assessments can be divided into two days if the RA deems that it would benefit the participant. However, to prevent data loss the baseline assessment should be completed on the same day, if possible, and must be completed within two weeks of the initial screening. If the baseline interview happens on multiple days, all of these days must be in the same week and the same baseline checklist can be used for all meetings.

Participants will be given water and snacks if they would like. They will also be given ample opportunities to take breaks during the baseline assessment. The baseline assessment consists of a BAC, oral fluid drug test, and self-report and interviewer-administered questionnaires (see Table 4.1).

At the baseline interview, the RA will remind the participant of her role: *to collect research data before, during and after treatment in order to see how well the treatment is working.* She will explain that research staff are separate from the treatment staff, and that information obtained from the participant during follow-up assessments will not be shared with the counselors. Baseline research information may be shared with the MICRA treatment staff for feedback purposes, but will not be shared with SWNARC treatment staff.

4.1.1 On-Site Communication of Information

Maintaining the boundaries between the data collection and the treatment arms is not always an easy task. The importance of the separation between the phases is embodied in the fact that different staff performs these two vital functions. Staff collecting data should be trained in maintaining this distinction. Staff should also acquire skills and resources to deal with situations that challenge the boundaries between treatment and data collection phase.

Outlining the flow of communication (what can be communicated and to whom?) is another way to maintain boundaries between research and treatment staff. The Communication Table in Appendix F outlines information that can be communicated between research and treatment staff.

4.1.2 Communication Flow

Questions that cannot be answered locally (by Dr. Robert Currier at 505-782-4717 or Donna Lupee, Program Coordinator, at 505-782-7284) should be forwarded to the Principal Investigator (PI), Dr. Kamilla Venner (kamilla@unm.edu or 505-925-2377).

Table 4.1 Baseline Assessments

	Time
BAC (only if baseline is on a different day than the screen)	3
Intercept Oral Fluid Drug Screen	5
RA-Administered Interview Measures	
Form 90 Interview	40
Addiction Severity Index	60
Locator Form	10
Self-Report Questionnaires	
Risk Behavior Questionnaire	10
Inventory of Drug Use Consequences-2R	15
Brief Symptom Inventory 18	5
Beck Hopelessness Scale	5
Condom Use Self-Efficacy	15
Alcohol/Drug Use: Confidence & Temptation	10
Scale of Ethnic Experience	15
Microaggressions Scale	15
Daily Spiritual Experience Scale	8
Total Time (minutes)	226
Total Time (hours)	3.77

4.2 Biological Assessments

4.2.1 Breath Alcohol Content

If the participant completes his or her screening on the same day as the baseline assessment, then the BAC does not have to be repeated. This should be noted on the Baseline Checklist. If the baseline assessment is on a separate day, then the participant must be given a BAC before completing the assessment. The results of the BAC are recorded on the baseline checklist. If the BAC is less than or equal to .05, continue on to the oral fluid screen. If the BAC is > .05, the RA will inform the individual of his or her BAC level and that it is not safe to drive. The RA will inquire about the individual's transportation to and from the screening. The RA may call someone to pick up the participant, or let him or her stay in the office until his or her BAC is less than or equal to .02. If the person insists on driving away, the RA will inform them that they have to call the police but will not try to restrain him or her from leaving the building. If BAC > .05, the individual must reschedule the baseline assessment for another day. Even if an

individual has a BAC of .05 or lower, the RA has the right to not continue with the assessment if the individual smells like alcohol or seems intoxicated or impaired by other drugs. It is important to be safe. In such cases, the RA will ask the person to reschedule for another day.

4.2.2 Oral Fluid Drug Screen

The Intercept Oral Fluid Drug Screening will be given at each research interview. The screening tests for the following drug categories: Amphetamines, Methamphetamines, Benzodiazepines, Cannabinoids, Cocaine, Opiates, and Oxycodone. The participant will rub a foam swab against their cheek for three minutes and then insert the swab into a fluid-filled vial. Only the participant's identification number will be written on the vial, and the vial will then be sent to a lab in Virginia via Fed Ex. The sample should be sent to the lab within a week of collection to obtain the best results. The PI and RA are able to access results through the Alere Website (https://www.scitest.us/; On-line Reporting Tab).

4.3 RA-Administered Assessments (* = used in Personal Feedback Report for MICRA)

4.3.1 Form 90 Interview*

The Form-90 obtains primary outcome data through a detailed, comprehensive assessment of daily alcohol and drug use patterns in the past 90 days. The measure uses a modified calendar review method to assess daily alcohol and drug use patterns and BAC/number of standard drinks on the heaviest day of drinking.

4.3.2 Addiction Severity Index - Southwest Native American Adaptation*

A second key domain in outcome assessment is the measurement of adverse consequences of use. Our standard instrument here will be the Addiction Severity Index (ASI) Southwest Native American Adaptation, a structured interview that has been in routine use at CASAA for over a decade and that was adapted for use in this Southwest Native American tribe. The ASI evaluates severity of life problems in a variety of areas, and it has well-established psychometric characteristics (McLellan, 1985).

4.3.3 Locator Form

The Locator Form is a standard CASAA assessment instrument. It provides information about contacts that know the participant and would be able to locate them if the RA is unable to contact the participant directly. The Locator Form is filled out in full at the baseline assessment and updated at each follow-up assessment, or whenever the RA has contact with the participant. Information from the locator form will be used to call, visit, or text message the participant, or call the participant's contacts in order to reach the participant for the follow-up interviews.

4.4 Self-Report Questionnaires (* = used in Personal Feedback Report)

4.4.1 Inventory of Drug Use Consequences – 2R (Recent)*

The Inventory of Drug Use Consequences (InDUC-2R) measures consequences in the previous four months from drinking alcohol or using drugs in five domains: physical, interpersonal, intrapersonal, impulse control, and social responsibility.

4.4.2 Self-Efficacy and Situation Temptation Scales (ADUSES Part I and II)*

The Self-Efficacy and Situation Temptation Scales (DiClemente, Carbonari, Montgomery, & Hughes, 1994) are two 20-item questionnaires with similar items. The Situation Temptation scale measures how tempted an individual would be to use alcohol or drugs in a particular situation; the Self-Efficacy scale measures how confident an individual is to abstain from using alcohol or drugs in those same situations.

4.4.3 Brief Symptom Inventory 18*

The BSI 18 is a brief self-report questionnaire whose 18 items yield continuous scores for the 3 dimensions of anxiety, depression, and somatization, as well as an overall global severity index. Derived from the SCL-90, it provides a symptom picture for the past week.

4.4.4 Beck Hopelessness Scale

Since suicide and hopelessness are comorbid with substance abuse and a concern for many Native American populations, we will use the Beck Hopelessness Scale (BHS) to assess these domains. The BHS consists of 20 items, is quick to administer and is less intrusive than a clinical interview.

4.4.5 Risk Behavior Questionnaire*

The Risk Behavior Questionnaire (RBQ) is a shortened version of the Risk Assessment Battery (Navaline et al., 1994) with added questions from the Sexual Behavior Interview (SBI; Calsyn et al., 2009). It will provide a behavioral measure of sexual practices in the past 4 months. It includes questions on the frequency of unprotected sex by partner type, the number of partners in the assessment period, and percentage of time sex occurred under the influence of substances.

4.4.6 Condom Use Self-Efficacy

The Condom Use Self-Efficacy Scale (CUSES; Brafford & Beck, 1991) will be given to measure confidence to use a condom, persuade a partner to use a condom, and use a condom while under the influence of substances. This measure has demonstrated excellent reliability across samples (α = .83-.93).

4.4.7 Scale of Ethnic Experience

In order to characterize the sample, it is important to ask about cultural identity and discrimination. The Scale of Ethnic Experience (SEE; Malcarne, Chavira, Fernandez, & Liu, 2006) consists of 32 items and yields four subscales of cultural identity, mainstream comfort, social affiliation and perceived discrimination for one's ethnic group.

4.4.8 Microaggressions Scale

The Microaggressions Scale (MA; Walters, 2010) measures daily events that communicate negative or hostile messages towards American Indians and that collectively can negatively impact mental health.

4.4.9 Daily Spiritual Experience Scale

The Daily Spiritual Experience Scale (Underwood & Teresi, 2002) taps feelings of connectedness to spirituality and has been adapted for the Southwest Native American people.

4.5 Ending the Baseline Assessment

When all assessment instruments have been completed, the RA will provide the participant with a $50 gift certificate to Halona Plaza (see Incentives SOP for details). The RA will enter the completed baseline assessment date into the Participant Enrollment log, record the estimated 4-month follow-up date, and provide the participant with an appointment card for the 4-month follow-up. Follow-up appointments should be scheduled approximately 2 weeks before the estimated 4-month follow-up date.

In Phase II, the RA will open the randomization envelope (see Chapter 5 for details) and inform the participant of their treatment assignment. For those assigned to SWNARC, the RA will inform the participant that his or her referral packet will be sent to SWNARC, and that SWNARC will call to schedule a date and time for the participant to go to SWNARC and complete the intake process. For Phase II participants assigned to MICRA and all Phase I participants, the RA will walk them over to a counselor's office and have them schedule the first treatment session. If all counselors are occupied, the RA will schedule an appointment for the participant with a counselor.

Chapter 5: Randomization (Phase II Only)

5.1 Introduction to Randomization

Randomization only applies to Phase II participants; all Phase I participants will receive MICRA. Randomization divides the study participants equally between two groups using a chance process that guards against the possibility that a certain type of participant (e.g., those with more severe substance use) ends up in one study condition more often than in another. Participants will be randomized upon completion of the baseline interview. Eighty individuals will be randomized (40 per treatment condition). No provisions have been made for replacement of participants that do not adhere to the protocol once treatment intervention has been assigned, although research interviews with these participants will continue to determine how they are doing at the follow-up interviews.

5.2 The Randomization Process

Once participants have completed all baseline assessments, the RA will determine the treatment assignment by pulling out the envelope with the appropriate number. Sixty cards have been numbered with 30 "Ms" and 30 "Zs" (M = MICRA; Z = SWNARC), placed in individual envelopes, and shuffled thoroughly. The envelopes are numbered sequentially from one to 60. The first person that consents and completes the baseline will receive the treatment assignment from envelope 1, the second individual will receive the assignment from envelope 2, and so on. The treatment assignment will be recorded on the Baseline Checklist. The envelopes will be shuffled by the PI, Co-PI, and RA before Phase II begins. A second randomization process will occur to accommodate the increase in recruitment (from 60 to 80) that was approved by the National Institute of Drug Abuse (funding agency) in March of 2012. Ten additional cards will be labeled with "MICRA" and ten will be labeled as "SWNARC." These cards will be placed in envelopes and shuffled, and the envelopes then will be labeled from 61 to 80. Similar to the process described above, the 61st through 80th participants will receive the treatment assignments listed on the cards in the envelopes corresponding to numbers 61 through 80.

5.3 Informing Participant of Treatment Assignment

After the assessments and evaluations are complete, the participant should be informed of the treatment assignment and given an outline of his or her responsibilities, based on the specific treatment assignment. For MICRA, participants will be given the therapist's name, session location, starting and ending dates and times. The participant will then attend the initial session(s). Participants randomized to SWNARC will be scheduled with Farrah and they will need to follow though with SWNARC Intake/Assessment processes. Once they complete the SWNARC intake/assessment process they will be assigned a therapist.

After a participant has been randomized to treatment, the goal is to maintain a good research relationship, prevent attrition from the study, and maximize the collection of data in a complete and timely manner.

5.4 Tracking Systems

Chapter 3 describes tracking systems used through the screening and recruitment phase. Participants will also be tracked in the Tracking Log and Participant Enrollment Log after they are randomized. The Tracking Log includes: 1) participant ID; 2) date; 3) time; 4) Activity; 5) Results; and 6) RA initials. All contact with participants should be documented in the Tracking Log. The Participant Enrollment Log includes: 1) name; 2) age and gender; 3) consent and baseline date; and 4) follow-up ideal and actual dates. Contact information for the participant on the Locator Form should also be updated on a regular basis (at research visits, and also at contacts in between these visits). A password-protected Linking Log will be kept on the RA's computer to link participant names and ID numbers, and also stored on the PI's private secure folder at CASAA, and these will be the only places where names and ID numbers are linked.

5.5 Taping Counseling Sessions

MICRA and SWNARC sessions will be taped by the counselor and saved with only the participant's ID number, session date, and session number (e.g., 1001 9.22.11 S1). If participants wish to turn off the recording during the session, that is permissible. The consent form does include information on audio recordings, so that prior to study enrollment individuals are made aware of the taping process, and the taping process also is mentioned during the jail informational sessions.

Counselors will receive standardized training in MI and CRA as well as coaching calls until they reach criterion and to maintain fidelity. Adherence will be monitored by digital audio recordings of counseling sessions and supervision. These digital files are e-mailed using Meo encryption software and downloaded to Sendspace for the trainers, Joseph "Bo" Miller and Vickie Mc Ginley, who are both licensed professionals and who have completed CITI training. If therapy drift is observed, the counselors will be retrained.

Additionally, tapes will be encrypted using MEO Encryption software and saved on a flash drive and then transferred to a secure folder at CASAA using the VPN, a secure direct connection to CASAA. Only the PI, RA, and coders will have access to the folder. The tapes will be coded by an undergraduate or graduate student who works at UNM, or the tapes might be coded by the PI. The coding is not done to code any personal information. All tapes will be destroyed after coding has been completed.

Chapter 6: Follow-up Research Assessments

6.1 Overview of Follow-up Assessments

Follow-up research visits will occur 4, 8 and 12 months after the baseline interview (only 4 and 8 months for Phase I). The follow-up interview can be split over multiple days if necessary, but it must be completed within one week. If the baseline interview took place over multiple days, the follow-up date will be calculated based on the Form 90 completion date. Follow-ups consist of both RA-administered and self-report questionnaires. Follow-ups are essential to the study outcomes because they provide information about treatment response. When presenting study findings, high follow-up rates (at least 80%) help to solidify confidence in the findings. The follow-up process is not restricted to the actual research interview: it begins as soon as the baseline interview is completed and continues until all follow-up data has been collected. Participants should be reminded to call the RA if they are planning to move or have a new phone number or address.

At the follow-up interviews, the RA will remind the participant of her role: *to collect research data before, during and after treatment in order to see how well the treatment is working.* She will explain that research staff are separate from treatment staff, and that information obtained during follow-up assessments will not be shared with the counselors. The division of responsibilities between the counselors and Research Assistant during treatment is defined so that serious issues that arise with the participant are referred to the therapist. When the active treatment is over, however, the situation becomes more difficult. The participant who – most likely – has established a good rapport with the research staff may use follow-up contact as ample time and opportunity to raise personal issues. Moreover, at this phase of the study, the participant may confuse data collection activities with aftercare services. It is important for the Research Assistant to identify the risk of crossing boundaries and to present such cases to the Project Coordinator.

Research interviews will generally occur in the MICRA offices, but can also occur at SWNARC in a private office or at the detention center. In the event that the participant is unwilling or unable to meet the interviewer at the treatment setting, the interview may be conducted over the phone. Home visits may be made by the RA to reschedule missed appoints or deliver reminder letters, but interviews will not be conducted in participants' homes.

6.2 Tracking Procedures

6.2.1 Routine Tracking Procedures

All participants will be sent a reminder letter one month before their scheduled follow-up date (see Appendix G for a sample letter). Letters should be designed with care to exclude information that would compromise the participant's confidentiality. If letters are returned to the MICRA offices because they could not be delivered, the RA will use contacts on the locator to find a correct mailing address for the participant or text message the individual. When research staff correspond with a participant or locator (i.e., phone, mail, etc.), this information should be recorded and entered into the Tracking

Log. This will allow staff to determine when the next contact should take place as well as types of contact that have been successful.

One week prior to the follow-up interview, the RA will call the participant to remind them about their interview, confirm attendance or reschedule as needed, and make sure that they have transportation to the interview. The RA will also call the participant one day before the interview to remind them about their appointment. If an answering machine is reached, it is a good idea to attempt calling again in order to speak with a person. If someone other than the participant answers record the person's name and relationship to the participant. This information helps determine the feasibility of leaving another message with the same person. It also helps getting convenient times to reach the participant or a change in her/her schedule.

The RA will continue to call or text message the participant until she is able to confirm the follow-up appointment. If the participant does not show up for the interview and cannot be contacted to reschedule, the RA will continue to call them until she is able to reschedule the follow-up. In cases where the RA cannot reach the participant by phone, the RA may visit the participant's house to try and locate the participant for the follow-up interview.

For those participants who cannot obtain transportation to the interview, the RA will call SWNARC to reserve a car so that she can pick up the participant at their house, bring them to the MICRA offices for the interview, and then return them to their house after the interview. When scheduling baseline or follow-up interviews, the RA will check with participants to see if they will need a ride to the MICRA offices.

To protect the confidentiality of participants when sending text messages, only the RA's first name and MICRA office number and a request for a return call or text will be included in the initial text message. If the RA receives a return text message, she will text back to confirm that it is indeed the participant. If it is the participant, the RA can proceed with scheduling the next follow-up appointment via text message. If the individual responding to the message is not the participant, then the RA will text message back asking the individual to pass along a message for the participant to call her back ("Please have him/her call Yvette at xxx-xxxx"). The cell phone will be stored in a locked file cabinet in the MICRA offices along with the locators and consents, and all messages will be immediately deleted after they are received. Text message exchanges will be documented in the study tracking logs.

If the participant does not come in for their follow-up research interview by the scheduled date (e.g., 4 months past the baseline interview), the RA will continue to contact them until the participant can be reached and the research interview is completed. This may include home visits. These repeated contacts will be done in a respectful manner that recognizes the importance of the participant to the research study. If the participant tells the RA that they do not want to do the follow-up at this time, the RA will ask if they can contact the participant again in a few weeks, or at the next follow-up.

The RA will continue trying to reach the participant through the date of their next follow-up. If the RA did not reach the participant for the previous follow-up (e.g., 4 mos), but does finally reach the participant to complete an interview **2 weeks or less prior to the next follow-up** (e.g., right before the date of the 8 mo follow-up), then that interview will count as the second follow-up (e.g., the 8 mo follow-up). If the participant is reached for an interview **prior to the 2 week window before the next follow-up**, but, for example, it is a month or two after the previous scheduled follow-up, then that interview will still count as the previous follow-up, and the RA will contact the participant again for the next follow-up and complete it as usual, but with **at least one month** in between follow-up appointments.

If a research interview has been missed, at the next interview the Form 90 and the ASI should be completed regarding the period from the last completed interview. If the participant cannot be reached for the final follow-up interview, the RA will continue contacting the individual for 4 mos. after the scheduled follow-up date.

6.2.2 Practical Strategies to Enhance Adherence and Retention

Although retention in one phase influences retention in another, drop-out from one phase does not necessarily imply drop-out from another; participants can be lost, resistant, or refusing additional contact and each of these types requires standardized decision rules for management. However, special attention should be paid to contacting refusing participants. Participants who state that they do not want to be contacted must not be contacted. Contacting these participants is disrespectful and may result in an IRB complaint or a complaint made to community representatives.

General guidelines to enhance adherence and retention are listed below:

- Collect some data, if possible. Prioritize primary outcome measures (e.g., Form 90, ASI)
- Be flexible in scheduling assessments on early morning and evenings. Check with participants about best days and times to come in.
- Provide local bus schedules
- Prepare waiting areas for family members that accompany participants.
- Send participants holiday and birthday cards to keep in touch and show appreciation for participant's involvement
- Offer incentives for transportation ($25 for less than 50 miles, $50 for > 50 miles)
- Pick participants up for follow-up interviews
- Conduct a phone interview
- Make a home visit
- Use text messaging if the participant has indicated that this is acceptable
- Conduct regular discussions among research staff as well as between research and clinical staff to clarify roles and responsibilities and to strategize about optimal ways of interacting with the specific participant
- Adopt an understanding, empathic, and respectful stance and show genuine interest in knowing why the participant wishes to drop out
- Offer a sympathetic ear to a participant who initiates a conversation about his/her life difficulties or about the lack of support they receive from their network (i.e.,

significant other, AA, friends); however, AVOID engaging in further discussion and refer the participant to the PC or PI who a) may be more experienced in this domain, and b) has less frequent interaction with the participant.

6.2.3 Working with Ambivalent Research Participants

See Table 6.1 for a list of risk factors that may be associated with non-adherence during enrollment, treatment, and follow-up. These factors may be explicitly expressed by participants or observed by the study staff.

Participants may choose to drop out for a variety of reasons. They may have the perception that they have given the same information over and over again. They may complain that the treatment is not effective because their substance use has not improved or that treatment is not warranted any more because they are able to abstain from drinking/using. Participants may also think that their contribution to the study is minimal. Some participants may have concerns about the time commitment or they may have transportation or other constraints that prevent their active participation in the study. On a general level, it is important to identify the reasons for non-adherence and to address them by allowing flexibility with the study procedures. If a participant expresses reservations about continuation of the study, the research staff should respectfully listen to these reservations and use the following techniques:

- Call participant to find out their standing regarding the study
- Explore reasons for not wanting to participate
- Inform participant that research visits can be resumed at any time
- Re-iterate number of research visits that still need to be completed
- If the participant indicates that they will not be coming back to the research visits, ask for permission to collect final Form-90 information by phone or in person
- Emphasize the participant's importance to the study regardless of drinking/using status
- Normalize the phenomenon of losing interest in the study
- Arrange a meeting between the participant and the PC and later the PI to:
    - Identify obstacles to compliance
    - Engage the participant in active problem-solving
    - Offer help with problems that may be an obstacle to compliance
- Request permission to re-contact at a later time

The art is to avoid eliciting a 'NO' response. Examples include:

> "It sounds as though today is not a good day for you to complete the interview. How about I give you a call next week and see if we can find a more convenient time?"
>
> "Thank you for your participation so far and for coming in today. I respect your wishes not to finish the interview today. Would it be okay if I called you in a few weeks just to check in?"

Another option is to thank the person for coming and not ask at that moment whether or not you can reschedule an interview. Perhaps it might be more effective to:

Follow-up with a thank you letter and mention that the research staff will try to call them and see if they have changed their mind.
Follow-up with a phone call only

Project Match (Monograph 7) suggests that the Research Assistant indicate that he/she does not have the authority to "dissolve the research agreement" and request that the participant speak with the PC/PI. This strategy serves several purposes:

Emphasizes the importance of the decision and the value of the participant's contribution to the study.
Provides participants with another opportunity to rethink their decision.
A person of greater authority may be able to more effectively address the concerns of the participant.

In some cases, it may be best to proceed with immediate referral to the PI. There are several reasons for immediate PI referral. First, the participant may have already spoken with the PC about the issue, or may want to speak to the PI about the PC. Second, it may be difficult to convince a refusing participant to attend two separate meetings or to speak with two different people. Given that the PI may be seen as a person with more authority, it may be more efficient to proceed with setting up a meeting/phone call with the PI. However, the preferred procedure may be site-specific. Before referring the participant to the PC/PI, the following information may facilitate a smooth hand-off:

-familiarity with the participant's reason(s) for not wanting to participate, and
-the perception/speculation of the Research Assistant of the participant's reasons to drop out of the study

If, despite all best efforts, the participant refuses to re-engage, accept their choice. Thank them for their participation thus far with a thank you letter signed by all members of the research team. Also, let the participant know that she/he can come back at any time, and ask if it is possible to mail study materials periodically.

Table 6.1 Enrollment, Treatment, and Follow-up Risk Factors

Enrollment Phase Risk Factors:	**Treatment Phase Risk Factors:**	**Follow-Up Phase Risk Factors:**
Expressed • Concerns about randomization • Expectations for being assigned a specific treatment • Concerns with one or some aspects of the study protocol • Other expressed enrollment risks Observed • Rescheduled screening appointments • No-show for screening appointments • BAC>0 at baseline interview • Problems with detoxification • Permanent address is different from current address • Duration of current address is less than 3 months • Plans to move in the next year • Other observed enrollment risks	Expressed • Dissatisfaction with treatment assignment • Dissatisfaction with treating clinician(s) • Difficulty to meet time demands • Other expressed treatment risks Observed • Rescheduled treatment appointments • No-show for treatment appointments • Unresponsive to or refusing routine scheduling procedures • Manifestation of clinical deterioration • Early drop out from treatment • Plans to move in the next year • Loss of housing • Unexpected social, occupational, or health event • Lost contact (disconnected phone or out of minutes, undelivered mail) • Other observed treatment risks	Expressed • Dissatisfaction with services provided • Dissatisfaction with treating clinician(s) • Difficulty to meet time demands • Other concerns expressed during follow-ups Observed • Loss of interest in the study due to end of treatment • Clinical deterioration • Plans to move in the next year • Loss of housing • Unexpected social, occupational, or health event • Other observed follow-up risks

6.3 Follow-up Assessments

Follow-up assessments are listed in Table 6.1. Phase I participants do not have a 12-month follow-up; because of this they will complete more questionnaires at the 8-month follow-up than the Phase II participants do. The procedures for the BAC and the oral fluid drug test are provided in Section 4.2. Descriptions of the assessments in Table 6.1 are given in Sections 4.3 and 4.4. Several questionnaires inquire about a different time period when given at follow-up than when given at baseline. These questionnaires include (period of interest at follow-up in parentheses):

Form-90 Interview (time since last research interview)
Addiction Severity Index (past 30 days and time since last research interview)
SCID (time since baseline interview)
Inventory of Drug Use Consequences-2R (time since last research interview)
**Locator form from the baseline interview is pulled out and updated at each follow-up and whenever study staff has contact with the participant

All other questionnaires inquire about the same time period at each research interview.

Table 6.1 Follow-up Assessments

	4 Mos.	8 Mos.	12 Mos. (Phase II only)
BAC	X	X	X
Intercept Oral Fluid Drug Screen	X	X	X
RA-Administered Interview Measures			
Form 90 Interview	X	X	X
Addiction Severity Index	X	X	X
Locator Form (not in database)	Update	Update	Update
Substance Dependence Symptoms (SCID)		X - Phase I only	X
Self-Report Questionnaires			
Risk Behavior Questionnaire (RBQ)	X	X	X
Inventory of Drug Use Consequences - 2R	X	X	X
Brief Symptom Inventory 18 (BSI 18)	X	X	X
Beck Hopelessness Scale (BHS)	X	X	X
Condom Use Self-Efficacy	X	X	X
Alcohol/Drug Use: Confidence & Temptation	X	X	X

Scale of Ethnic Experience		X- Phase I only	X
Microaggressions Scale (MA)		X- Phase I only	X
Daily Spiritual Experience Scale	X	X	X

6.4 Ending the Follow-up Assessment

When all assessment instruments have been completed, the RA will provide the participant with $50 cash as compensation (see Incentives SOP for details).
The RA will enter the completed follow-up date into the Participant Enrollment log.

If follow-ups remain, the RA will record the next estimated follow-up date in the Participant Enrollment Log and provide the participant with an appointment card for that follow-up. The RA will also outline the remaining parts of the study for the participant, thank him or her for participating in the study, and emphasize how important his or her participation is.

If it is the participant's last follow-up, the RA will give the participant a Certificate of Completion and thank the participant for his or her contributions to the study. The RA will answer any final questions about the study and encourage the participant to call if he or she has any questions about the study in the future.

Chapter 7: Data Management Procedures

7.1 Quality Control Procedures

7.1.1 General Instructions for Completing Forms

Use black ballpoint pen (not pencil) for completing all interview-based forms. The first page of all of the self-administered forms contains specific instructions to the participant on how to respond to the questionnaire. An administrative area is also on the first page of each form for identification and linkage of the instrument to a particular time point. (Note: The Locator Form does not include a place for ID # because it is stored separately from the assessment forms and contains identifying information) The administrative section should be completed before giving the questionnaire to the participant. Make no erasures and do not use correcting fluid/white out. All self-administered forms should be carefully checked once returned for incomplete corrections, stray marks, skipped items, and items with more than one response indicated.

Print all text responses legibly; do not use cursive writing. Always retain a copy of each paper form completed either by interview, or self-administered in the permanent MICRA participant file.

Record all times in 24 hour format (also called international time, e.g., 00:00 = 12 Midnight, 06:00 = 6 AM, 20:00 = 8PM, etc.).

Record all dates in month/day/year order. Prompts on the paper forms are in the format: mm/dd/yyyy.

7.1.2 Missing Responses and Forms

Do not leave responses blank on a form. Unanswered responses embedded in a question sequence that was validly skipped because the items were not applicable are not permitted. Blank responses are not automatically assumed to be "Unknown" or "No." Be explicit in the recording and entry of data on the study forms. When information is unavailable and will never be known place equal ("=") signs through the blank space. For example, a missing height not recorded would appear:

Height ==.= in.

If an entire form cannot be located and the information cannot be recovered, write "Missing" on the session checklist and date and initial the note. If known, include a brief comment about why the form was not completed.

7.1.3 Corrections

Corrections should be made in the following manner:

-Cross out the original response with a single line in such a way that it is still legible.
-Write the correct response above or to the side of the original response.
-Date and initial the correct response.

For example: What is the participant's gender? Male ~~X~~ Female X

Do not use white out or erasures at any time.

7.1.4 Data Protection and Verification

No participant names will be used but rather only client ID numbers. The codes that link the name of the participant and the study ID will be kept confidential by the PI and UNM Project related staff and students and will be stored on the secure CASAA network. In addition, we have a Certificate of Confidentiality. If for some reason there is a breach of confidentiality, an adverse event will be reported to all required parties.

The Quality Assurance (QA) Monitor (Roberta Chavez) will visit the Southwest Native American tribe on a monthly basis to review research form completion and provide feedback to the RA on assessment completion. The QA Monitor will note any protocol violations in the Protocol Violation Log.

7.2 Data Entry and Transfer

All data will be double-entered in separate databases to prevent data entry errors. Data will be entered at the Southwest Native American MICRA offices first by the research assistant at Southwest Native American tribe on a desktop, and then double entered by a UNM MICRA team member trained in data entry. Once the data is entered, the two records will be compared electronically to identify discrepancies. The hard copy of the data will be reviewed to determine which entered value was correct. Discrepancies will be corrected by a supervisor based on source documents with notations and initials on the source documents if necessary. This procedure has been shown to result in less than one entry error per 10,000 (as compared with 3-5% error on single pass data entry by research assistants).

In order to transport these data to UNM from the Southwest Native American tribe, a VPN connection will be set up by CASAA's Information Technologist Matt O'Nuska. The deidentified data file will be saved to the PI's private Novell drive and will be backed up as part of CASAA's routine weekly back-up system. Scott Tonigan, Ph.D. is the statistician on this grant, so he will have access. Anyone else needing access would require PI permission to conduct data analyses or work on poster presentations and manuscripts. There will be one data file with identifying information: (1) the link between participant names and study ID numbers. This datafile will be password protected on the PI's private Novell drive at CASAA.

7.4 Data Ownership

The MICRA data belongs to the Southwest Native American people, and the Southwest Native American Tribal Council must approve all publications and presentations within a timely manner prior to outside release. National Institute of Drug Abuse and University of New Mexico Human Research Review Committee officials reserve the right to audit the data files to ensure compliance with research procedures. To protect participant confidentiality, the forms linking participant names to data forms will not be shared with the Tribal Council and only the PI, Co-PI and RA will have access to these linking

documents during the study. The link between names and research data will be destroyed once all data has been entered and verified. The hard copies of the data will remain in the Southwest Native American tribe at the Tribal Recovery Center in locked file cabinets. The director of the Southwest Native American Tribal Recovery Center (Paula Stifler) and the tribal council administrator will be provided with file cabinet keys, and individuals wishing to access the data must complete a MICRA file access log. Hard copies of the data will be destroyed five years after all tribally-supported publications have been published. The study PI will keep an electronic copy of the data, and the Tribal Council will also retain an electronic copy of the data.

7.5 Data Analysis Plan

The primary dependent measure of use derived from the Form 90 and the saliva drug tests will be percent days abstinent from: alcohol, amphetamine, cannabis, cocaine, and inhalants. Secondary outcomes measures include other self-report assessments such as self-reported days of substance use and oral saliva drug results, self-efficacy, negative consequences, cultural identity, microaggressions and sexual risk behaviors. Outcome data will be analyzed using two-group MANOVA comparing MICRA and TAU conditions on key dependent measures: (1) percent days abstinent from all substances of abuse as measured from timeline follow-back, and (2) level of substance related problems as measured by the InDUC. The endpoint for this analysis will be 4-month follow-up and baseline levels of the dependent measures will be entered as covariates. Later analysis will explore outcomes across 12 months post-randomization. Secondary analyses will employ hierarchical linear modeling (HLM) for modeling effects over time given we have at least 3 time points. Exploratory analyses will also encompass outcomes on secondary measures such as ASI, cultural identity, microaggressions, brief symptom inventory, and sexual risk behaviors. Alpha level will be set at .05. The study's statistician or PI will analyze these data using SPSS software and Amos.

Appendix A

SOUTHWEST NATIVE AMERICAN MICRA PROJECT
P. O. BOX 339
Southwest Native American, NM 87327

REFERRAL/ASSESSMENT REPORT

Date: _____

Client's Name: _____ **Referral Date: _____**

Referring Agency: _____ **Cause#:**

Date of Intake: _____ **Date of Assessment:_____**

Date Case Staffed:_____

Assigned Counselor: _____

Recommended Treatment Plan:

Client is receiving outpatient treatment services with the Southwest Native American MICRA Project

Outpatient Treatment Services to be provided by Southwest Native American MICRA Project:

1.
2.
3.

Referrals to be made:

Counselor's Signature: _____ **Date: _____**

Clinical Supervisor: _____ **Date: _____**

cc: Client/file/Client management/Referring agency

Appendix B: Phase I Sample Screening Script

(Assessment process can be interpreted in the Southwest Native American Language if participant does not fully understand English)

Good Morning/Good Afternoon. My name is Yvette Yamutewa, I am the research/administrative assistant with the Southwest Native American MICRA Project. I am the person who collects research data before, during and after treatment in order to evaluate the effectiveness of treatment. I will be the person in charge of doing the screening and consent process, the baseline as well as the 4 and 8 month follow up visits. Thank you for coming in today. I really appreciate your patience in getting together to meet with one another. It shows how much determination you have to help yourself. I understand you have expressed interest to participate in the Research study and that we have received your referral from the Southwest Native American Recovery Center.

We will be starting out by doing the screening & consent process to determine if you are eligible for the study. It will take at least an hour to do the necessary paperwork to determine your eligibility. Do you have any questions before we proceed?

Let's start out by discussing a little bit about the study. May I share with you what the MI/CRA Study is about? Southwest Native American Pueblo in collaboration with the University of New Mexico has teamed up to do a research study to see if Motivational Interviewing (MI) and Community Reinforcement Approach (CRA) will work for our Southwest Native American People. This is a non-confrontational and strengths based model that focuses on building motivation for change. We provide outpatient substance abuse counseling and with your permission we would like to pay you for your participation in the research study which will be in the form of a gift certificate after the initial intake interview and cash incentives at 4, and 8 month follow-ups. We will not force you to stay in the study if you do not wish to continue and we will honor and respect your decision. I would also like to inform you that I will not be in charge of your treatment process as you will be working one on one with a counselor here within the MICRA Project and that all information obtained from you during your follow up assessments will not be shared with your counselor but Baseline information may be shared for feedback purposes.

Do you think this study might be something you're interested in? (Depending on whether the client is interested…) Wonderful that you would like to take part in the research study. The next step is to determine if you would be eligible to take part in the study, but first we would need to do an alcohol breathalyzer test before we proceed. Each participant who agrees to continue with the screening is asked to voluntarily provide us with a BAC. Your BAC information will not be shared with your referring source; again your information will be kept confidential. With your permission, I would like to administer the BAC. (If BAC is beyond .05, then participant must be informed that their BAC is higher than expected and reschedule the Screening and Consent Process to another date and time.)

Another important item I would like to stress is that all information gathered while participating with the project will be kept confidential and the only time any

information can be released is if you give us permission by signing a Release of Information Form.

Next we will be completing a form about your alcohol and drug use. It will take approximately 30 minutes to complete. I will be asking you questions that pertain to alcohol or substance use within your lifetime. (After completing the SCID, the RA will determine whether the participant meets the eligibility criteria for substance abuse or dependence. If participant is eligible, the Consent form can be explained more in depth and questions will be answered if the participant has any prior to signing the form. The HIPAA Form will be signed during this time.)

(After all screening documents have been completed) Thank you for coming in today to complete all the necessary paperwork to determine your eligibility for this Research Study. Since you have decided to participate in this study I will go ahead and schedule an appointment for you to come back in and do the entire assessment process, unless you have time to complete some of the forms today? (Depending on yes or no) Do you have any questions or concerns pertaining to anything we discussed today or anything relating to the study? (Hand participant appointment slip for assessment process) Thank you once again for coming in today and hope to see you on your next scheduled appointment. Take care! Elahkwa.

Appendix C: Phase II Sample Screening Script

(Assessment process can be interpreted in the Southwest Native American Language if participant does not fully understand English)

Good Morning/Good Afternoon. My name is Yvette Yamutewa, I am the research/administrative assistant with the Southwest Native American MICRA Project. I am the person who collects research data before, during and after treatment in order to evaluate the effectiveness of treatment. I will be the person in charge of doing the screening and consent process, the baseline as well as the 4, 8, and 12 month follow up visits.

Thank you for coming in today. I really appreciate your patience in getting together to meet with one another. It shows how much determination you have to help yourself. I understand you have expressed interest to participate in the Research study and that we have received your referral from the Southwest Native American Recovery Center.

We will be starting out by doing the screening & consent process to determine if you are eligible for the study. It will take at least an hour to do the necessary paperwork to determine your eligibility. Do you have any questions before we proceed?

Let's start out by discussing a little bit about the study. May I share with you what the MI/CRA Study is about? Southwest Native American Pueblo in collaboration with the University of New Mexico has teamed up to do a research study to see if Motivational Interviewing (MI) and Community Reinforcement Approach (CRA) will work for our Southwest Native American People. This is a non-confrontational and strength based model that focuses on building motivation for change. You will receive outpatient substance abuse counseling and with your permission we would like to pay you for your participation in the research study which will be in the form of a gift certificate after the initial intake interview and cash incentives at 4, 8, 12 month follow-ups. We will not force you to stay in the study if you do not wish to continue and we will honor and respect your decision. I would also like to inform you that I will not be in charge of your treatment process as you will be working one on one with a counselor and that all information obtained from you during your follow up assessments will not be shared with your counselor but baseline information may be shared for feedback purposes.

There are two programs participating in the study, the MICRA project and Southwest Native American Recovery Center. If we find that you are eligible for the study, we will put your name in a randomization program which means you will receive your treatment services either with MICRA or Southwest Native American Recovery Center. The purpose of randomization is to make sure that the groups of participants who receive the two treatments are balanced in terms of things like age, education, etc. I will not know which treatment you will receive, and you must be okay with not knowing which treatment you will get. Do you have questions about the randomization process? If you are assigned to SWNARC we will not lose all contact with you. I will continue to stay in touch with you by doing follow ups and to provide you with your incentives.

Do you think this study might be something you're interested in? (Depending on whether the client is interested…) Wonderful that you would like to take part in the

research study. The next step is to determine if you would be eligible to take part in the study, but first we would need to do an alcohol breathalyzer test before we proceed. Each participant who agrees to continue with the screening is asked to voluntarily provide us with a BAC. Your BAC information will not be shared with your referring source; again your information will be kept confidential. With your permission, I would like to administer the BAC. (If BAC is beyond .05, then participant must be informed that their BAC is higher than expected and reschedule the Screening and Consent Process to another date and time).

Another important item I would like to stress is that all information gathered while participating with the project will be kept confidential and the only time any information can be released is if you give us permission by signing a Release of Information Form.

Next we will be completing a form about your alcohol and drug use. It will take approximately 30 minutes to complete. I will be asking you questions that pertain to alcohol or substance use within your lifetime. (After completing the SCID, the RA will determine whether the participant meets the eligibility criteria for substance abuse or dependence. If participant is eligible, the consent form can be explained more in depth and questions will be answered if the participant has any prior to signing the form. The HIPAA Form will be signed during this time).

(After all screening documents have been completed) Thank you for coming in today to complete all the necessary paperwork to determine your eligibility for this Research Study. Since you have decided to participate in this study I will go ahead and schedule an appointment for you to come back in and do the entire assessment process, unless you have time to complete some of the forms today? (Depending on yes or no) Do you have any questions or concerns pertaining to anything we discussed today or anything relating to the study? (Hand participant appointment slip for assessment process) Thank you once again for coming in today and hope to see you on your next scheduled appointment. Take care! Elahkwa.

Appendix D: Roles and responsibilities of a Phase I research volunteer

Welcome to the MICRA Study! You have decided to participate in an important treatment research project that requires your involvement over the next 8 months. The study has two parts, **treatment** and **research**, with equally important, but different roles carried out by different study staff members. The **research** portion of the study is designed to gather information that will help to evaluate the treatment you receive as a study participant. This is done by meeting with you at different time points to gather confidential information about different areas of life such as family relations, work, and the health of your mind, body and spirit. The **treatment** portion of the study involves meeting with a MICRA counselor on a weekly basis for 12-16 weeks.

Timeline for Participation

You will meet with the Research Assistant, Yvette Yamutewa, at three different time points. Each meeting will last approximately 2-5 hours and will include paper questionnaires and an interview. Here is an outline of the research visits you will have during the study:

Study Phase	Treatment				Research Follow-up			
Month Number	1	2	3	4	5	6	7	8
Research Visit Scheduled	X			X				X

Research Participant Responsibilities

- Provide accurate information about alcohol and drug use and other areas of your life
- Stay in contact with the research team for all 8 months and notify us of any changes in your address or telephone number
- Provide us with emergency contact names and numbers in case we lose touch with you

Our Responsibilities

- Treat you with respect and keep all information confidential unless it relates to abuse or harm to self or others
- We will you compensate you for your time and travel to each research interview [$50 Halona gift certificate for first interview, $50 cash for the second two]

We want to hear how things are going for you whether you feel you are doing well or not, and regardless of whether you complete treatment. Remember, your participation in this important study will help to improve treatment services offered to other Southwest Native Americans in the future. Your ongoing participation in follow-up interviews is vitally important! Elah'kwa.

Appendix E: Roles and Responsibilities of a Phase II Research Volunteer

Welcome to the MICRA Study! You have decided to participate in an important treatment research project that requires your involvement over the next 12 months. The study has two parts, **treatment** and **research**, with equally important, but different roles carried out by different study staff members. The **research** portion of the study is designed to gather information that will help to evaluate the treatment you receive as a study participant. This is done by meeting with you at different time points to gather confidential information about different areas of life such as family relations, work, and the health of your mind, body and spirit. While the **treatment** portion of the study is different depending on your random assignment to MICRA or SWNARC, the **research** portion of the study is the same for everyone.

Timeline for Participation

You will meet with the Research Assistant, Yvette Yamutewa, at four different time points. Each meeting will last approximately 2-5 hours and will include paper questionnaires and an interview. Here is an outline of the research visits you will have during the study:

Study Phase	Treatment				Research Follow-up							
Month Number	1	2	3	4	5	6	7	8	9	10	11	12
Research Visit Scheduled	X			X				X				X

Research Participant Responsibilities

- Provide accurate information about alcohol and drug use and other areas of your life
- Stay in contact with the research team for all 12 months and notify us of any changes in your address or telephone number
- Provide us with emergency contact names and numbers in case we lose touch with you

Our Responsibilities

- Treat you with respect and keep all information confidential unless it relates to abuse or harm to self or others
- We will you compensate you for your time and travel to each research interview [$50 Halona gift certificate for first interview, $50 cash for the three follow-ups]

We want to hear how things are going for you whether you feel you are doing well or not, and regardless of whether you complete treatment. Remember, your participation in this important study will help to improve treatment services offered to other Southwest Native Americans in the future. Your ongoing participation in follow-up interviews is vitally important! Elah'kwa.

Appendix F: Communication between Research and Treatment Staff

	Circumstances of communication about specific participant information
Counselor to RA	None
Counselor to PC	All content areas of the MICRA treatment coordination checklist
RA to counselor	None. If the RA has concerns about a participant the report should be made to the PC who will address the issue with the PI.
RA to PC	Any concerns about a participant.
PC to RA	Any safety issues
Access to information	
Baseline assessment	RA has access to all information. Counselors have access to the assessments that relate to the feedback report but no others; there are procedures in place to deal with clinical issues (e.g., discussing w/PC or Co-I, Dr. Currier)
Follow-up assessments	RA only

RA = Yvette Yamutewa
PC = Donna Lupee (role of PC overrides role as counselor)
Counselor = Everett Homer

Appendix G: Sample 4-month Follow-up Letter

[Insert date here]
P.O. Box
Southwest Native American tribe, New Mexico

Dear [Insert Participant's Name],

Greetings/Keshi! I am writing to inform you about your upcoming appointment scheduled for Tuesday, November 23, 2010 at 1:30 PM. This appointment is for your Four (4) month follow up with our program. The appointment could last approximately 3-4 hours depending on your availability.

If for any reason this date and time will not be convenient for you, please contact me at 782-7282 as to when you would like to meet to complete the follow up session.

Hope to hear from you soon. Take Care!

Sincerely,

Yvette Yamutewa
Research /Administrative Assistant

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